SERBIA EMERGENCY COVID-19 RESPONSE PROJECT

SUBPROJECT: CONSTRUCTION OF A NEW DIAGNOSTIC BUILDING WITH BSL-3 LABORATORY AT THE “TORLAK“ INSTITUTE OF VIROLOGY, VACCINES AND SERA

ENVIRONMENTAL AND SOCIAL IMPACT ASSESSMENT

NOVEMBER 2023

BELGRADE, SERBIA

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ENVIRONMENTAL AND SOCIAL IMPACT ASSESSMENT REPORT (ESIA)

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ABBREVIATIONS

AoI	Area of Influence
BAS	Building Automation System
BSC	Biosafety Cabinet or Biological Safety Cabinet
BSL	Biosafety Level
CIA	Cumulative Impact Assessment
EC	European Commission
EHS	Environment, Health and Safety
EIA	Environmental Impact Assessment
ESF	Environmental and Social Framework
ESIA	Environmental and Social Impact Assessment
ESMP	Environmental and Social Management Plan
ESMS	Environmental and Social Management System
ESS	Environmental and Social Standards
EU	European Union
EUNIS	European Nature Information System
Euratom	European Atomic Energy Community
GBV	Gender-based Violence
GHG	Greenhouse Gas
HEPA	High-Efficiency Particulate Air
HR	Human Resources
HVAC	Heating, Ventilation, and Air Conditioning
IFC	International Finance Corporation
ISO	International Organisation for Standardization
IUGS	International Union of Geological Sciences
JV	Joint Venture
KBA	Key Biodiversity Area
KPI	Key Performance Indicator
LBM	Laboratory Biosafety Manuel
LMP	Labor Management Procedure
MoH	Ministry of Health
MPA	Multiphase Programmatic Approach
OECD	Organisation for Economic Co-operation and Development
OHS	Occupational Health and Safety
PAD	Project Appraisal Document
PCU	Project Coordination Unit
PLC	Programmable Logic Controller
PPE	Personal Protective Equipment
PS	Performance Standard
RS	Republic of Serbia
SEA	Sexual Exploitation and Abuse

SECRP	Serbia Emergency COVID-19 Response Project
SEP	Stakeholder Engagement Plan
SEPA	Serbian Environmental Protection Agency
SH	Sexual Harassment
SOP	Standard Operating Procedures
ToR	Terms of Reference
WB	World Bank
WBG	World Bank Group
WHO	World Health Organization

GLOSSARY

Implementing Agency	Ministry of Health
Associated Facility	Facilities or activities that are not funded as part of the project and, in the judgment of the Bank, are: (a) directly and significantly related to the project; and (b) carried out, or planned to be carried out, contemporaneously with the project; and (c) necessary for the project to be viable and would not have been constructed, expanded or conducted if the project did not exist. For facilities or activities to be Associated Facilities, they must meet all three criteria.
AoI	The area likely to be affected by the project, including all its ancillary aspects, such as power transmission corridors, pipelines, canals, tunnels, relocation and access roads, borrow and disposal areas, and construction camps, as well as unplanned developments induced by the project (e.g., spontaneous settlement, logging, or shifting agriculture along access roads).
Borrower	Republic of Serbia
Project Owner	The Project Coordination Unit of the Ministry of Health of Republic of Serbia
ESIA	Environmental and Social Impact Assessment
Lender	WBG or World Bank Group
Sub-project (Sub-project of SECRP)	Construction of a new diagnostic laboratory building with BSL-3 laboratory at the “Torlak“ Institute of Virology, Vaccines and Sera, Belgrade under the Serbia Emergency COVID-19 Response Project (SECRP)
Project Area	The area where the Sub-project will be constructed within the existing Torlak Institute of Virology, Vaccines and Sera, Belgrade and potential locations used for construction works such as mobilization area.

EXECUTIVE SUMMARY

Background

Republic of Serbia has received a loan from the World Bank in the amount of EUR 92 million equivalent for “Serbia Emergency COVID-19 Response Project” (SECRP). The objectives of the SECRP are: (a) to respond to the threat posed by COVID-19 and (b) to strengthen the national health system for public health preparedness in Serbia.

The SECRP consists of the following components:

- Component 1: Emergency COVID-19 Response
- Component 2: Implementation Management and Monitoring and Evaluation

Component 1

Component 1 will provide immediate support to Serbia to enable limiting the local transmission of SARS-CoV-2 through containment strategies. This component has three subcomponents.

Subcomponent 1.1 Case Detection, Confirmation, Contact Tracing, Recording, Reporting

This subcomponent will, inter alia, help strengthen national reference and public health laboratories and epidemiological capacity for early detection and confirmation of cases and support the establishment of a BSL-3 laboratory.

Subcomponent 1.2. Physical Distancing Measures and Communication Preparedness

This subcomponent combines activities listed in Component 1 of the global Multiphase Programmatic Approach (MPA) Project Appraisal Document (PAD) under Social Distancing Measures and Communication Preparedness. Communication preparedness activities will include developing and testing messages and materials to be used in a pandemic.

Subcomponent 1.3: Health System Strengthening

This subcomponent aims assistance to be provided to the health care system for preparedness planning to provide optimal medical care, maintain essential community services, and minimize risks for patients and health personnel. Strengthened clinical care capacity will be achieved, inter alia, through the procurement of ambulances and other vehicles, hospital beds, X-ray devices, computed tomography (CT) scanners and I X-ray devices to be installed in community health centres.

Component 2

Component 2 will cover the costs associated with project management and coordination.

Under the scope of the Subcomponent 1.1 of the SECRP a new diagnostic building with biosafety level 3 (BSL-3) (Sub-project) within existing Torlak Institute of Virology, Vaccines and Sera will be constructed.

The new diagnostic building with BSL-3 laboratory will;

- strengthen disease surveillance systems, national reference and public health laboratories, and epidemiological capacity for early detection and confirmation of cases;
- support epidemiological investigation;
- strengthen risk assessment;
- and provide on-time data and information for guiding decision-making and response and mitigation activities.

In order to provide laboratory support to the system of epidemiological surveillance, warning and rapid response to possible threats to public health at the national and global level[1], it is necessary to develop capacities for detection through the isolation of the above-mentioned microorganisms and the implementation of in-house (internal) diagnostic tests.

The establishment of a BSL3 laboratory will open the possibility of developing in-house tests and their use, both for diagnostic purposes and for scientific research, as well as the introduction of new diagnostic procedures that could not be carried out at the existing of BSL-2 laboratory. The development and use of in-house (internal) diagnostic tests will allow the laboratory to be independent in diagnosing pathogenic microorganisms and to provide a timely and effective response to an epidemic, pandemic or the appearance of a n“w "threaten”ng" infectious agent which is especially important given that in times of high global demand, there can be enormous difficulties in obtaining commercial diagnostic kits (as in the case of the SARS-CoV-2 pandemic).

The environmental and social risks of the Sub-project have been proposed to be rated as “Substantial” in accordance with World Bank Environmental and Social Framework (ESF), therefore, an Environmental and Social Impact Assessment study (ESIA) including the Environmental and Social Management Plan (ESMP) in line with the requirements of World Bank Environmental and Social Standards (ESSs) which are designed to avoid, minimize,

[1] The threat to public health is represented by microorganisms that cause various diseases that occur in Serbia from time to time - endemic (mouse fever, West Nile fever, tularemia, brucellosis, tuberculosis, Q fever, etc.). In addition, as history testifies, there is always the possibility that infected travelers from other countries will cause an epidemic caused by a microorganism that is not present in Serbia or by a so far unknown causative agent. In addition, climate change contributes to the spread of microorganisms to new areas, and the threat to public health that would arise because of the use of biological weapons cannot be completely ruled out.

reduce or mitigate the adverse environmental and social risks and impacts of projects and Serbian legislation have been prepared. The Sub-project is not included in List 1 (projects that require EIA) or List 2 (projects that may require EIA) in the “Regulation on the List of Projects Requiring a Mandatory Impact Assessment and List of Projects that May Require an Environmental Impact Assessment of Official Gazette of RS, no. 114/2008, therefore environmental impact assessment report according to national legislation has not been required.

The purpose of the ESIA study is to describe the Sub-project, identify and assess the severity of potential environmental and social impacts and risks on receptors and identified resources; develop and describe mitigation measures that will be taken to prevent or minimize any potential negative effects and maximize the potential benefits for the construction and operation phases of the Sub-project. The ESIA study conducted for the Sub-project includes desktop reviews of project documents, literature and database, site visits and observations, background measurements, meetings, interviews, focus group discussions with stakeholders

Project Description

The Sub-project will be constructed within the existing Torlak Institute of Virology, Vaccines and Sera (Torlak Institute) in Belgrad which is a national institution for the prevention, treatment, and monitoring of infectious diseases. It is one of the oldest institutions of this kind in the world, with a tradition and experience of more than 95 years.

Torlak Institute monitors, studies, examines, identifies, introduces, and implements professional and scientific methods of prevention and diagnosis of infectious diseases, performs scientific research and educational activities with the aim of developing new technologies and improving vaccines production. As a national vaccine producer, the Institute supplies healthcare institutions performing public health activities in the Republic of Serbia with vaccines from the compulsory immunization program, as well as with other vaccines needed. In addition to vaccines, the institute produces sera and other immunobiological and diagnostic products, medical devices, and food supplements. The Torlak Institute performs trade, i.e., the import and export of medicines, medical devices, food supplements and raw materials to produce medicines and other devices.

There are four reference national laboratories operating within the Torlak Institute:

- National laboratory for influenza and other respiratory viruses,
- National laboratory for poliomyelitis and enteroviruses,
- National laboratory for rubella, morbilli, varicella and other rashes, and
- National laboratory for viral haemorrhagic fevers and Arboviruses (arthropod-borne viruses).

Existing laboratories of the Torlak Institute are standard and BSL-2 laboratories.

The national laboratories of the Torlak Institute are a part of the European laboratory network of the World Health Organization (WHO) and have full membership status as the WHO accredited laboratories. The laboratories have achieved inter-laboratory cooperation with microbiological laboratories in the Republic of Serbia and the related laboratories in Europe.

The new diagnostic building with BSL-3 will be operated under Torlak Institute. The capacity and existing organizational structure of the Torlak Institute will be used for Sub-project purposes.

The Sub-project has been designed as a diagnostic laboratory building with Biosafety Level 3 which will fulfil the requirements for handling pathogenic agents that require such a level of biosafety, like SARS-CoV-1, yellow fever virus, West Nile virus, eastern equine encephalitis virus, and MERS-CoV but also various bacterial, fungal and rickettsia pathogens. The Sub-project will help strengthening Serbia's national laboratory system since there is currently no facility in Serbia that can handle pathogens requiring a BSL-3 or higher.

The new diagnostic building with BSL-3 will be designed, constructed, and operated in accordance with the requirements of WHO Laboratory Biosafety Manual, 3rd edition, 2004 and 4th edition, 2020.

The new diagnostic building with BSL-3 will be located in settlement Jajinci on the southern edge of Belgrade within existing premises of Torlak Institute with a total area of 52,000 m^2.

The new diagnostic laboratory building will consist of 4 floors (basement, ground floor and 3 upper floors), with total area of approximately 4,200 m^2 in which one BSL-3 laboratory will be established in a total area of approximately 150 m^2. The building is structured as right and left wings. The BSL-3 laboratory will be established at the left wing of the building. Torlak Institute will use the right wing for basic Immunology, Allergology and Bacteriology laboratories with biosafety level lower than BSL-3.

The construction of the new diagnostics building with BSL-3 laboratory will include site preparation, levelling works, excavation, rough construction works and mechanical and electrical installations.

Electricity required for construction activities will be supplied from city grid through 33 V transmission line.

Water required for construction activities, dust suppression and domestic use will be provided from municipality network using existing Torlak Institute infrastructure.

The construction of the Sub-project is planned to be started at Q4 2023 and last for 6 (six) months.

For the operation phase; water need will be provided through a connection from the existing municipality network.

Electricity will be provided from the existing national grid through a transformer station which will be built next to the existing building of Torlak Institute.

Domestic wastewater generated during operation of the new diagnostic building with BSL-3 will be disposed through a connection with the existing city sewage infrastructure. The BSL-3 laboratory will be constructed as dry-lab There will be a limited amount of liquid waste (5lt/day) generation during operation of the BSL-3 laboratory. This liquid waste will be autoclaved for decontamination and then disposed to the sewerage system. The amount of solid contaminated waste is expected to be 20 kg/day. Solid waste will also be autoclaved for decontamination and then sent to a licenced landfill according to the national legislation. Another type of waste will be the liquid waste from emergency eyewash/body wash shower. The liquid waste will be collected in a collection tank and will be chemically decontaminated before disposal through authorized operators.

Additionally, a key focus will be placed on providing universal access to these facilities, ensuring the building is accessible to all individuals, regardless of their physical abilities. Furthermore, life and fire safety measures will be incorporated into the design to safeguard the well-being of both staff and community. Fire detection and alarm systems will be in place and emergency equipment will include appropriate fire extinguishers and fire blankets. Fire-fighting equipment will be available at strategic points in corridors and hallways. It will be ensured that fire extinguishers are regularly inspected and maintained. Fire warnings, instructions and escape routes will be displayed clearly within the building.

By prioritizing these environmental and social considerations, the Sub-project strives to create a responsible and inclusive environment while upholding high standards of environmental and social management.

The BSL-3 laboratory within the scope of the Sub-project will be designed, constructed, and operated in accordance with the requirements of WHO Laboratory Biosafety Manual, 3rd edition, 2004 and 4th edition, 2020.

The BSL-3 laboratory will be certified by an independent third-party prior to operation regarding the required design and operational parameters. The certification process of the Sub-project will be conducted using the tools provided in Tables 5–7 (Laboratory Safety Surveys) of the WHO Biosafety Manual (3rd edition, 2004).

The Sub-project has been publicised by the Serbian Ministry of Health through its website. A public consultation meeting was held with the approval of the Scoping Report. During the ESIA phase, field study was carried out with stakeholders.

Legal Framework

Serbia officially applied for European Union for membership on 22 December 2009 and accession negotiations are currently ongoing. Having acquired the EU candidate country for membership status, Serbia has developed a set of environmental laws in line with the EU legislation in recent years. Serbia has adopted majorly the EU regulatory requirements on Environmental Impact Assessment (EIA) into national legislation, including the EIA Directive (Directive 92/11/EC).

An overview on the institutional and regulatory framework regarding health care and environmental protection applicable for the sub-project is provided below;

- Constitution of Serbia (Official Gazette of RS, No. 98/06, 115/21, 16/22)
- Law on Health Care (Official Gazette of RS, No. 25/19)
- Law on Public Health (Official Gazette of RS, No. 15/16)
- Law on Environmental Protection (Official Gazette of RS No. 135/04, 36/09, 72/09, 43/11, 14/16, 95/2018),
- Law on Strategic Impact Assessment (Official Gazette of RS" No. 135/04, 88/10)
- Law on the Environmental Impact Assessment (Official Gazette of RS No. 135/04, 88/10)
- Regulation on Medical Waste Management (Official Gazette of RS, No. 48/19)
- Law on Waste Management (Official Gazette of RS, No. 36/09, 88/10, 14/16, 95/18)
- Law on Medicines and Medical Devices (Official Gazette of RS, No. 30/10, 107/12, 113/17,105/17)
- Law on Nature Protection (Official Gazette of RS, No. 36/09, 88/10, 91/10 -Corr., 14/16, 95/18, 71/21)
- Law on Health and Safety at Work (Official Gazette of RS, No. 101/05, 91/15, 113/17)
- Law on Planning and Construction (Official Gazette of RS, No. 72/09, 81/09, 64/10, 24/11, 121/12, 42/13 ,50/13 ,98/13, 132/14, 145/14, 83/18, 31/19, 37/19, 9/20, 52/21)

Also, Environmental and Social Standards (ESS) of the WB ESF have been taken into consideration in the ESIA studies and development of the relevant mitigation measures and monitoring plan. The planned diagnostic building with BSL-3 will involve working with indigenous or exotic agents that can be transmitted through air and can cause serious or potentially lethal infections. Given the nature of the studies, the workers, the community and the environment are likely to be exposed to health risks due to exposure to infectious microorganisms and pathogens and hazardous materials (if not properly treated and managed), therefore ESS 1, ESS2, ESS3, ESS 4, ESS 6, ESS 8 and ESS 10 are applicable for the sub-project. The sub-project will also comply with the WBG Environmental, Health, and Safety (EHS) General Guidelines, WHO Guidelines related to health care facilities which are benchmark International Good Practice Standards, including IFC EHS guideline for Health Care Facilities. More specifically, the WHO Laboratory Biosafety Manual (4th edition, 2020) is directly applicable as international best practice requirements to the proposed diagnostic building with BSL-3 laboratory.

Environmental and Social Impacts and Mitigation Measures

Construction phase:

Construction phase will include site preparation, levelling works, excavation, rough construction works and mechanical and electrical installations. It is expected that a total of 40 workers will be employed for construction activities. There will be no camp site for construction workers. The construction material such as bricks, sand, gravel and aggregate will be stored at a designated area within the Sub-project site.

The environmental and social impacts associated with the construction phase of the project regarding geology and soil quality, water and wastewater management, waste management, air quality, noise, traffic, biodiversity and OHS risks will be temporary and their significance will be negligible to low when defined mitigation measures are taken. On the other hand, the impacts of community misperception and concerns and fire and life safety are high without the mitigation measures. Regarding life and fire safety risks the Sub-projectwill develop and implement life and fire safety plan and Emergency Preparedness and Response Plan in line with national legislation and international standards.

In order to prevent adverse impacts of community misperception and concerns the Sub-project will develop and maintain effective communication with stakeholders and will implement Stakeholder Engagement Plan.

The mitigation measures are defined and presented in details in Chapter 7 of this report.

Operation phase:

The environmental and social impacts associated with the operation phase of the Sub-project regarding geology and soil quality, water and wastewater management, waste management, air quality, noise, traffic and biodiversity are negligible to low when defined mitigation measures are taken. On the other hand the significance of impacts of exposure to infectious microorganisms, accidental release of pathogens, transport of hazardous materials and community misperception and concerns are high. Key mitigation measures that will be taken are;

- Strict adherence to design requirements,
- Commissioning and Certification of the BSL-3 Laboratory in accordance with WHO Laboratory Biosafety Manual,
- Biosafety Management and Biosecurity Management of the BSL-3 laboratory,
- Training of the personnel,
- Emergency Preparedness and Response,
- Medical Surveillance of the personnel,

- Decontamination of the equipment and BSL-3 laboratory area,
- Infectious waste is autoclaved before disposal,
- Exhaust air is filtered with HEPA filters.

The mitigation measures are defined and presented in details in Chapter 7 of this report.

Environmental and Social Management Plan (ESMP)

An Environmental and Social Management Plan (ESMP) which outlines potential environmental and social risks related with the proposed sub-project, mitigation measures to be implemented, parties responsible for implementing and monitoring, evaluation criteria and associated costs has been prepared for construction and operation phases. The implementation of the environmental and social commitments of the ESMP will be monitored through a detailed Environmental and Social Monitoring Plan.

The Project Coordination Unit under the Ministry of Health of the Republic of Serbia will be responsible for the implementation of the ESMP including the supervision of contractors and overall risk management. PCU will review the Environmental and Social Monitoring reports to be submitted by contractors and will regularly submit these reports to MoH and WB. The ESMP presents measures to manage the potential environmental and social risks of the sub-project. Torlak Institute will be responsible to provide compliance to national legislation and international standards to prevent the workers, the community and the environment from biohazards during operation. Torlak Institute will ensure the required resources in place to manage biosafety and biosecurity of the BSL-3 laboratory. A biosafety committee will be established and critical roles and responsibilities for successfully managing a biosafety program at the BSL-3 laboratory will be assigned. Torlak Institute will assign a laboratory director, biosafety officer, laboratory personnel and support personnel with the appropriate competency and training. Roles and responsibilities of the staff are described in Project Description of the ESIA Report. The estimated cost for the implementation of the ESMP will be €425,000.

Stakeholder Engagement

Within the scope of the project, three stakeholder consultation meetings have been organized so far. The first one was held on February 24, 2021 during the preparation of the draft ESMF and SEP documents for the Serbia Emergency Covid-19 Response Project (SECRP). The second meeting took place on May 22, 2023 following the ESIA Scoping. In the days following the meeting, social baseline and impact assessment interviews for ESIA were conducted. The last meeting was held on October 20, 2023 to announce the ESIA results to stakeholders.

The stakeholder engagement activities are defined and presented in details in Chapter 9 of this report.

1 INTRODUCTION

1.1 Sub-Project Background

An Environmental and Social Impact Assessment (ESIA) has been conducted for the construction of a new diagnostic building with biosafety level 3 (BSL-3) laboratory at the “Torlak“ Institute of Virology, Vaccines and Sera subproject (hereinafter “Sub-project”).

The Sub-project is under the scope of “Serbia Emergency COVID-19 Response Project” (SECRP) for which the Republic of Serbia has received a loan from the World Bank in the amount of EUR 92 million equivalent. The objectives of the SECRP are: (a) to respond to the threat posed by COVID-19 and (b) to strengthen the national health system for public health preparedness in Serbia.

The SECRP consists of the following components:

- Component 1: Emergency COVID-19 Response
- Component 2: Implementation Management and Monitoring and Evaluation

The Sub-project is included in Subcomponent 1.1 of Component 1 of SECRP.

Component 1

Component 1 will provide immediate support to Serbia to enable limiting the local transmission of SARS-CoV-2 through containment strategies. This component has three subcomponents.

1. *Subcomponent 1.1 Case Detection, Confirmation, Contact Tracing, Recording, Reporting*

This subcomponent will, inter alia, help strengthen national reference and public health laboratories and epidemiological capacity for early detection and confirmation of cases and support the establishment of a BSL-3 laboratory.

Establishing a BSL-3 laboratory: The capacity of the Torlak Institute of Virology, Vaccines and Sera will be strengthened by establishing a laboratory which fulfils requirements for handling pathogens such as yellow fever virus, West Nile virus, eastern equine encephalitis virus, SARS-CoV-1 and MERS-CoV but also various bacterial, fungal and rickettsia pathogens. The new diagnostic laboratory will help strengthening Serbia’s national laboratory system since there is currently no facility in Serbia that can handle pathogens requiring a BSL-3 or higher.

The objective of establishing the BSL-3 laboratory is to help:

a) strengthen disease surveillance systems, national reference and public health laboratories, and epidemiological capacity for early detection and confirmation of cases;
b) support epidemiological investigation;
c) strengthen risk assessment;
d) and provide on-time data and information for guiding decision-making and response and mitigation activities.
e) Procurement of equipment for BSL-3 laboratory will also be financed under one of its subcomponents of the Serbia Emergency COVID-19 Response Project (SECRP).
f) The new diagnostic building with BSL-3 laboratory at the Torlak Institute will not be used for research on animals.

Subcomponent 1.2. Physical Distancing Measures and Communication Preparedness

This subcomponent combines activities listed in Component 1 of the global Multiphase Programmatic Approach (MPA) Project Appraisal Document (PAD) under Social Distancing Measures and Communication Preparedness. Communication preparedness activities will include developing and testing messages and materials to be used in a pandemic.

Subcomponent 1.3: Health System Strengthening

This subcomponent aims assistance to be provided to the health care system for preparedness planning to provide optimal medical care, maintain essential community services, and minimize risks for patients and health personnel. Strengthened clinical care capacity will be achieved, inter alia, through the procurement of ambulances and other vehicles, hospital beds, X-ray devices, computed tomography (CT) scanners al(e) X-ray devices to be installed in community health centres.

Component 2

Component 2 will cover the costs associated with project management and coordination.

The environmental and social risks of the construction and operation of the Sub-projecthave been proposed to be rated as “Substantial” in accordance with World Bank Environmental and Social Framework (ESF). Therefore, an Environmental and Social Impact Assessment study (ESIA) including the Environmental and Social Management Plan (ESMP) in line with the requirements of World Bank Environmental and Social Standards (ESSs) which are designed to avoid, minimize, reduce or mitigate the adverse environmental and social risks and impacts of projects and Serbian legislation have been required.

In this context, Joint Venture (JV) of "Enacta Ltd. (Serbia) and 2U1K Engineering and Consultancy Inc. (Türkiye) and 2U1K International Ltd. have been assigned for conducting the ESIA studies, by the Ministry of Health (MoH) of the Republic of Serbia who is the Project-owner.

In addition to World Bank ESSs and national legislation, ESIA has been developed in compliance with the World Bank'Group's applicable Environment, Health and Safety (EHS) guidelines, WHO Laboratory Biosafety Manual (2020), Biorisk Management: Laboratory Biosecurity Guidance (2006) and other relevant international guidelines.

1.2 Sub-Project Objective/Sub-Project Overview

Biosafety levels for laboratories are designated based on a composite of the design features, construction, containment facilities, equipment, practices and operational procedures required for working with agents from various risk groups.

Biosafety Level–1 (basic)

Biosafety level 1 (BSL-1) applies to laboratory settings in which personnel work with low-risk agents that pose little to no threat of disease in healthy adults. An example of a microbe that is typically worked with at a BSL-1 is a non-pathogenic strain of E. coli.

A BSL-1 laboratory typically consists of work taking place on benches without the requirement of use of special contaminant equipment or facility design. A BSL-1 laboratory requires standard microbial practices. It does not require special practices or to be isolated from surrounding facilities.

Biosafety Level – 2 (basic)

Biosafety level -2 (BSL-2) covers laboratories that work with agents associated with human diseases (i.e., pathogenic or infections organisms) that pose a moderate health hazard to personnel and the environment. There is effective treatment and preventive measures against these pathogens, and the risk of spreading the infection is limited. Examples of agents typically worked with in a BSL-2 include equine encephalitis viruses and HIV, as well as Staphylococcus aureus (staph infections). An example of such a laboratory is a microbiology laboratory in a hospital, public health institutes and, in fact, the largest number of laboratories are BSL-2.

Biosafety Level – 3 (containment)

A BSL-3 laboratory typically includes work on either indigenous or exotic agents that be transmitted through air and can cause serious or potentially lethal infections. Examples of microbes worked with in a BSL-3 includes like yellow fever virus, West Nile virus, eastern equine encephalitis virus, SARS-CoV-1 and MERS-CoV but also various bacterial, fungal and rickettsia pathogens. There are preventive measures and effective treatment against these microorganisms.

What makes working in BSL-3 laboratories completely safe, both for employees and for the environment and the entire community, are the special requirements regarding the construction of the facility, ventilation systems and equipment, which are the main features of BSL-3 laboratories. Namely, in BSL-3 laboratories there is a ventilation system with a directed flow of air from the "clean" to the "dirty" part of the laboratory, and air purification[2] before being discharged into the outside environment, which ensures that only air without microorganisms leaves the laboratory. Additionally, in BSL-3 laboratories, all potentially infectious material is handled within a biologically safe cabinet.[3]

BSL-3 laboratories are staffed only by highly educated personnel who are trained to work and behave in laboratories of the 3rd level of biological safety. During work in these laboratories, it is mandatory to use personal protective equipment such as space suits, glasses, gloves, shoe covers, and sometimes respirators, for the purpose of protecting the staff and preventing the spread of infection in the environment and the community.

All infectious waste from the laboratory is decontaminated in an autoclave, a device in which all microorganisms are destroyed by steam at high temperatures and under elevated pressure.[4] After sterilization, the waste becomes non-infectious and non-hazardous, and can leave the laboratory only as such.

Procedures for working in BSL-3 laboratories are clearly defined and must be strictly followed, and access to such laboratories is limited and strictly controlled.

Proper use and maintenance of equipment and strict adherence to standard operating procedures and rules of good microbiological practice prevent the exit of microorganisms from the laboratory to the outside environment, and considering the fact that laboratory animals, sharp objects and breakable laboratory dishes will not be used for work in the laboratory, and thus the possibility of staff infection will be minimized.

Biosafety Level – 4 (maximum containment)

As the highest level of biological safety, a BSL-4 laboratory requires maximum containment features and consists of work with highly dangerous and exotic biological agents such as the Ebola virus and the Marburg virus that pose a high risk of life-threatening disease that may be transmitted via the aerosol route and effective treatment and preventive measures are generally not available.

[2] The exhaust air passes through HEPA filters, which ensures that only micro-organism-free air is released to the outside environment.

[3] A biologically safe cabinet is a specially constructed cabinet designed to protect personnel, the work surface, the laboratory, and the environment from exposure to infectious aerosols, in which air continuously moves in horizontal layers and, after passing through HEPA filters, is released to the outside environment. The HEPA filter effectively retains all known disease-causing agents.

[4] which is also used to sterilize surgical instruments in hospitals.

1.3 Sub-Project Justification

In order to provide laboratory support to the system of epidemiological surveillance, warning and rapid response to possible threats to public health at the national and global level[5], it is necessary to develop capacities for detection through the isolation of the above-mentioned microorganisms and the implementation of in-house (internal) diagnostic tests.

The establishment of a BSL3 laboratory opens the possibility of developing in-house tests and their use, both for diagnostic purposes and for scientific research, as well as the introduction of new diagnostic procedures that could not be carried out in the existing space of BSL-2 laboratory.

Unlike commercial tests, the development and use of in-house (internal) diagnostic tests allows the laboratory to be independent in diagnosing pathogenic microorganisms and to provide a timely and effective response to an epidemic, pandemic or the appearance of " new "threatening" infectious agent. This is especially important given that in times of high global demand, there can be enormous difficulties in obtaining commercial diagnostic kits (as in the case of the SARS-CoV-2 pandemic).

The prerequisite for the development of *in-house* (internal) diagnostic tests, for the analysis of the virus genome and the determination of the sensitivity of the virus to antiviral drugs, is the isolation of the virus from patient samples. To begin with, isolation of viruses[6] such as West Nile virus, dengue virus, SARS-CoV-2, hantaviruses and others is planned. Cultivation of bacterial infectious agents[7] and determination of sensitivity to drugs are also planned. All these analyses contribute to the improvement of the quality of the health system's response to the threat of infectious diseases because they enable more efficient prevention of the spread of the epidemic and better treatment of the consequences of infectious diseases. Also, the safety of healthcare workers is significantly improved.

The BSL-3 laboratory will be available not only to the "Torlak" Institute, whose primary activity is in the field of virology, but also to other diagnostic and scientific research institutions in Serbia. Torlak Institute has already developed and has been implementing training procedures and will adapt these procedures for the BSL-3 laboratory. Basic and specific training programs will be developed for the external researchers ,ta king into consideration all specific and rigid requirements regarding biosafety and biosecurity procedures. The researchers will work under the supervision of the employees of the Torlak Institute.

[5] The threat to public health is represented by microorganisms that cause various diseases that occur in Serbia from time to time - endemic (mouse fever, West Nile fever, tularemia, brucellosis, tuberculosis, Q fever, etc.). In addition, as history testifies, there is always the possibility that infected travelers from other countries will cause an epidemic caused by a microorganism that is not present in Serbia or by a so far unknown causative agent. In addition, climate change contributes to the spread of microorganisms to new areas, and the threat to public health that would arise because of the use of biological weapons cannot be completely ruled out.

[6] from the Risk Group-3 of pathogenic microorganisms

[7] from the Risk Group-3 of pathogenic microorganisms

1.4 ESIA Requirements

The ESIA report for the Sub-project has been prepared according to the WB's Environmental and Social Framework (ESF).

An ESIA Report has not been prepared according to Serbian legislation since the Sub-project is not included in List 1 (projects that require EIA) or List 2 (projects that may require EIA) in the "Regulation on the List of Projects Requiring a Mandatory Impact Assessment and List of Projects that May Require an Environmental Impact Assessment of Official Gazette of RS, no. 114/2008, official letter is provided in Appendix A. For the financing of the Sub-project , ESIA report is prepared in line with the requirements of WB's Environmental and Social Framework (Environmental and Social Standards).

The purpose of the ESIA study is to describe the Sub-project , identify and assess the severity of potential environmental and social impacts and risks on receptors and identified resources; develop and describe mitigation measures that will be taken to prevent or minimize any potential negative effects and maximize the potential benefits for the construction and operation phases of the Sub-project. This document represents the Draft ESIA report which has been prepared in line with the WB ESSs as well as national requirements, which are detailed in *Chapter 4: Institutional and Regulatory Framework* and *Chapter 5: Scope and Methodology of the ESIA*. The applicable national laws and regulations have also been specified in a regulatory framework document provided in Appendix B.

The mitigation measures proposed by the ESIA study are included in an accompanying ESMP which is presented in Appendix C.

1.5 Key Steps in the ESIA Process

ESIA is a systematic process that predicts and evaluates the impacts of a project on various aspects of the physical, biological, cultural and socioeconomic environment. This is followed by the identification of appropriate mitigation measures to avoid, reduce, remedy, offset or compensate for adverse impacts relevant to the nature and scale of the project. The key steps of the ESIA process are presented in Figure 1-1.

Information about the key steps outlined below is described in *Chapter 5: Scope and Methodology of the ESIA*.

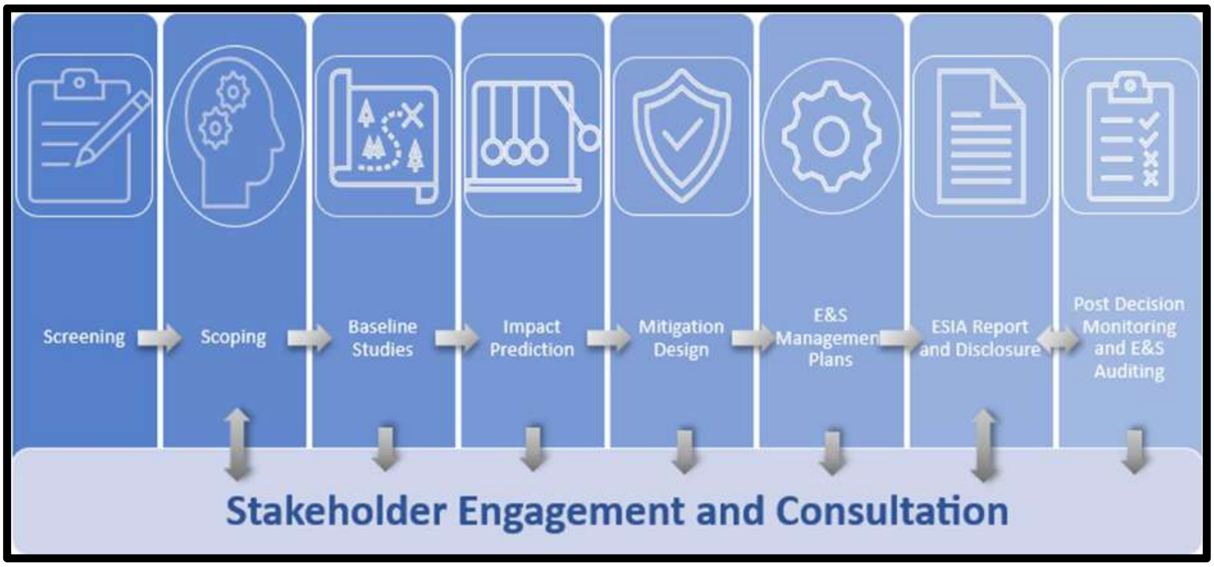


Figure 1-1. ESIA process

1.6 Current Status of the Sub-Project at ESIA Stage

Available information regarding design, construction and operation of the Sub-project has been included in the ESIA Study. Significant changes in the design are not expected; on the other hand, if changes occur during the ESIA process, these will be reviewed and assessed by environmental and social consultant and additional relevant mitigation measures may need to be identified and implemented as necessary if the impacts will differ from those identified in this ESIA Report.

1.7 Outline of the ESIA

The structure of the ESIA report is outlined below in Table 1-1.

Table 1-1. ESIA Report Structure

Chapter	Contents
Executive Summary	Provides an overview of the results of the environmental and social impact assessment studies carried out for the Project and also the legal framework, institutional arrangement, and the budget for the ESMP implementation.
Chapter 1 – Introduction	Presents a brief background to the proposed Project, Project rationale, the national EIA and international ESIA processes and the purpose and structure of the ESIA report.
Chapter 2 – Project Description	Describes the proposed Project components, including an overview of ancillary infrastructure / Project activities.
Chapter 3 – Project Alternatives	Discusses the Project alternatives that have been considered in the ESIA process
Chapter 4 – Institutional and Regulatory Framework	Describes the legislative, policy and administrative requirements, as well as international good practise requirements applicable to the proposed Project.

Chapter	Contents
Chapter 5 – Scope and Methodology	Describes the ESIA Process followed for the proposed Project and the associated impact assessment methodology employed.
Chapter 6 – Environmental and Social Baseline	Provides a detailed baseline assessment of environmental and social conditions including land use, geology, soil erosion, hydrology and hydrogeology, waste and wastewater management, air quality, noise, traffic, biodiversity, cultural heritage, community health and safety)
Chapter 7 – Environmental and Social Risks and Impacts and Mitigation Measures	Presents the predicted impacts to environment and socio-economic as a result of the proposed Project. Presents the management and mitigation recommendations.
Chapter 8 – Cumulative Impact Assessment	Presents the cumulative impacts that are a result of existing Projects
Chapter 9 – Stakeholder Engagement	Summarises the stakeholder engagement activities undertaken for the ESIA Project to date.
Chapter 10 – Environmental and Social Management	Introduces the Environmental and Social Management Plan that present the mitigation measures for the identified environmental and social impacts with the proposed monitoring activities and responsible parties.
Appendices	Contains a list of appendices within the ESIA Report.

The ESIA Report is supported by the following appendices:

Appendix A: Official Letters
Appendix B: Environmental, Health and Safety and Social (EHSS) Legislation Review
Appendix C: Environmental and Social Management Plan and Environmental and Social Monitoring Plan (provided as a separate document)
Appendix D: Chance Find Procedure
Appendix E: Responsibilities of Laboratory Diagnostics Division
Appendix F: Background Measurement Reports
Appendix G: Decontamination with Hydrogen Peroxide

2 SUB-PROJECT DESCRIPTION

The Sub-project will be constructed within the existing Torlak Institute of Virology, Vaccines and Sera (Torlak Institute) in Belgrade, which is a national institution for the prevention, treatment, and monitoring of infectious diseases. It is one of the oldest institutions of this kind in the world, with a tradition and experience of more than 95 years. The Sub-project location is given in Figure 2-1. Torlak Institute monitors, studies, examines, identifies, introduces, and implements professional and scientific methods of prevention and diagnosis of infectious diseases, performs scientific research and educational activities with the aim of developing new technologies and improving vaccines production. As a national vaccine producer, the Institute supplies healthcare institutions performing public health activities in the Republic of Serbia with vaccines from the compulsory immunization program, as well as with other vaccines needed. In addition to vaccines, the institute produces sera and other immunobiological and diagnostic products, medical devices, and food supplements. The Torlak Institute performs trade, i.e., the import and export of medicines, medical devices, food supplements and raw materials to produce medicines and other devices.

There are four reference national laboratories operating within the Torlak Institute:

- National laboratory for influenza and other respiratory viruses,
- National laboratory for poliomyelitis and enteroviruses,
- National laboratory for rubella, morbilli, varicella and other rashes, and
- National laboratory for viral haemorrhagic fevers and Arboviruses (arthropod-borne viruses).

Existing laboratories of the Torlak Institute are standard and BSL-2 laboratories.

The national laboratories of the Torlak Institute are a part of the European laboratory network of the World Health Organization (WHO) and have full membership status as the WHO accredited laboratories. The laboratories have achieved inter-laboratory cooperation with microbiological laboratories in the Republic of Serbia and the related laboratories in Europe.

The Sub-project will be operated under the Torlak Institute. The capacity and existing organizational structure of the Torlak Institute as well as the existing infrastructure of electricity, water, wastewater and transportation will be used for Sub-project purposes. Waste and wastewater management of the Sub-project is detailed in related chapters of the report.

The Sub-project has been designed as a diagnostic laboratory building with Biosafety Level 3 (BSL-3). The BSL-3 laboratory within the scope of the Sub-project will fulfil the requirements for handling pathogenic agents that require such a level of biosafety, like SARS-CoV-1, yellow fever virus, West Nile virus, eastern equine encephalitis virus, and MERS-CoV but also various bacterial, fungal and rickettsia pathogens. The Sub-project will help strengthening Serbia’s national laboratory system since there is currently no facility in Serbia that can handle pathogens requiring a BSL-3 or higher.

The BSL-3 laboratory will be available not only to the "Torlak" Institute, whose primary activity is in the field of virology, but also to other diagnostic and scientific research institutions in Serbia. Torlak Institute consists of a total area of 5.2 Ha.

The new diagnostic laboratory building consists of 4 floors (basement, ground floor and 3 upper floors), with total area of approximately 4,200 m^2 in which one BSL-3 laboratory will be established in a total area of approximately 150 m^2. The general layout of the Sub-project is given in Figure 2-1.

The building is structured as right and left wings. The BSL-3 laboratory will be established at the left wing of the building, the general layout of left and right wings of building is given in Figure 2-2. The MoH will use the right wing for basic Immunology, Allergology and Bacteriology laboratories with biosafety level lower than BSL-3.

2.1 Sub-Project Location

The Sub-project location is in settlement Jajinci on the southern edge of Belgrade. The Sub-project area is a state-owned land already within the existing Torlak Institute and there will be no land acquisition and/or restriction to lands/assets and resources use within the scope of the Sub-project.

The Torlak Institute in a fenced area includes an administrative building and four national reference laboratories for diagnostics. The complex is located in an urban area, surrounded by commercial and residential buildings. The Sub-project will be located on the north side of the institute within the fenced area. On the north of the Sub-project at a distance of about 100 meters, Faculty of Pharmacy is located. Between the Faculty of Pharmacy and the Torlak Institute lies the Zavodska Street. On the east, at the border of the institute is the Vojvode Stepe Street. Across the Vojvode Stepe Street, there is an open area used for car parking. The close residential buildings to the Sub-project are at about 150 m distance to the south-east and west of the Sub-project site. The closest business is an auto sales shop at 170 meters to the south-east. The location of the Sub-project and closest residential buildings are given in Figure 2-1 and Figure 2-3 respectively.

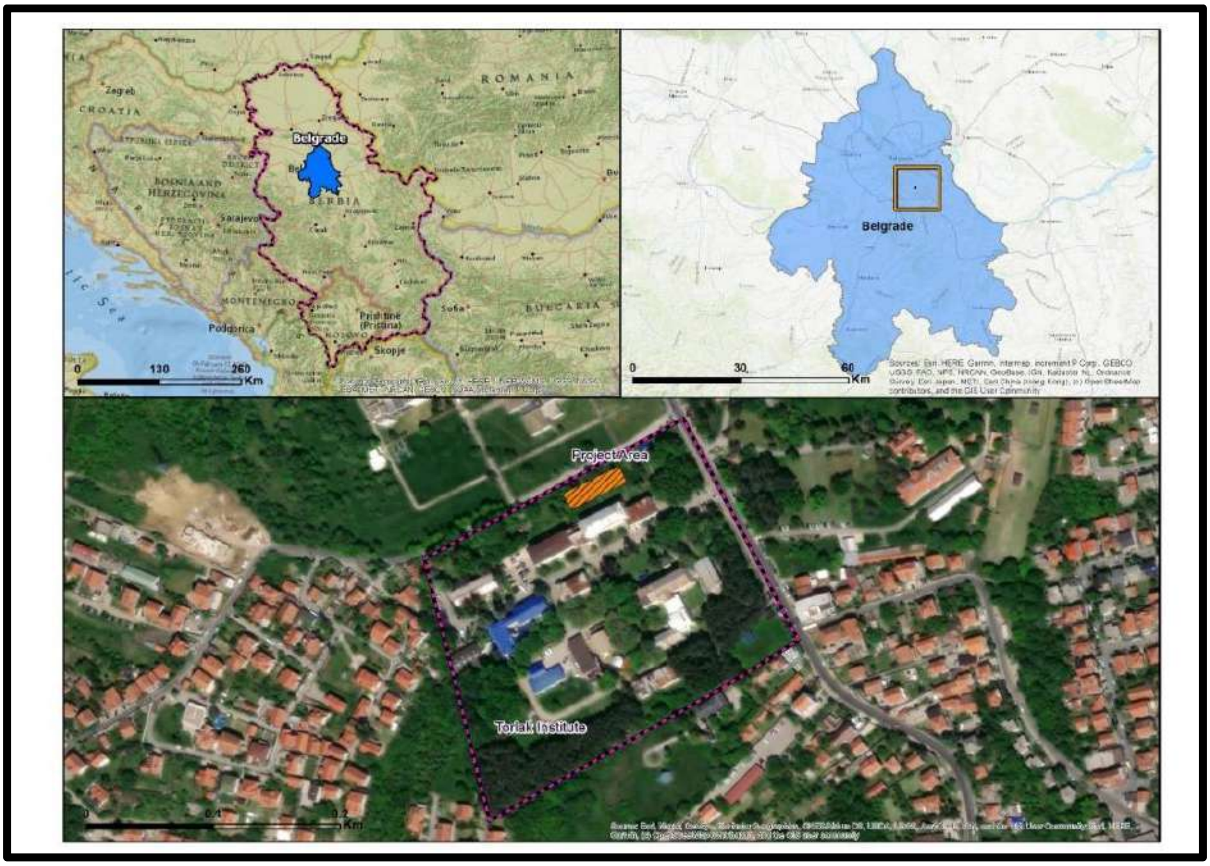


Figure 2-1. Sub-Project Location

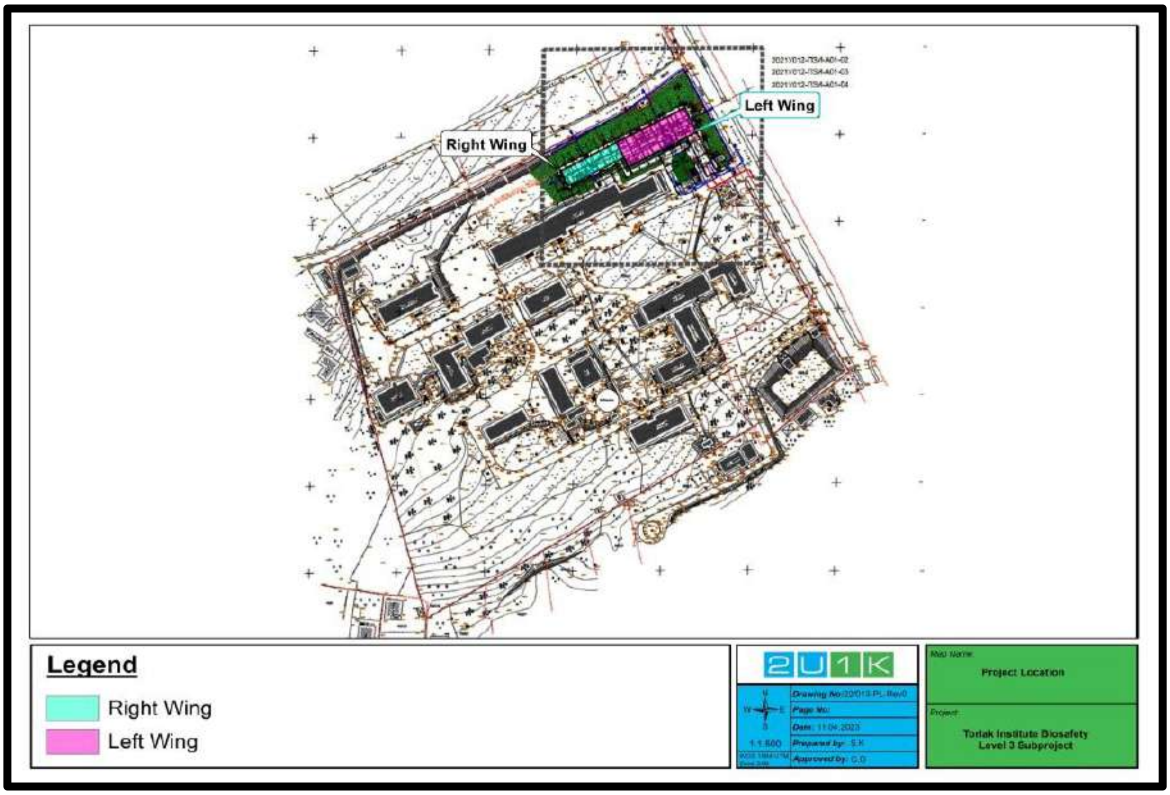


Figure 2-2. General Layout of Left and Right Wings of the Building

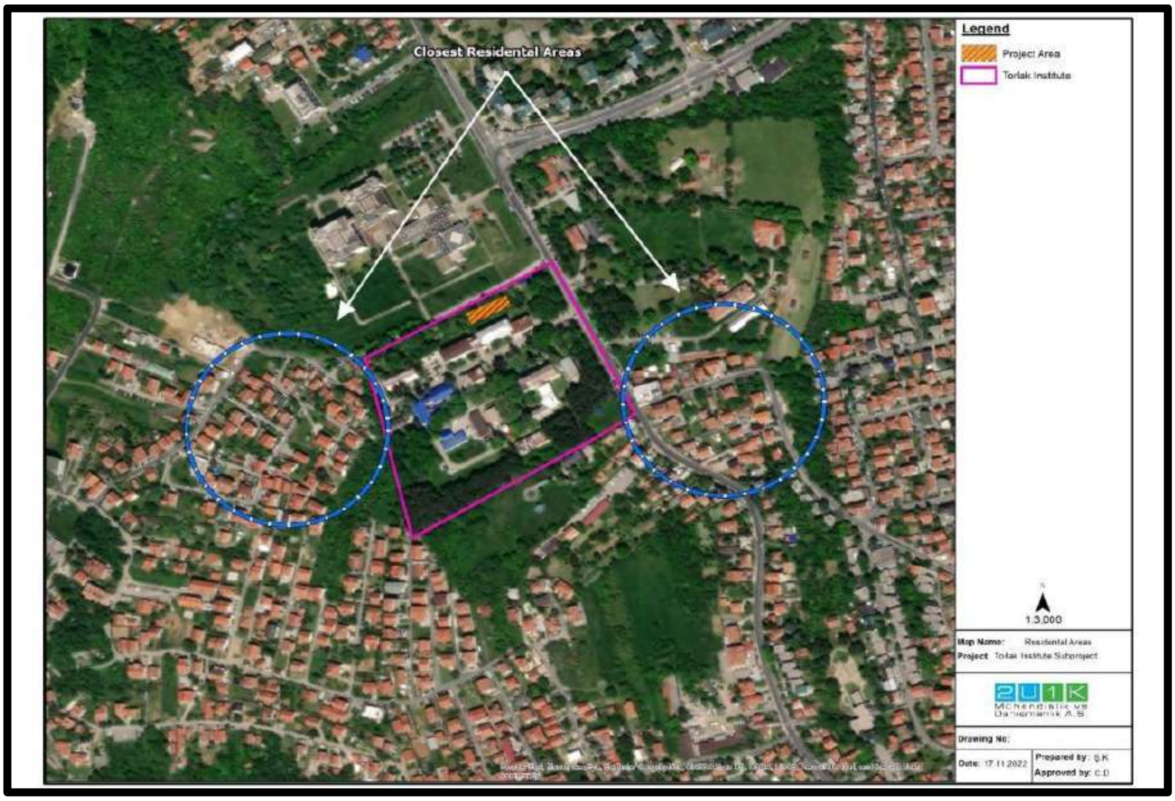


Figure 2-3. Closest Residential Buildings around the Sub-Project Area

2.2 Sub-Project Components

The new diagnostic laboratory building will be constructed in left and right wings and 4 floors with a total area of approximately 4,200 m^2 (

Table 2-1). The general layout of the Sub-project is given in Figure 2-1.

Within the scope of the Sub-project's electricity works, a transformer station next to the existing building of Torlak Institute will be built. Capacity of the transformer station is 1000 kVa. Two underground connection lines for the transformer station (10kV, type XHE 49-A 3x (1x150) mm^2) will have approximately 200 m length (Figure 2-4).

Left wing basement will consist of a car park for the use of the laboratory employees exclusively. The basement with 619.1 m^2 area will a have space of 16 cars and only be used by the employees with restricted access. The ground floor will be used for the registration and admission of patients and samples (Table 2-2). The BSL-3 laboratory will be located at the 1st floor of the building (Table 2-3). 2nd and 3rd floor will include HVAC room and technical rooms (Table 2-4 and Table 2-5). At the right wing, ground floor and 1st floor will provide space for Immunology, Allergology and Bacteriology laboratories. 2nd and 3rd floors will consist of the handling area (Table 2-6-Table 2-9).

Table 2-1. Diagnostic Laboratory Building Area by Floor

Floor	Left Wing) (Area m^2)	Right Wing (Area m^2)
Basement	619.1	-
Ground Floor	582.75	287.89
1st Floor	588.05	283.9
2nd Floor	607.35	296.34
3rd Floor	611.59	296.34
Total	3,008.84	1,164.47
Total Area (Left Wing+Right Wing)	4,173.31	

Table 2-2. Ground Floor-Left Wing Floor Plan

No	Ground –loor - Left Wing	m²	Final Finishing	
			Floor	Wall
L.0.01	Waiting room for patients for virological bacteriological immunological and allergology analyses and immunization	59.98	PVC	Gypsum board / Dispersion paint
L.-0.01a	Corridor # 1	56.27	PVC	Gypsum board / Dispersion paint
L.-0.01b	Corridor # 2	59.22	PVC	Gypsum board / Dispersion paint
L-0.02	COVID and non-COVID patients, treasury	29.62	PVC	Gypsum board / Dispersion paint
L-0.03	Mission and sampling for virological, bacteriological, immunological and allergology analyses and immunization	20.42	PVC	Clean room panels
L-0.04	Admission and sampling for virological, bacteriological, immunological and allergology analyses and immunization	16.30	PVC	Clean room panels
L-0.05	dmission and sampling for virological, bacteriological, immunological and allergology analyses and immunization	16.30	PVC	Clean room panels
L-0.06	Material reception and processing	28.11	PVC	Clean room panels
L-0.06A	Material elevator	/	/	/
L-0.07	Waiting room for COVID-19 patients	26.06	PVC	Gypsum board / Dispersion paint
L-0.07A	COVID-19 patients sampling	10.08	PVC	Clean room panels
L-0.08	COVID-19 patients sampling	10.31	PVC	Clean room panels
L-0.09	COVID-19 patients sampling	14.71	PVC	Clean room panels
L-0.10	Reception and sorting of Covid samples from the field	10.04	PVC	Clean room panels
L-0.10A	Sanitary–pass - COVID/Non COVID	10.00	PVC	Clean room panels
L-0.10B	Lobby	9.50	PVC	Clean room panels
L-0.10C	Material platform	/	/	/
L-0.11	Toilet for Covid-19 patients- disabled	4.09	Granite ceramic tiles	Granite ceramic tiles
L-0.12A	Non-Covid patients toilet lobby	2.50	Granite ceramic tiles	Granite ceramic tiles
L-0.12B	Non-Covid patients t–ilet - Men	5.96	Granite ceramic tiles	Granite ceramic tiles
L-0.12C	Non-Covid patients t–ilet - Women	6.77	Granite ceramic tiles	Granite ceramic tiles
L-0.12D	Non-Covid patients t–ilet - Disabled	4.61	Granite ceramic tiles	Granite ceramic tiles
L-0.13	Locker room with toilet and sh–wers - Women	38.25	Granite ceramic tiles	Gypsum board / Dispersion paint
L-0.14	Locker room with toilet and sh–wers - Men	18.38	Granite ceramic tiles	Gypsum board / Dispersion paint
L-0.15	Locker–Room - Official Visitors	4.28	Granite ceramic tiles	Gypsum board / Dispersion paint

No	Ground –loor - Left Wing	m^2	Final Finishing	
			Floor	Wall
L-0.16	Storage room	32.74	PVC	Gypsum board / Dispersion paint
L-0.17	Dining room	27.55	Granite ceramic tiles	Gypsum board / Dispersion paint
L-0.18	Decontamination and decontaminated material disposal	13.20	PVC	Clean room panels
L-0.18A	Output sanitary pass for decontamination room	1.83	PVC	Clean room panels
L-0.18B	Input sanitary pass for decontamination room	2.24	/	/
L-0.19A	Winds–ield - Non-Covid-19 patience entrance	7.06	Granite ceramic tiles	Gypsum board / Dispersion paint
L-0.19B	Winds–ield - staff and materials entrance	4.28	Granite ceramic tiles	Gypsum board / Dispersion paint
L-0.19C	Windshield-disinfected material exit	4.02	Granite ceramic tiles	Gypsum board / Dispersion paint
L-0.20	Staircase	22.04	Granite ceramic tiles	Dispersion paint
L-0.21	Passenger elevator	/	/	/
L-0.22	Freight elevator	/	/	/
L-0.23	Toilet for Covid-19 Patients (men and women) with lobby	6.03	Granite ceramic tiles	Granite ceramic tiles
	Net Area	582.75		

Table 2-3. 1st Floor-Left Wing Floor Plan

No	1st –loor - Left Wing	m²	Final Finishing	
			Floor	Wall
L-1.0	Corridor	43.72	PVC	Wall
L-1.0A	Corridor	44.63	PVC	Plasterboard/ dispersion
L-1.0B	Lobby	4.87	PVC	plasterboard/ dispersion
L-1.1	Entrance sanitary pass for materials	4.96	PVC	plasterboard/ dispersion
L-1.1A	Elevator platform for materials	/	/	clean room panel
L-1.1B	Corridor	29.93	PVC	/
L-1.2	Entry pass/Air chamber for stuff (with shower and eyewash)	11.10	PVC	clean room panel
L-1.2A	Output pass/ Air chamber for stuff (with shower and eyewash)	12.03	PVC	clean room panel
L-1.3	Samples st–rage - freezers	18.02	PVC	clean room panel
L-1.4	BSL3 Virology laboratory- virus isolation	31.72	PVC	clean room panel
L-1.4A	BSL 3 Virology laboratory serological procedures	26.19	PVC	clean room panel
L-1.4B	Bacteriology laboratory	29.17	PVC	clean room panel
L-1.5	Transient autoclave	2.69	/	clean room panel
L-1.6	Transient auto clave	2.69	/	/
L-1.7	Platform for decontaminated waste material	/	/	/
L-1.8	Room for disposal of decontaminated material	20.39	PVC	/
L-1.9	Lobby for stuff	18.78	PVC	clean room panel
L-1.9A	Corridor	14.52	PVC	clean room panel
L-1.10	Room for working with infected materials- 1 (polio and enteroviruses)	23.60	PVC	clean room panel
L-1.11	Space for working with infectious materials-2 (coxsackie test)	28.24	PVC	clean room panel
L-1.11A	The reporting room	5.70	PVC	clean room panel
L-1.11B	Lobby	4.18	PVC	plasterboard/ dispersion
L-1.12	Room for working with infectious materials-3 (morbid	14.77	PVC	clean room panel
L-1.12A	Lobby	7.85	PVC	clean room panel
L-1.13	Room for working with infectious materials-4 (grip)	12.93	PVC	clean room panel
L-1.14	Laboratory- clinical examination	20.47	PVC	clean room panel

No	1st –loor - Left Wing	m²	Final Finishing	
			Floor	Wall
L-1.15	Electrical room	5.05	granite ceramic	clean room panel
L-1.16	Laboratory for the preparation of cell banks	26.35	PVC	plasterboard/ dispersion
L-1.16A	Storage for cell banks and liquid nitrogen bottles	3.22	PVC	clean room panel
L-1.17	Laboratory for the preparation of cell lines	30.58	PVC	clean room panel
L-1.17a	Lobby	5.35	PVC	clean room panel
L-1.18	Room for decontamination of infectious waste	10.94	PVC	clean room panel
L-1.18A	Monitoring room	5.80	PVC	clean room panel
L-1.19	Laboratory for the preparation of media and solution	25.73	PVC	plasterboard/ dispersion
L-1.19A	Platform for consumable	/	/	clean room panel
L-1.19B	Changing room with shower	12.52	granite ceramic	/
L-1.20	Men`s and women`s toilet with vestibule	7.32	granite ceramic	granite ceramic tiles
L-1.21	Stair landing	9.90	PVC	granite ceramic tiles
L-1.22	Staircase	12.14	granite ceramic	dispersion paint
L-1.23	Passenger elevator	/	/	/
L-1.24	Freight elevator	/	/	/
	Net Area	588.05		

Table 2-4. 2nd Floor-Left Wing Floor Plan

No	2nd Floor- Left Wing	m²	Final Finishing	
			Floor	Wall
L-2.01	Staircase Lobby	9.9	granite ceramic tiles	dispersion paint
L-2.02	Staircase	12.14	granite ceramic tiles	dispersion paint
L-2.03	Passenger Elevator	/	/	/
L-2.04	Freight Elevator	/	/	/
L-2.05	Handling Area	502.9	PVC	dispersion paint
L-2.06	HVAC room-heating substation and HEPA filters	73.61	Epoxy	semi-dispersion paint
L-2.07	Service Corridor	8.8	Epoxy	semi-dispersion paint
	Net Area	607.35		

Table 2-5. 3rd Floor-Left Wing Floor Plan

No	3rd Floor- Left Wing	m²	Final Finishing	
			Floor	Wall
L-3.01	Staircase Lobby	9.9	granite ceramic tiles	dispersion paint
L-3.02	Staircase	12.14	granite ceramic tiles	dispersion paint
L-3.03	Passenger Elevator	/	/	/
L-3.04	Freight Elevator	/	/	/
L-3.05	Handling Area	576.24	PVC	dispersion paint
L-3.06	HVAC room-heating substation and HEPA filters	13.31	Epoxy	semi-dispersion paint
	Net Area	611.59		

Table 2-6. Ground Floor-Right Wing Floor Plan

No	Ground Floor - Right Wing	m^2	Final Finishing	
			Floor	Wall
D-0.1	Corridor # 1	44.03	PVC	gypsum board / dispersion paint
D-0.1A	Lobby	3.12	PVC	gypsum board / dispersion paint
D-0.1B	Corridor # 2	26.46	PVC	gypsum board / dispersion paint
D-0.2	Office	10.93	PVC	gypsum board / dispersion paint
D-0.2A	Office	12.15	PVC	gypsum board / dispersion paint
D-0.3	Dining Room	23.00	Granite ceramic tiles	gypsum board / dispersion paint
D-0.4	Office	14.74	PVC	gypsum board / dispersion paint
D-0.4A	Laboratory vessels washing	10.52	PVC	clean room panels
D-0.5	Serological diagnostics (referent laboratories)	18.82	PVC	clean room panels
D-0.5A	Fluorescent microscope room 3	3.27	PVC	clean room panels
D-0.6	Immunology	26.02	PVC	clean room panels
D-0.7	Allergology	16.00	PVC	clean room panels
D-0.8	Bacteriology	14.40	PVC	clean room panels
D-0.9	Auto-vaccine production	16.06	PVC	clean room panels
D-0.10	Serological diagnostics - Respiratory viruses	15.01	PVC	clean room panels
D-0.11	Decontamination	7.87	PVC	clean room panels
D-0.12	Freight elevator for materials	5.87	/	/
D-0.13	Staff toilet - Men	3.10	Granite ceramic tiles	granite ceramic tiles
D-0.14	Staff toilet - Women	3.10	Granite ceramic tiles	granite ceramic tiles
D-0.15	Pantry	5.87	PVC	gypsum board / dispersion paint
D-0.16	Windshield - staff entrance	7.55	Granite ceramic tiles	gypsum board / dispersion paint
	Net Area	287.89		

Table 2-7. 1st Floor-Right Wing Floor Plan

No	1st Floor - Right Wing	m²	Final Finishing	
			Floor	Wall
D-1.1	Toilet- women	3.06	granite ceramics	clean room panel
D-1.2	Toilet- man	3.06	granite ceramics	plasterboard/ granite ceramics
D-1.3	Reporting room	9.73	PVC	plasterboard/ dispersion paint
D-1.4	Archive	15.28	PVC	plasterboard/ dispersion paint
D-1.5	Warehouse	17.81	PVC	plasterboard/ dispersion paint
D-1.6	Visualization room/ sequencing product	10.99	PVC	clean room panel
D-1.6a	Lobby	5.46	PVC	clean room panel
D-1.7	PCR product purification	10.63	PVC	clean room panel
D-1.8	Room for sequencing	10.99	PVC	clean room panel
D-1.9	Combined elevator	/	/	/
D-1.10	Staircase	10.40	granite ceramics	dispersion
D-1.11	Room for PCR devices	16.26	PVC	clean room panel
D-1.12	Room for working with processed materials (sample instillation)	9.87	PVC	clean room panel
D-1.13	Room for working with processed materials (sample instillation)	9.85	PVC	clean room panel
D-1.14	Room for working with non infectious and sterile materials (MM Miks)	11.02	PVC	clean room panel
D-1.15	Room for deeps	10.80	PVC	clean room panel
D-1.16	Cold room for sample storage (-20°C)	9.74	PVC	thermopanel
D-1.17	Corridor 1	34.12	PVC	plasterboard/ dispersion paint
D-1.18	Changing room 2	2.98	PVC	plasterboard / granite ceramics
D-1.19	Corridor 2	24.50	PVC	plasterboard / dispersion paint
D-1.20	Space for decontamination for infectious samples- storage and delivery of infectious material	9.60	PVC	clean room panel
D-1.21	Area for working with infectious materials 3	12.87	PVC	clean room panel
D-1.22	Area for working with infectious materials 2	12.04	PVC	clean room panel
D-1.23	Area for working with infectious materials 1	22.84	PVC	clean room panel
	Net Area	283.90		

Table 2-8. 2nd Floor-Right Wing Floor Plan

No	2nd Floor - Right Wing	m²	Final Finishing	
			Floor	Wall
D-2.01	Staircase	10.40	Granite ceramics tiles	dispersion paint
D-2.02	Service Elevator	/	/	/
D-2.03	Handling Area	285.94	PVC	dispersion paint
	Net Area	296.34		

Table 2-9. 3rd Floor-Right Wing Floor Plan

No	3rd Floor - Right Wing	m²	Final Finishing	
			Floor	Wall
D-2.01	Staircase	10.40	Granite ceramics tiles	dispersion paint
D-2.02	Service Elevator	/	/	/
D-2.03	Handling Area	285.94	PVC	dispersion paint
	Net Area	296.34		

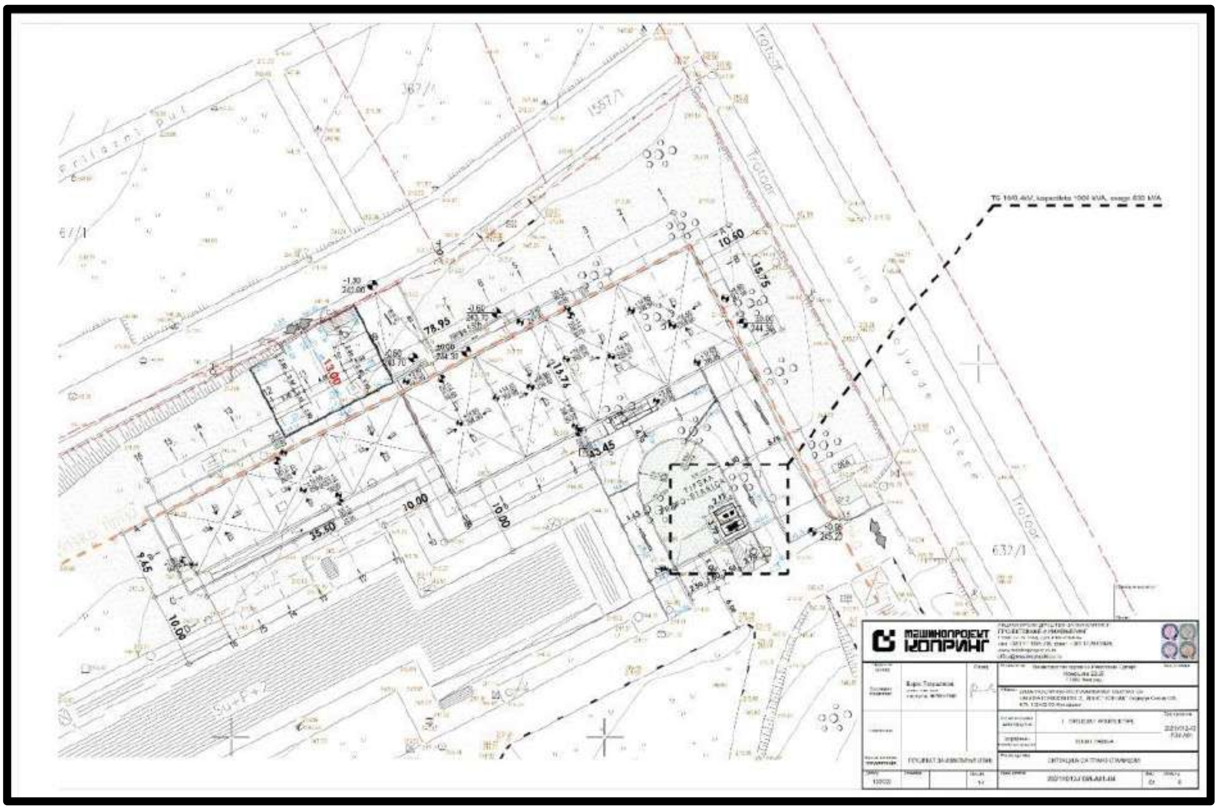


Figure 2-4. Transformer Station

2.3 BSL-3 Laboratory Design Requirements

The construction of the new diagnostics building with BSL-3 laboratory will include site preparation, levelling works, excavation, rough construction works and mechanical and electrical installations. The construction company will be selected through a public tender process. It is expected that a total of 40 workers will be employed for construction activities. There will be no camp site for construction workers. The construction material such as bricks, sand, gravel and aggregate will be stored at a designated area within the Sub-project site.

Electricity required for construction activities will be supplied from city grid through 33 V transmission line.

Water required for construction activities, dust suppression and domestic use will be provided from municipality network using existing Torlak Institute infrastructure.

The existing infrastructure has the capacity for waste and wastewater management of BSL-3 laboratory considering the limited amount generated compared to Torlak Institute.

The construction of the Sub-project is planned to be started at Q4 2023 and last for 6 (six) months.

The design of the new diagnostic building with BSL-3 will ensure efficient water and sanitation facilities, proper waste collection and treatment systems, and effective wastewater treatment. The aim is to minimize the environmental footprint of the Sub-project and promote sustainable practices.

Water need during operation will be provided through a connection from the existing municipality network.

Electricity required for BSL-3 laboratory operations will be provided from the existing national grid through a transformer station which will be built next to the existing building of Torlak Institute. Capacity of the transformer station is 1000 kVa. Two underground connection lines for the transformer station (10kV, type XHE 49-A 3x (1x150) mm2) will have approximately 200 m length.

Domestic wastewater generated during operation of the new diagnostic building with BSL-3 will be disposed through a connection with the existing city sewage infrastructure. The BSL-3 laboratory will be constructed as dry-lab There will be a limited amount of liquid waste (5lt/day) generation during operation of the BSL-3 laboratory. This liquid waste will be autoclaved for decontamination and then disposed to the sewerage system. The amount of solid contaminated waste is expected to be 20 kg/day. Solid waste will also be autoclaved for decontamination and then sent to a licenced landfill according to the national legislation. A total of ten regional sanitary landfills and two more that are not of the regional type have been built in accordance with the EU standards, by the end of 2021 in Serbia[8]. There is an operational regional sanitary landfill "Vinca" Belgrade with a capacity of 200,000 ton/year. There is also Energy-to-Waste PPM Project between Beo Čista Energija and the City of Belgrade which is in final commissioning phase. Another type of waste will be the liquid waste from emergency eyewash/body wash shower. The liquid waste will be collected in a collection tank and will be chemically decontaminated before disposal through authorized operators. Details of generated waste and waste management are provided in Chapter 7.3.

Additionally, a key focus will be placed on providing universal access to these facilities, ensuring the building is accessible to all individuals, regardless of their physical abilities. Furthermore, life and fire safety measures will be incorporated into the design to safeguard the well-being of both staff and community. Fire detection and alarm systems will be in place and emergency equipment will include appropriate fire extinguishers and fire blankets. Fire-fighting equipment will be available at strategic points in corridors and hallways. It will be ensured that fire extinguishers are regularly inspected and maintained. Fire warnings, instructions and escape routes will be displayed clearly within the building.

[8] Waste Management Program Of The Republic Of Serbia For The Period 2022-2031

By prioritizing these environmental and social considerations, the Sub-project strives to create a responsible and inclusive environment while upholding high standards of environmental and social management.

The BSL-3 laboratory within the scope of the Sub-project will be designed, constructed, and operated in accordance with the requirements of WHO Laboratory Biosafety Manual, 3rd edition, 2004 and 4th edition, 2020.

The BSL-3 laboratory will be certified by an independent third-party prior to operation regarding the required design and operational parameters. The certification process of the Sub-project will be conducted using the tools provided in Tables 5–7 (Laboratory Safety Surveys) of the WHO Biosafety Manual (3rd edition, 2004).

With respect to the commissioning and certification of BSL laboratories, the Sub-project will refer to the below listed international standards, guidelines and regulations including but not limited to:

- WHO Laboratory Biosafety Manual, 3rd edition, 2004 and 4th edition, 2020,
- CWA 15793:2008 Laboratory Biorisk Management Standard,
- CDC-NIH Biosafety at Microbiological and Biomedical Laboratories, 6th edition, 2020,
- NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (DRM), 2019, and
- NIH Biosafety Level 3 Laboratory Certification Requirements, 2006
- ISO 14644 series, Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones
- NSF/ANSI 49 or ISO 12469
- ANSI/ASSP Z9.14:2020 Testing and Performance-Verification Methodologies For Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) Ventilation Systems
- Canadian Biosafety Standard, 3rd., November 2022
- CAN/CSA-B64.10-M88: Backflow Prevention Devices-Selection, Installation, Maintenance, and Field Testing
- The Federal Select Agent Program (FSAP, USA) policy statement published in November 2014
- ASME N511. In-Service Testing of Nuclear Air-Treatment, Heating, Ventilating, and Air-Conditioning Systems

2.3.1 Laboratory Design and Facilities

As mentioned above the BSL-3 laboratory will be designed according to design features, construction, containment facilities, equipment, practices and operational procedures required by the WHO Laboratory Biosafety Manuals and meet the basic design requirements given in Figure 2-5.

1. The laboratory will be separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory will be restricted. Passage through a series of two self-closing will be ensured for entry into the laboratory from access corridors. Doors must be lockable. All windows will be closed and sealed.
2. Each laboratory room will contain a hands-free controlled sink for handwashing located near the room exit door as well as an eye-wash station.
3. The interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled as well as the laboratory furniture will be constructed for easy cleaning and decontamination. Seams, if present, will be sealed. Walls, ceilings, benchtops and floors will be smooth, impermeable to liquids, and resistant to the chemicals and disinfectants normally used in the laboratory.
4. BSL-3 laboratories will be equipped for decontamination of laboratory waste using an incinerator, an autoclave, and/or another method of decontamination, depending on the biological risk assessment. If infectious waste is transported out of the laboratory, it will be transported in unbreakable and leakproof containers according to national or international regulations, as appropriate.
5. Biological safety cabinets will be located away from doors, from room supply louvers, and from heavily travelled laboratory areas.
6. A ducted exhaust air ventilation system will be provided. This system will create directional airflow, which draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air will not be recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements and specific agent manipulations and use conditions. The outside exhaust will be HEPA-filtered. Laboratory personnel will verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow will be provided at the laboratory entry. Consideration will be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms will be considered to notify personnel of HVAC system failures.
7. HEPA-filtered exhaust air from a Class II biological safety cabinet (BSC) will be recirculated into the laboratory and the cabinet is tested and certified at least annually. When exhaust air from Class II BSCs is to be discharged to the outside through the building exhaust air system, the cabinets will be connected in a manner that avoids any

interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III BSCs are used, they should be directly connected to the exhaust system. If Class III BSCs are connected to the supply system, it will be done in a manner that prevents positive pressurization of the cabinets.

8. Continuous flow centrifuges or other equipment that may produce aerosols will be contained in devices that exhaust air through HEPA filters before discharge into the laboratory. These HEPA systems will be tested at least annually. HEPA filters will be replaced when needed. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.
9. Vacuum lines will be protected with liquid disinfectant traps and HEPA filters, or their equivalent. As an alternative portable vacuum pumps (also properly protected with traps and filters) may be used.

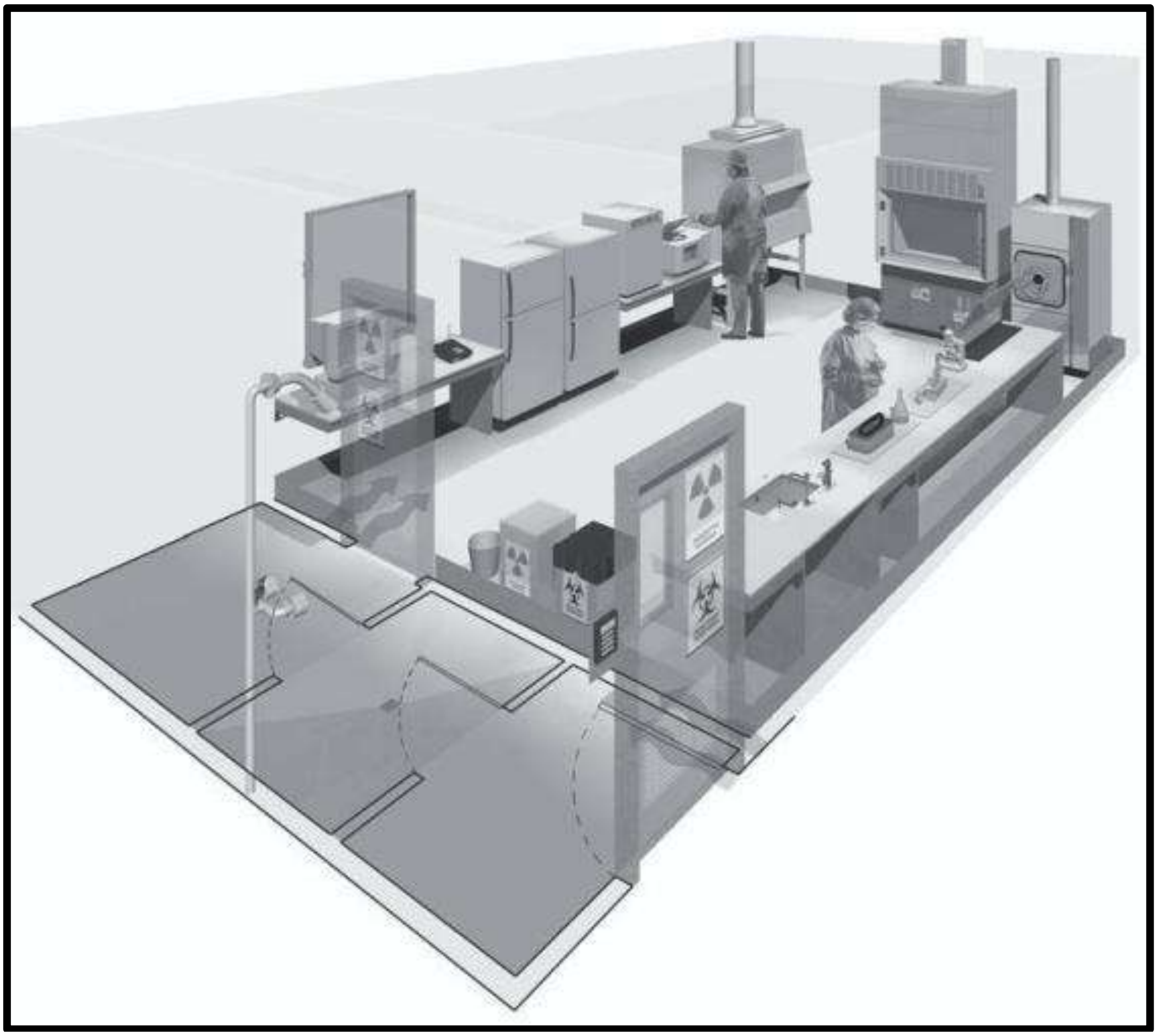


Figure 2-5. A Typical BSL-3 Laboratory (WHO Biosafety Manual, 3rd edition,2004)

2.3.2 Biosafety Management

Torlak Institute management will be responsible for the overall management of the new diagnostics building with BSL-3. Torlak Institute will establish and implement a biosafety management program according to the requirements defined in WHO Biosafety Manual, 4th edition in order to prevent infections among personnel and to protect the public, the environment, from harm by preventing the inadvertent release of biological material. They are responsible for ensuring funding to support the biosafety programme management and for providing oversight of the implementation and ongoing review of the programme components. Torlak Institute will;

- Commit to appropriately address and manage the risks associated with the biological agents being handled,
- Appoint responsible people for biosafety (inc. biosafety committee including biosafety officer),
- Identify all risks related to work activities and control risks to an acceptable and practical level,
- Develop practices and policies to control risks and monitor regularly to ensure continued effectiveness and relevance,
- Provide appropriate training framework for personnel in biosafety practices and biosecurity awareness,
- Ensure the roles and responsibilities of all personnel are clearly set out and understood,
- Ensure laboratory activities in relation to laboratory biosafety, and its associated policies and procedures are compatible with national and international guidelines and regulations.

Laboratory Diagnostics Division of the Torlak Institute will develop and implement a biosafety manual specific to BSL-3 laboratory for performing laboratory practices safely in accordance with best practice and applicable national or international regulations. which includes organization- specific policies, Standard Operating Procedures (SOPs) and supporting programmes and plans including but not limited to:

- biosecurity plan and laboratory access system,
- occupational health programme
- personnel management and training programme,
- SOP development,
- facility design plans,
- laboratory equipment purchase, installation and maintenance plan,
- decontamination and waste management system,
- emergency/incident response,

- record and document management system, inventory control plan, and
- communication plan.

Laboratory Diagnostics Division of Torlak Institute has already developed and have been implementing SOPs (such as SOPs for waste handling and disposal, use of personal protective equipment, operation and maintenance of laboratory equipment, decontamination of laboratory space, etc.) and will adapt these SOPs specific to the BSL-3 laboratory.

The biosafety programme will be reviewed periodically to ensure continued suitability, adequacy and effectiveness. In order to achieve this the BSL-3 laboratory will have record-keeping and review systems which must include incident reporting and investigation and audits and inspections which provide information on the effectiveness of a biosafety programme.

Torlak Institute will assign critical roles and responsibilities for successfully managing a biosafety programme at the BSL-3 laboratory. The number of staff working at the BSL-3 laboratory will be about 25. About 5 of the total number of staff will be hired externally and the rest will be assigned internally within the Torlak Institute providing competency with required qualities and trainings.

Biosafety committee will be established to act as an independent review group for biosafety issues and will report to senior management. Biosafety committee will;

- participate in the development of biorisk policies covering biosafety and biosecurity and SOPs,
- include a representative cross-section of expertise, appropriate to the nature and scale of the activities undertaken,
- review and approve protocols and risk assessments for work involving biological materials,
- review and approve proposals for new work or significant modifications to the potential risk associated with existing activities,
- review information relating to significant accidents / incidents, data trends, associated local / organizational actions and associated communication needs,
- ensure issues addressed are formally recorded, actions allocated, tracked and closed out effectively;
- meet at a defined and appropriate frequency, and/or when otherwise required.

Biosafety officer will also be assigned for the BSL-3 laboratory in order to provide advice and guidance to personnel and management on biological safety issues. The Biosafety officer with sufficient training and experience will support developing, implementing, maintaining and continually improving a biosafety and biosecurity programme.

BSL-3 Laboratory Director/Manager will be assigned who is responsible for implementing and promoting biosafety to ensure the safety of all personnel, contractors, and visitors to the facility, and to protect the public and the environment from hazards arising from the work being performed in the laboratory.

Laboratory personnel and support personnel will be assigned who are responsible for supporting and contributing to a biosafety programme while performing their daily activities.

2.3.3 Biosecurity Management

According to WHO Biosafety Laboratory Manual, 4th edition, biosecurity refers to institutional and personnel security measures designed to prevent the loss, theft, misuse, diversion or intentional release of biological agents being handled in the laboratory. Addressing laboratory biosecurity risks in many ways parallels and complements that of biosafety risk management. Effective biosafety practices are the foundation of laboratory biosecurity and biosecurity risk control measures must be performed as an integral part of an institution's biosafety programme management.

Torlak Institute will ensure risk assessments are conducted and measures are taken in order to control any biological risks to the workers and the community. The biosecurity program is a part of commissioning and certification process of the BSL-3 laboratory. Risk assessment and the generation of related documentation will be conducted prior to commissioning of the BSL-3 laboratory. The Biosafety committee working on biosecurity issues will ensure the daily implementation, training, annual re-evaluation, the update of the related plans and procedures and practice drills for the biosecurity program during operation as risk assessment is an on-going process. Biosecurity management program is required to be re-evaluated when re-commissioning and re-certification occur. Torlak Institute will conduct the risk assessment for the BSL-3 laboratory in-house and ensure the critical personnel is appointed for the studies. Risk assessment will include hazard identification, evaluation of risks, development of a risk control strategy and selection and implementation of risk control measures. During risk assessment below review areas will be considered:

- Facility security plans;
- Physical security;
- Data and electronic technology systems;
- Security policies for personnel;
- Policies regarding access to laboratory;
- Specimen accountability;
- Receipt of agents into the laboratory;
- Transfer or shipping of agents from the laboratory;
- Emergency response plans; and
- Reporting of incidents, unintentional injuries, and security breaches.

According to the risk assessment;

- Procedures will be developed including description of the biological agent(s), its quantities, storage location and use, the person responsible, documentation of internal and external transfers, and an inactivation and/or disposal of the materials.
- Sensitive information including research data, diagnostic results, lists of key personnel, security plans, access codes, passwords, storage locations and biological agent inventories will be identified, labelled and protected. Sharing sensitive information with unauthorized individuals will be strictly prohibited.
- Laboratory biosecurity training will be provided in addition to biosafety training for all personnel according to the outcomes of the risk assessment. The training will also include a review of relevant national standards and the institution-specific procedures. Security related roles and responsibilities of personnel in everyday and emergency scenarios will also be defined.
- Physical security counter measures will be established to prevent unauthorized access of outside adversaries (that is those who do not have a legitimate presence in the facility and have malicious intent such as criminals, terrorists and extremists/activists) and also to minimize the threat from insiders (that is those who have a legitimate presence in the facility such as employees and approved visitors) who do not require access to a particular asset.
- The transfer of biological agents will comply with national and international rules for packaging, marking, labelling and documentation. The process will be controlled according to the assessed biosecurity risks of the biological agent being transported to ensure proper oversight within the biosecurity programme.
- An incident/emergency response protocol will be written and followed to ensure proper reporting, and to facilitate investigation, root-cause analysis, corrective action and process improvement.

2.4 BSL-3 Laboratory Commissioning and Certification

The commissioning and Certification of the Sub-project will be in line with WHO Biosafety Laboratory Biosafety Manual, 3rd edition, 2004 and 4th edition, 2020.

According to WHO Biosafety Laboratory Biosafety Manual, 3rd edition, 2004 laboratory commissioning may be defined as the systematic review and documentation process signifying that specified laboratory structural components, systems and/or system components have been installed, inspected, functionally tested, and verified to meet national or international standards, as appropriate. These requirements will be established by the design criteria and design purpose of the relevant building system.

The commissioning process provides the institution and the surrounding community with a greater degree of confidence that the structural, electrical, mechanical and plumbing systems, containment and decontamination systems, and security and alarm systems will operate as designed, to assure containment of any potentially dangerous microorganisms being worked with in a particular laboratory or animal facility.

Commissioning of the BSL-3 laboratory will be conducted by a commissioning team including:

- Mechanical Engineer/Technologist specialised in BSL-3 laboratories;
- HVAC Controls specialist;
- Electrical Engineer;
- Architect;
- Life Safety Specialist; and
- Operations & Maintenance Specialist.

A commissioning agent will be retained who is independent of the architectural, engineering and construction firms involved in the design and construction.

2.4.1 Essential Tests for Installation of the BSL-3 Laboratory

Construction contractors will test equipment and critical components for the first time while a team is present, and test results are properly recorded. During construction, the following devices and components will be tested:

Leak testing of supply and exhaust duct work,

- Leak test should be conducted in all the duct portions that are potentially exposed to contamination i.e. from respective containment rooms to isolation valves;
- All welds and duct joints shall be fully exposed and accessible for inspection and repair until testing is completed and validated;
- Duct and plenums should be isolated by closing isolation valves, which shall be pressurized to 1000 Pa. All the joints need to be physically inspected for any leakage;
- If any leakage is found, it needs to be repaired and again pressurized to 1000 Pa; and
- Leakage can be tested by soap bubble test or pressure decay method.

Acceptance criteria:

- No leakage assessed by soap bubble test in duct is acceptable;
- Alternatively, duct work may be tested by pressure decay method; and
- Pressure drop less than 0.1% duct volume /min is acceptable.

Factory testing of HEPA filters, HEPA filter housings, isolation valves, air tight gates and other critical components

- HEPA filter housing, isolation valves, Air-tight gates and other critical components should be tested and reported at the manufacturing unit by pressure decay method by certified third party organization.

Acceptance criteria:

- Pressure drop less than 0.1% duct volume /min is acceptable; and
- HEPA filters should be tested/certified against ISO/IEC 17025 by third party organization.

Acceptance criteria:

- HEPA filters having leakage less than 0.01% to 0.3 micrometre particles are acceptable; and
- Integrity of HEPA filters and filter housings should be tested in situ by soap bubble test and pressure decay method after installation.

Acceptance criteria:

- No leakage in filter housing is acceptable;
- Any pinhole leakage found during scanning is repaired and scanned again;
- Pressure drop less than 0.1% duct volume /min is acceptable; and
- HEPA filter having leakage less than 0.01% down to 0.3 micrometre particles is acceptable.

Leak testing of containment spaces

The goal of containment space testing is to identify and reduce leakage through containment barriers like walls, floors, ceilings, penetrations for utility lines, ducts, and electrical conduits. Testing is done by pressuring positive pressure by approximately 125 Pa and monitoring the air pressure during the test period. The following methodology will be used for testing:

- Sealing the supply and exhaust openings, closing all doors and other openings in the containment perimeter;
- Installing inclined manometer/ pressure differential meter of minimum 0-1000 Pa scale and 10 Pa least count;
- Pressuring positive pressure to 125 Pa;
- Visual inspection of possible leakage spaces;
- Soap bubble testing;

- Repairing any leakage observed;
- Repeating the test with 250 Pa;
- Monitoring pressure decay test for 20 minutes;
- Record pressure differential after every minute; and
- Release the pressure slowly after completion of monitoring period.

Acceptance criteria:

- Pressure drops less than 125 Pa (Half of original 250 Pa) in 20 minutes.

Differential pressures and/or directional air flows between adjacent areas as per design parameters

- Differential pressure meter/ pressure manometers installed at predetermined spaces monitored and readings recorded while doors are operated as per SOP;
- Negative pressures of different pressure zones should not equalize during normal operating of doors; and
- Directional air flow is tested with the visual inspection of smoke patterns while testing is conducted with the help of smoke generating pencil.

Acceptance criteria:

- Unidirectional smoke pattern from low contamination to high contamination area.

Field testing of Biological Safety Cabinets

- Critical performance tests:
  - HEPA filter installation integrity test;
  - Work zone integrity test;
  - Biosafety cabinet integrity test;
  - Down flow velocity test;
  - Face (Inflow) velocity test;
  - Air flow smoke pattern test;
  - Supply and Exhaust Fan interlocking control test; and
  - Alarm operational check
- Non-critical tests:
  - Vibration;
  - Sound level;
  - Lighting; and
  - UV light.

Acceptance criteria:

- The BSC validation according to NSF/ANSI 49 or ISO 12469 standards are acceptable.

Testing of Air-lock

- Air-lock doors should be tested for leakage by Soap bubble test and Pressure decay test as detailed above;
- Once dirty side door of air lock is opened, air lock gets contaminated; therefore, outer side door/ clean side door should only be opened after air lock has been decontaminated;
- Formalin fumigation is one of the methods recommended for gaseous decontamination; and
- Testing of air lock should be done as per SOP adopted for the lab.

Acceptance criteria:

- The proper air lock decontamination system as per SOP adopted is acceptable.

Testing of steam autoclaves

Steam autoclaves are tested depending upon the number of programs available in the Programmable Logic Controller (PLC). Effectiveness of decontamination depends on loading factors, material being decontaminated that influence the temperature to which material is subjected and the contact time. Packaging, container size, and positioning in the autoclave must all permit steam penetration and be done in a way that allows for open steam circulation. Some significant decontamination programs are intended for/directed towards:

- Liquids;
- Liquids with pre vacuum;
- Nonporous solid materials;
- Nonporous solid materials with vacuum;
- Fabric material with pre and post vacuum;
- It should be ensured that gauges, thermocouples are calibrated. For testing of effective sterilization, chemical indicators can be used. Biological indicators are recommended for the same; and
- Chamber temperature should always be more than 121 or 134ºC as per the case. During testing if chamber temperature comes down from 121ºC or from the set temperature, then time counter should be reset to zero.

Acceptance criteria:

- Appropriate working of chemical/biological indicators is acceptable.

Testing of interlocking of airlock doors, pass box doors, entry-exit doors, autoclave doors etc.

Interlocking of dirty side door and clean side door is tested as per SOP adopted for the laboratory. Both side doors should not be opened at the same time. Once the dirty side door is opened in air lock/ pass box/ autoclave, then the clean side door should open only after the chamber has been decontaminated as per the SOP adopted in the lab. In case of entry/exit doors, once the dirty side door is opened then the clean side door should open only after dirty side door has been closed and shower has been taken (it is also recommended that dirty side door should open after one air change of the shower room).

Acceptance criteria:

- The working of interlocking of doors as per SOP adopted is acceptable.

Functioning of all critical parameters will be repeated and demonstrated by authorized person/team or project management consultant for the facility, in the presence of the laboratory Biosafety Officer. Final testing and commissioning will take place in presence of committee/project team that may include third party. All performance parameters and adjustments/replacements if any carried out during testing will be documented for future reference.

2.4.2 Recommissioning of BSL-3 Laboratory

Due to the critical nature of the secondary containment system as BSL3, re-commissioning will occur on an annual basis or when there are “major changes to” or “major problems with” the laboratory HVAC system. The initial commissioning testing procedure will be repeated as part of the re-commissioning effort, and data trends showing the continuation of airflow into the laboratory during normal, failure, and emergency operational modes will also be included. Ideally, re-commissioning takes place during scheduled maintenance, cleaning or upgrade BSL3 shutdowns.

2.4.3 Verification of BSL-3 Laboratory

Regularly checking machinery and procedures for ongoing effectiveness in between validations is known as verification (e.g., testing the performance of an autoclave using biological indicators, viewing airflow gauges to confirm fan function in a BSC). Verification includes comparing the accuracy of a piece of equipment to an applicable standard or SOP.

The minimum facility verification standards for BSL-3 laboratory are therefore will be carried out and documented as follows both initially and annually. Therefore, initial and annual minimum facility verification requirements for BSL-3 laboratories will be performed and documented as below:

- The means of detecting air flow (tell tale, magnehelic or digital gauge, Baulin-Tube®, etc.) has been confirmed to accurately reflect observed air flow. It is recommended, but not required, that digital or magnehelic gauges be calibrated annually;
- Inward directional airflow has been confirmed by observation for the laboratory;
- Decontamination systems (autoclave, room decontamination systems, digesters, liquid effluent systems, etc.) have been confirmed to be operating correctly;
- If a Building Automation System (BAS) has the capacity to monitor and record performance measurements e.g., differential pressures, the entity is encouraged to capture and store data from potential failure events, drills, etc. This information may provide verification of system performance. In addition, any programmed BAS alarms should be verified for proper functioning;
- All alarms have been checked and are functioning according to established specifications;
- Laboratory HVAC HEPA filters have been certified annually;
- Exhaust fan motors have been checked and routine maintenance conducted;
- The laboratory has been checked for unsealed penetrations, cracks, breaks, etc. and these have been repaired if present;
- All biological safety cabinets have been validated annually;
- Seals on centrifuges have been checked and replaced if required; and
- Drench showers, eye wash stations, and hands free sinks have been confirmed to be operating properly.

2.4.4 Certification of BSL-3 Laboratory

Laboratory certification is the systematic examination of all safety features and processes within the laboratory (engineering controls, personal protective equipment and administrative controls). The certification process includes the examination of biosafety practices and procedures. The certification process also includes the verification of on-site equipment and system performance that are present and have been installed in the physically built facility.
Laboratory certification is an on-going quality and safety assurance activity that should take place on a regular basis.
BSL-3 laboratory certification will be conducted to ensure that:

- Proper engineering controls are being used and are functioning adequately as designed;

- Appropriate site and protocol specific administrative controls are in place;
- Personal protective equipment is appropriate for the tasks being performed;
- Decontamination of waste and materials has been adequately considered and proper waste management procedures are in place; and
- Proper procedures for general laboratory safety, including physical, electrical and chemical safety are in place.

Adequately trained safety and health or biosafety professionals may conduct laboratory certification activities. Institutions may employ personnel having the appropriate skill-set required for conducting audits, surveys or inspections (these terms are used interchangeably) associated with the certification process. However, the laboratories may consider engaging or be required to engage a third party to provide these services.

Biosafety laboratory facilities will develop audit, survey or inspection tools to help ensure consistency in the certification process. Care must be taken to ensure that these tools are used only by appropriately trained personnel, and that they are not used as a substitute for a sound professional biosafety assessment.

The certification process of the Sub-project will be conducted using the tools provided in Tables 5–7 (Laboratory Safety Surveys) of the WHO Biosafety Manual (3rd edition, 2004). Findings of the audit, survey or inspection will be discussed with laboratory personnel and management. Within the laboratory, an individual will be identified and made responsible for ensuring that corrective actions are taken for all deficiencies identified during the audit process. Certification of the laboratory should not be completed, and the laboratory should not be declared functional, until deficiencies have been adequately addressed.

Re-certification of the facility will be performed on an annual basis, as a minimum. A comparison should be made to the baseline established during initial certification. Detailed records of the certification process and test results must be maintained to provide an accurate operations history of the laboratory. During the course of developing the certification criteria for a specific building, the following is a list of critical areas to inspect or validate that testing has been completed prior to BSL3 laboratory operational start-up. Records will be retained in the laboratory safety operations file for a predetermined length of time consistent with local health and safety regulations.

2.4.5 BSL-3 Laboratory Certification Checklist

2.4.5.1 Evaluation of Administrative Controls and Ability to Facilitate Maintenance Operations to Ensure Occupant Safety and Facility Integrity

2.4.5.1.1 Review Background Materials That Affect Maintenance Operations

- Obtain and review Commissioning Report;
- Review architectural and mechanical drawings to ensure design intent is being met;
- Review biosafety policies and procedures (SOPs) for the laboratory (facility);
- Training of occupants and maintenance staff;
- Evaluate administrative and engineering procedures to determine if they meet;
- Requirement list of the program;
- Review waste management procedures;
- Assess laboratory accident response protocols;
- Evaluate decontamination procedures for appropriateness with respect to the protocols, being conducted or anticipated;
- Review integrated pest management program; and
- Review SOPs for document retention, maintenance, and lab procedures.

2.4.5.1.2 Inspect and Evaluate

Finishes, penetrations & caulking integrity for architectural elements such as doors, around the ceilings, lighting fixtures, electrical devices, etc. within containment to meet requirements for:

- Cleanability of all surfaces including furniture;
- Smoothness of all surfaces;
- Sealed seams and penetrations;
- Monolithic, slip resistant floors;
- Surface impermeability to liquids;
- Resistance of surfaces to chemicals, disinfectants and moderate heat;
- Gas tightness for decontamination;
- Pest management requirements;
- Non-operable windows; and
- Bioseals.

2.4.5.1.3 Inspect Room Layout, Placement of Equipment and Equipment Condition

- Evaluate autoclave verification testing procedures, inspect logs;
- Evaluate access control and exit procedures;
- Evaluate availability of;
    - Emergency equipment,
    - Emergency two-way communication system,
    - System provided for electronic transfer of information to outside of containment,
    - Emergency lighting,
    - Working fire extinguisher,
    - Availability of chemical spill kit within containment.
- Evaluate redundancy requirements for particular facility such as air handling units, exhaust fans, decontamination system components (e.g. pumps & HEPA filters);
- Assess location of BSL3 labs in relation to BSL2, support labs, offices and break rooms, elevators, loading docks, etc. for effects on laboratory pressurization and airflow. This includes operational condition of doors;
- Presence of an anteroom w/ or w/o a shower;
- Storage provided for donning clean protective clothing and safety equipment;
- Hands-free sink located near exit of laboratory;
- Office location outside of containment;
- Inspect signage for proper posting;
    - Biohazard sign,
    - Agents used,
    - Names and telephone number for laboratory management,
    - Special requirements such as required use of PPEs, personnel access,
    - Review list of all mechanical controls and their locations, and
    - Review start up and shut down procedures in case of emergency.

2.4.5.1.4 Evaluate Maintenance Frequency and Review Maintenance Logs

- Autoclaves;
- BSC filters;
- Centrifuges;
- Door/equipment locks;
- HVAC balancing;
- HVAC belts;
- HVAC Motors/Sheaves;
- Lights; and

- Plumbing.

2.4.5.2 Validation of Engineering Controls

- Validate that extra capacity is present on both supply and exhaust systems and quantify the estimated spare capacity (must document how extra capacity was calculated or estimated);
- Ensure single pass air flow;
- Measure directional air flow, pressure relationships, air changes and record data; and
- Directional air flow must be established from clean areas into contaminated areas. In the event that multiple containment zones exist within a laboratory or laboratory suite, sequentially more negative pressure differentials must be established so that the more contaminated spaces are maintained at a negative pressure with respect to less contaminated areas. Pressure differentials across doorways must be measured using a device calibrated against a primary standard. Ideally, at least -0.05 in WG (Water Gauge, -12.5 Pa) should be maintained from clean areas to more contaminated areas (see. Figure 2-6). In no case should the differential be less than -0.03 in. WG (-7.6 Pa) when the door is closed.

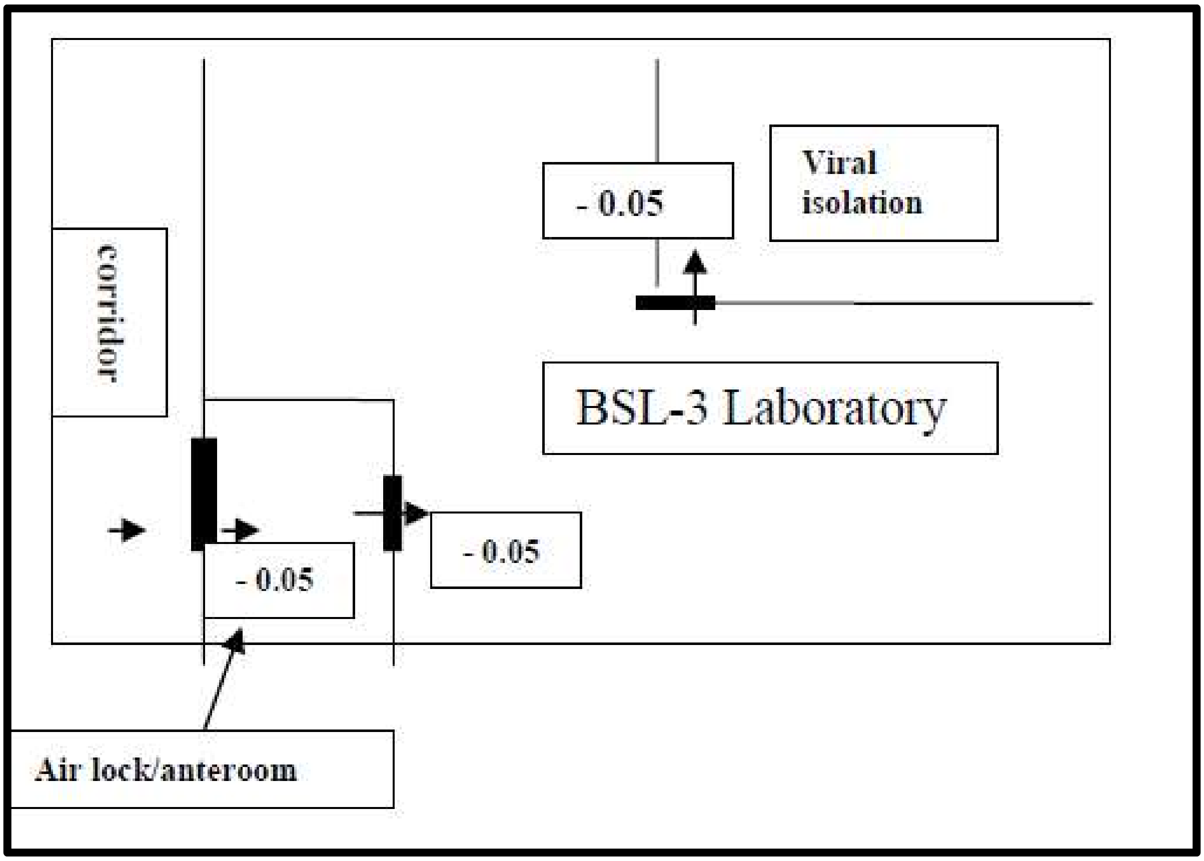


Figure 2-6. Illustrative Figure Showing Air Flow Requirements

- Develop HVAC system and electrical systems failure tests consistent with laboratory design parameters. Perform tests and record data. To verify correct operations these tests should include at a minimum:
    - Normal operations to emergency power;
    - Emergency power in normal operations;
    - Loss of supply fans (individual and in combination);
    - Loss of exhaust fans (individual and in combination);
    - Building automation system (BAS) maintains operational set points during all scenarios and return to normal operations;
    - Upon reboot BAS must retain operational set points;
    - If an uninterrupted power supply (UPS) is installed, verify operation of relays;
    - Provide UPS for BAS;
    - Assess if UPS is operational; and
    - Ensure that laboratories are maintained at negative pressure with respect to less contaminated areas.
- Assess HVAC equipment condition:
    - Visually inspect; Belts, Belt guards, Wiring, Duct supports and connections, Guide wires (if applicable), Dilution air dampers (if applicable), Bearings (high pitched squealing), Ductwork system workmanship, damage, etc;
    - Ensure that motor operating temperatures are maintained within equipment specifications;
    - Ensure that interlock between supply and exhaust is operational;
    - Verify correct placement of biological safety cabinets with respect to supply and exhaust diffusers, doors and traffic patterns; and
    - Use smoke at the face of the cabinet to ensure that the air curtain is not being disrupted by supply or exhaust diffusers placed in proximity of the cabinet(s) or opening and closing doors and traffic patterns.
- Perform smoke tests to demonstrate directional airflow:
    - Doors;
    - Vents;
    - Windows;
    - Autoclave; and
    - Other vented areas.

- Inspect and challenge door interlock systems and automatic door closers:
    - Door closers are required;
    - Ensure that doors automatically close and latch;
    - Interlocks required;
    - Check operability;
    - Open and close doors in all possible sequences; and
    - Ensure that delay set points are tight enough to preclude inadvertent over ride of interlock.
- Test all alarms:
    - HVAC Failure Alarm;
    - Availability of air flow alarms showing if the room has gone positive under normal conditions or if door is open for greater than 20 seconds;
    - Availability of a visual indication for personnel to be aware if the room is under positive or negative pressure prior to entering into the lab;
    - Review fire alarm annual documentation; and
    - Review security alarm annual documentation.
- Discharge exhaust assessment (as a measure of performance):
    - Inspect rooftop landscape for re-entrainment opportunities;
    - Laboratory exhaust stacks- minimum 3m height above highest point on roof;
    - Check Exhaust stack locations and discharge velocities;
    - Exhaust velocity = 15-20 m/s or 3000-4000 fpm;
    - Is all aerosol-producing equipment exhausted by certified HEPA filtration devices?
    - Ensure that continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory;
    - Ensure that discharge of local exhaust ventilation (LEV) devices is removed from air intakes to prevent re-entrainment; and
    - Consider local conditions (e.g., HEPA filters on exhaust, dilution air).
- Verification of air change rates (ACR) in containment spaces:
    - ACR is determined during design based on sensible and latent heat loads contaminants and odors that require containment space usage;

  - Measure supply and exhaust air volumes using a device calibrated annually;
  - Calculate ACR; monitor trends; and
  - In no case should the ACR be less than 6/hr for labs and 10/hr for animal facilities.

- Review biological safety cabinet (BSC) validation data:
  - BSCs must be on an annual validation schedule;
  - Verify that BSCs are located away from doors and vents;
  - Verify that installation of BSC is correct for cabinet type;
  - Inspect HEPA filter installations;
  - Review validation documentation for all exhaust HVAC HEPA installations;
  - Verify that HEPA filters are on portable air vacuum systems at point of use and at the barrier; and
  - Visually inspect; Isolation valves for decon, Decon and challenge ports, Scanning access.

- Validate MEP (Mechanical, Electrical Plumbing):
  - Inspect for adequate illumination;
  - Verify that circuit breakers are outside of containment;
  - Backflow prevention for lab water system;
  - Sinks and drains properly marked;
  - Availability of emergency power for critical systems;
  - Availability of hands free emergency eyewash;
  - Availability of emergency shower;
  - Caulking and sealing requirements for electrical devises such as conduits, boxes, lights, etc;
  - Validate provision for dedicated vacuum pump, if present; and
  - Inspect effluent decontamination system, if present.

- Validate autoclave availability, operations and bioseal integrity:
  - Test interlocks;
  - Confirm cycle –test load;
  - Visually inspect bioseal;
  - Smoke test bioseal;

- Validate maintenance of sterilization temp. of 121 degrees for 60 minutes;
- Autoclave-out capability directly from the BSL3 facility in new facilities;
- In older facilities where autoclave-out may not be available, an autoclave must be available near the BSL-3 facility so that containment of biohazardous waste is maintained; and
- Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) is considered if recommended by the biosafety unit/department.

2.4.5.3 Review SOPs

- Autoclave & Decontamination:
    - To decontaminate materials before removing them from the biosafety cabinet;
    - If an autoclave is available near but outside the BSL-3 facility, ensure adequate decontamination procedures in place for wet and dry biohazardous materials that leave the facility;
    - Assess the travel route to nearest autoclave avoids public corridors;
    - Assess procedures for use of and disposal of PPEs;
    - Assess procedures for decon of equipment that leaves the facility for repair or discontinuation of use;
    - Review storage and transport of biohazardous materials;
    - Assess type of disinfectant to be used and if it is of adequate strength and type for the biohazardous materials in use in the facility; and
    - Validate schedule and frequency of changing HVAC filters on vacuum lines.
- Safety SOPs:
    - Identification of responsible person for BSL-3 facility;
    - Use, storage and disposal of Personal Protective Equipment;
    - Documented limited personnel access to BSL-3 facility;
    - Procedures for maintenance to enter BSL-3 facility;
    - Hand washing procedures are in place;
    - Use of mechanical pipetting devices; NO mouth pipetting;
    - Use of sharps prohibited unless absolutely required and then use should be managed by protocol;
    - Procedures in place to minimize production of aerosols;

  - Decontamination procedures are in place;
  - Training program is in place and documentation available for training and refresher courses of all personnel allowed in the BSL-3 facility;
  - Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel;
  - A biosafety manual specific to the laboratory has been prepared and adopted; and
  - Biosafety precautions are incorporated into standard operating procedures.

- Occupational Health Monitoring (where appropriate):
  - Blood/ Serum Storage;
  - Vaccinations;
  - High-risk (immune suppressed, pregnant, etc.) individuals;
  - Health screening; and
  - Annual updates of Exposure Control Plan to include documentation of all locations where BSL3 agents or materials are used or stored.

- Biohazardous Materials Use Authorization (e.g., Human Pathogen Registration, Recombinant DNA Registration, Select Agent, etc.):
  - Current BUA (Biohazardous Materials Use Authorization);
  - Symptomology page; and
  - Procedures for how samples are received.

3 SUB-PROJECT ALTERNATIVES

This section summarizes the alternatives to and in the Sub-project and briefly explains why the current features are selected.

3.1 No-Project Activity Alternatives

The 'no project' alternative considers the scenario in which the existing Torlak Institute of Virology, Vaccines and Sera will continue its operation without any extensions and the current services or will be kept as it is.

Currently there are no facilities in Serbia that can handle pathogens like SARS-CoV-1, yellow fever virus, West Nile virus, eastern equine encephalitis virus, and MERS-CoV but also various bacterial, fungal and rickettsia pathogens requiring a BSL-3 or higher. Having an appropriate laboratory would allow for widening the research related to detection of viral presence in air, wastewater, soil and elsewhere. The establishment of a BSL-3 laboratory will enable Torlak Institute to develop in-house tests and their use, both for diagnostic purposes and for scientific research, as well as the introduction of new diagnostic procedures that could not be carried out in the existing space of BSL-2 laboratory. The development and use of in-house (internal) diagnostic tests allows the laboratory to be independent in diagnosing pathogenic microorganisms and to provide a timely and effective response to an epidemic, pandemic or the appearance of a new "threatening" infectious agent. On the other hand, no Project activity will lead to;

Limited disease detection and monitoring: Health diagnostics laboratories play a crucial role in detecting and monitoring various diseases and health conditions. Without having these laboratories, there may be delays in diagnosing illnesses, leading to the spread of infectious disease in public at national and international level as in COVID-19. In addition, we may come across increased morbidity and mortality rates, and a lack of data for effective public health interventions.

Inefficient treatment and management: Diagnostics laboratories provide essential tests and analyses that aid in the accurate diagnosis of diseases and guide appropriate treatment decisions. Without a diagnostics laboratory, healthcare providers may face challenges in determining the most effective treatment strategies. This can lead to inappropriate or delayed treatments, compromising patient outcomes and increasing healthcare costs.

Reduced public health surveillance: Diagnostics laboratories are essential for surveillance programs that track the occurrence and spread of diseases within a population. Without these laboratories, there may be limited capacity to monitor disease trends, detect outbreaks, and implement timely control measures. This can hinder public health efforts to prevent and respond to infectious diseases, jeopardizing community health and safety.

Impaired research and development: Health diagnostics laboratories support research and development activities related to disease understanding, new drug development, and the evaluation of treatment effectiveness. The absence of a diagnostics laboratory can hinder scientific advancements, limit the ability to develop innovative diagnostic tools and therapies, and impede progress towards improved healthcare outcomes.

In summary, in case of not establishing of a new diagnostics laboratory with BSL-3, Serbia will continue to lack the potential of early detection and confirmation of in question cases and early response to the threat of infectious diseases which potentially compromise individual and community health being, besides will continue missing the opportunity to strengthen its epidemiological capacity, national reference, and public health laboratories.

3.2 Technology Alternative

Biosafety level designations are based on a composite of the design features, construction, containment facilities, equipment, practices and operational procedures required for working with agents from the various risk groups.[9] Table 3-1 below relates risk groups to the biosafety level of laboratories designed to work with organisms in each risk group (see. Table 3-2).

Table 3-1. The Classification of Infective Microorganisms by Risk Group[10]

Risk Group 1 (no or low individual and community risk)	A microorganism that is unlikely to cause human or animal disease.
Risk Group 2 (moderate individual risk, low community risk)	A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
Risk Group 3 (high individual risk, low community risk)	A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
Risk Group 4 (high individual and community risk)	A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

Table 3-2. Relation of Risk Groups to Biosafety Levels, Practices and Equipment[11]

Risk Group	Biosafety Level	Laboratory Type	Laboratory Practices	Safety Equipment
1	Basic-Biosafety Level 1	Basic teaching, research	GMT	None; open bench work
2	Basic-Biosafety Level 2	Primary health services; diagnostic services, research	GMT plus protective clothing, biohazard sign	Open bench plus BSC for potential aerosols

[9] WHO Biosafety Manual (3rd edition, 2004)

[10] WHO Biosafety Manual (3rd edition, 2004)

[11] WHO Biosafety Manual (3rd edition, 2004)

Risk Group	Biosafety Level	Laboratory Type	Laboratory Practices	Safety Equipment
3	Containment-Biosafety Level 3	Special diagnostic services, research	As Level 2 plus special clothing, controlled access, directional airflow	BSC and/or other primary devices for all activities
4	Maximum Containment-Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC, or positive pressure suits in conjunction with Class II BSCs, double-ended autoclave (through the wall) filtered air

Risk control measures for the Sub-project have been determined according to the biological agents to be handled, laboratory activities to be performed and potential transmission routes. The Sub-project has been designed as a diagnostic laboratory building with BSL-3.

As an alternative, BSL-4 laboratories have not been selected for the Sub-project purposes for many reasons including the risk group of microorganisms which are aimed to be handled within the Sub-project. According to the WHO Laboratory Biosafety Manual Fourth Edition and Associated Monographs, Laboratory Design and Maintenance 2020, the laboratories requiring maximum containment measures (BSL-4) are very expensive to plan, design and build. Besides, the operation and maintenance of these laboratories are also very highly costed. These laboratories require a very high level of technical expertise and experience, for planning, design, construction, operation and maintenance. Before starting a BSL-4 laboratory project, trained and experienced personnel should be available for all aspects of the project which can be a challenge considering there are few such laboratories in the world. Also, such laboratories must comply with highly detailed national legislation and guidance, even before being given permission to operate, and they may be subject to numerous regulatory inspections on a regular basis.[12]

The BSL-3 laboratory will not compromise any biosafety measures but will ensure required containment characteristics for handling the target pathogens.

3.3 Project Area Alternatives

The project area selection was limited within the existing complex of Torlak Institute of Virology, Vaccines and Sera. Torlak Institute comprises national laboratories and other facilities that are already in operation for decades for the prevention and diagnosis of infectious diseases. Torlak Institute performs scientific research and educational activities with the aim of developing new technologies and improving vaccines production. The institute enables the effective use of skilled and experienced professionals especially in workflow and risk management in emergencies regarding community health and safety for the new diagnostics laboratory. The capacity and public recognition of the institute in terms of biosafety and biosecurity was also considered as favourable conditions in the project area selection. Moreover, the existing

[12] WHO Biosafety Manual (4th edition, 2020)

infrastructure such as water, electricity and existing roads will be used for the Sub-project, which will limit the environmental and social impacts during construction phase.

Therefore, the options of choosing other locations outside the Torlak Institute for the BSL-3 laboratory were became irrelevant and site selection process for the proposed new diagnostic laboratory building with BSL-3 Laboratory was confined to the premises of the Torlak Institute.

4 INSTITUTIONAL AND REGULATORY FRAMEWORK

The Chapter outlines the regulatory framework and applicable standards that should be met/followed from the construction to the Sub-project's lifetime. In this context, in case of differences between national regulation and international standards, the most stringent requirement will be taken into account.

4.1 National Key Institutions

The Ministry of Health

The national key institution responsible for managing environmental and social issues related to the Sub-project is the Ministry of Health.

The Ministry of Health is the central authority and has operational units for health service organization, health insurance, public health and programmed health care, European integration and international cooperation, pharmaceuticals and medical devices, controlled psychoactive substances and precursors, inspection operations, biomedicine and the internal audit group (Ministry of Health, 2018)[13]. Mandate for Ministry of Health is regulated by the 2017 Law on Ministries and the 2019 Health Care Law. According to Serbia Health System Review 2019 Report of World Health Organization it is the major decision-maker in the Serbian health system, responsible for determining health policy, planning and oversight, passing health care standards, determining quality control mechanisms, controlling the quality of health care, and developing and implementing public health programmes and investments. The Ministry of Health is also in charge of health insurance, safeguarding and improving population health, health inspection and supervision of health services.

Ministries and state agencies are responsible for administrative and regulatory functions of the health system. In addition, some relevant health care functions are entrusted to lower government levels. At a "macro" level, the health system in Serbia is predominantly steered by government institutions, whereas some selected functions are devolved to the level of the 2007 Law on the Territorial Organization of the Republic of Serbia ("Official Gazette of RS", No. 129/07, 18/16, 47/18, 9/20 - other laws):

- the Autonomous Province of Vojvodina and its six cities and 39 municipalities: the governing bodies are the Province Government of Vojvodina, the Province Secretariat for Health Social Policy and Demography and the Province Health Insurance Fund;
- the City of Belgrade and its 17 municipalities: the governing bodies are the City Council with the Mayor, Deputy Mayor and members, and the City Secretariat for Health Care; and

[13] Serbia Health System Review 2019, World Health Organization 2019

- cities, in total 23 (including those in Vojvodina), and 150 municipalities (including those in Vojvodina): the governing bodies are the city and municipality authorities.

Publicly owned health institutions comprise a wide network at the primary, secondary and tertiary level and are overseen by the Ministry of Health. As of late 2016, this network comprised 355 health institutions.

Primary care, organized at municipality level, includes: preventive care, emergency care, general medicine, health care for women and children, dental care, occupational medicine, physical medicine and rehabilitation, the health visitor services, as well as laboratory and other diagnostics.

The Ministry of Environmental Protection

The Ministry of Environmental Protection is the relevant authority responsible for the formulation and implementation of environmental policy. Other aspects of environmental management of projects are dealt by several other institutions, among which are the Serbian Agency for Radiation Protection and Nuclear Safety (SRPNSA), the Serbian Environmental Protection Agency, the Institute of Natural Conservation (INP), the Institute of Professional Sciences. Serbian Health, Labor Inspectorate, OHS Inspectorate and Ministry of Construction, Transport and Infrastructure (MCTI).

Ministry of Environmental Protection performs the tasks of state administration, prescribed by Article 6 of the Law on Ministries ("Official Gazette of RS" No. 128/20, 116/22), namely: management of chemicals and biocidal products, implementation of the Convention on Chemical Weapons in accordance with the law, management of waste, except for radioactive waste, creation of conditions for access and implementation of projects within the scope of that ministry that are financed from the funds of the pre-accession funds of the European Union, donations and other forms of development assistance ; approval of cross-border transport of waste and protected plant and animal species, as well as other tasks specified by law.

4.2 National Legislation

Serbia officially applied for European Union for membership on 22 December 2009 and accession negotiations are currently ongoing. Serbia has mostly adopted the European Union regulatory requirements on Environmental Impact Assessment (EIA) into national legislation, including the EIA Directive (Directive 92/11/EC). Serbia ratified the Aarhus Convention in 2009 and provisions of the Aarhus Convention were incorporated into the environmental regulation, including the Law on Environmental Impact Assessment and the Law on Strategic Environmental Impact Assessment.

The Law on Environment Protection is the framework national environmental law. The law regulates the integral system of environmental protection ensuring the human right to live and develop in a healthy environment as well as developing a balanced economy and protection of the environment in Serbia.

The Law on Strategic Impact Assessment regulates the conditions, manner, and procedure for assessing the impact of certain plans and programs, on the environment.

The Law on the Environmental Impact Assessment regulates the following:

- Process of Environmental Impact Assessment,
- Content of the Environmental Impact Assessment Study,
- Participation of interested authorities and organizations and the public (Within seven days from the date of receipt of the application for the EIA Study approval, the competent authority shall inform the project developer, the authorities, organisations and the public concerned about the time and venue for public consultation, presentation and debate on the EIA Study. Public debate may not be held sooner than 20 days from the date when the public was informed. The project developer shall participate in the public presentation and debate on the EIA Study. The Minister shall prescribe more precisely the procedure for public consultation, presentation and debate),
- Cross-border notification for projects that can have significant impacts on the environment of another state, and;
- Monitoring.

The national environmental impact assessment procedure comprises the phases of screening and scoping, impact assessment and public consultation.

According to the Decree on the List of projects for which Environmental Impact Assessment Study (EIA) is required („List 1) and the List of projects for which Environmental Impact Assessment Study could be required (“List 2), the future investor should recognize if EIA Study is required, could be required or not required for the future investment, which directly depends on predicted operations and capacities on the future site location.

If the future project is placed on the List 1, the Site needs to prepare Application Form for determination of scope and content of EIA Study and to submit Application to the competent authority together with other required documents. If the future project is placed on the List 2, the Site needs to prepare Application Form for determination of the need for development of the EIA Study, and to submit Application to the competent authority together with other required documents.

The Sub-project is not included in List 1 (projects that require EIA) or List 2 (projects that may require EIA) in the “Decree on establishing the List of Projects for which the Impact Assessment is mandatory and the List of Projects for which the EIA can be requested and is out of scope of the national EIA regulation.

National laws and regulations are provided below within two sub-headings: “General Laws and Regulations” refer to all laws, regulations, acts etc. that the Sub-project is affiliated from a wider perspective. “Specific Laws and Regulations” heading gives more specific regulations and acts which are about laboratory safety and biosafety issues.

General Laws and Regulations

- Constitution of Serbia (Official Gazette of RS, No. 98/06, 115/21, 16/22)
- Law on Public Health (Official Gazette of RS, No. 15/16)
- Law on Health Care (Official Gazette of RS, No. 25/19)
- Law on Medicines and Medical Devices (Official Gazette of RS, No. 30/10, 107/12, 113/17 - other law, 105/17 - other law)
- Law on Environmental Protection (Official Gazette of RS, No. 135/04, 36/09, 36/09 - other law, 72/09 - other law, 43/11 - US, 14/16, 76/18, 95/18 - other law)
- Law on Occupational Safety and Health (Official Gazette of RS, No. 101/05, 91/15, 113/17 (other law))
- Labor Law (Official Gazette of the Republic of Serbia, No. 24/05, 61/05, 54/09, 32/13, 75/14, 13/17 - us, 113/17, 95/18)
- Law on Climate Change (Official Gazette of RS, No. 26/21)
- Law on Environmental Impact Assessment (Official Gazette of RS, No. 135/04, 36/09)
- Decree on determining the List of projects for which an EIA is mandatory and the List of projects for which an EIA can be requested (Official Gazette of RS, No. 114/08)
- Regulation on the contents of requests for the necessity of Impact Assessment and on the contents of requests for specification of scope and contents of the EIA (Official Gazette of RS, No. 69/05)
- Regulation on the procedure of public inspection, presentation and public consultation about the EIA (Official Gazette of RS, No. 69/05)
- Law on Strategic Environmental Impact Assessment (Official Gazette of RS, No. 135/04, 88/10)
- Law on Nature Protection (Official Gazette of RS, No. 36/09, 88/10, 91/10 -Corr., 14/16, 95/18 - other law, 71/21)
- Law on Waters (Official Gazette of RS, No. 30/10, 93/12, 101/16, 95/18, 95/18 - other law)
- Law on Waste Management (Official Gazette of RS, No. 36/09, 88/10, 14/16 and 95/18- other law)
- Law on Soil Protection (Official Gazette of RS, No. 112/2015)

- Law on Transport of Dangerous Goods (Official Gazette of RS, No. 104/16, 83/18, 95/18 - other laws, 10/19 - other law)
- Law on Planning and Construction (Official Gazette of RS, No. 72/09, 81/09 - amendment, 64/10 - US, 24/11, 121/12, 42/13 - US, 50/13 - US, 98/13 - US, 132/14, 145/14, 83/18, 31/19, 37/19 - other law, 9/20, 52/21)

Sub-Project Specific Laws, Regulations and Standards

- Law on Air Protection (Official Gazette of RS No. 36/09 ,10/13, 26/21)
- Decree on limit values of emissions of pollutants into the air from combustion plants (Official Gazette of RS, No. 6/16, 67/21)
- Decree on measurements of emissions of pollutants into the air from stationary sources of pollution (Official Gazette of RS, No. 5/16)
- Decree on the treatment of ozone depleting substances (ODS), as well as conditions for issuing licenses for import and export of these substances (Official Gazette of RS, No. 114/13, 23/18, 44/18 - other law, 95/18 - other law)
- Decree on acting with fluorinated greenhouse gases, as well as conditions for issuing licenses for import and export of these gases (Official Gazette of RS, No. 120/13 and 44/18 - other law)
- Law on Chemicals (Official Gazette of RS, No. 36/2009, 88/2010, 92/2011, 93/2012 and 25/2015)
- Regulation on the List of Classified Substances (Official Gazette of RS, No. 22/20)
- Regulation on the classification, packaging, labeling and advertising of chemicals and certain products in accordance with the UN Globally Harmonized System for Classification and Labeling (Official Gazette of RS, No. 105/13, 52/17, 21/19)
- Regulation on the Register of Chemicals (Official Gazette of RS, No. 16/16, 6/17, 117/17, 44/18 - other law, 7/19, 93/19, 6/21, 126/21)
- Regulation on the content of the safety data sheet (Official Gazette of RS, No. 100/11)
- Regulation on how to keep records on chemicals (Official Gazette of RS, No. 31/11)
- List of substances of concern (Official Gazette of RS, No. 94/13, 101/16, 22/18, 86/21)
- Regulation on permits for carrying out transport activities, i.e. permits for the use of particularly dangerous chemicals (Official Gazette of RS, No. 6/17, 29/18)
- Instruction on determining preventive measures for safe storage, storage, or use of particularly dangerous chemicals (Official Gazette of RS, No. 6/17)
- Regulation on restrictions and prohibitions of production, marketing and use of chemicals (Official Gazette of RS, No. 90/13, 25/15, 2/16, 44/17, 36/18, 9/20, 57/22)

- Regulation on limit values for pollutants in surface and groundwater and sediment and deadlines for reaching them (Official Gazette of RS, No. 50/12)
- Decree on the limit values of pollutants in water and deadlines for their reach (Official Gazette of RS, No. 67/11, 48/12, 1/16)
- Regulation on storage, packaging and labelling of hazardous waste (Official Gazette of RS, No. 92/10, 77/21)
- Regulation on the form of the document on the movement of waste and instructions for its completion (Official Gazette of RS, No. 114/13)
- Regulation on the form of the document on the movement of hazardous waste, the form of the prior notification, the method of its delivery and the instructions for filling them in (Official Gazette of RS, No. 17/17)
- Regulation on the form of daily records and annual report on waste with instructions for its completion (Official Gazette of RS, No. 7/20, 79/21)
- Regulation on the conditions, method and procedure of waste oil management (Official Gazette of RS. No. 71/10)
- Regulation on the list of electrical and electronic products, measures prohibiting and limiting the use of electrical and electronic equipment containing hazardous substances, methods and procedures for waste management of electrical and electronic products (Official Gazette of RS, No. 99/10)
- Regulation on the method and procedure for managing waste fluorescent tubes containing mercury (Official Gazette of RS, No. 97/10)
- Decree on products that become special waste streams after use, form of daily records on the quantity and type of manufactured and imported products and annual report, method and deadlines for submitting the annual report, obligees to pay the fee, criteria for calculation, amount and method of calculation and payment of the fee (Official Gazette of RS, No. 54 /10, 86/11, 15/12, 3/14, 95/18 - other law, 77/21)
- Law on packaging and packaging waste (Official Gazette of RS, No. 36/09 and 95/18)
- Law on Fire Protection (Official Gazette of the Republic of Serbia, No. 111/09, 20/15, 87/18 - other law, 87/18, 87/18 - other law)
- Law on Disaster Risk Reduction and Emergency Management (Official Gazette of RS, No. 87/18)
- Law on the Protection of the Population from Infectious Diseases (Official Gazette of RS, No. 15/2016, 68/2020 and 136/2020)
- Rulebook On Medical Waste Management (Official Gazette of RS, No. 48/2019)
- Regulation on preventive measures for safe and healthy work related to exposure to biological hazards (Official Gazette of RS, No. 96/10, 115/20)

- Regulation on preventive measures for safe and healthy work to prevent the occurrence and spread of infectious disease epidemics (Official Gazette of RS, No. 94/20)
- Law on Protection from Noise in the Environment (Official Gazette of RS, No. 96/21)
- Regulation on preventive measures for healthy and safe work when exposed to carcinogens or mutagens (Official Gazette of RS, No. 96/11, 117/17)
- Regulation on previous and periodic medical examinations of employees at workplaces with increased risk (Official Gazette of RS, No. 120/07, 93/08, 53/17)
- Regulation on preventive measures for safe and healthy work when exposed to chemical substances (Official Gazette of RS, No. 106/09, 117/17, 107/21)

<u>Regulations for Laboratories for Public Health Services</u>

- Expert-methodological instructions for conducting fever surveillance West Nile (GZN) in the human population on the territory of the Republic of Serbia in the summer/autumn 2017 season (The Epidemiological Surveillance Department of the Institute of Public Health of Serbia “Dr. Milan Jovanović Batut” in cooperation with the Clinic for Infectious and Tropical Diseases and the Institute for Virology, Vaccines and Serums “Torlak”)
- Regulation on establishing the Crisis Management Plan (Official Gazette of RS, No. 90/15)
- Program for control, prevention, suppression and eradication of avian influenza in the Republic of Serbia, Ministry of Agriculture, Forestry and Water Management of RS, 2006
- Public health strategy in the Republic of Serbia 2018–2026 (Official Gazette of RS, No. 61/18)
- Regulation on the List of particularly dangerous infectious animal diseases and the List of infectious animal diseases that must be registered, as well as on the manner of their registration and deregistration (Official Gazette of RS, No. 49/06)
- Guidelines on the manner and procedure for keeping records and reporting on health surveillance of the migrant population – refugees, asylum seekers and asylees
- Regulation on the conditions in terms of facilities, equipment, means of work, as well as in terms of professional staff that must be fulfilled by the laboratory (Official Gazette of RS, No. 45/10)
- Regulation on measures for early detection, diagnosis, prevention of spread, suppression and eradication of African swine fever (Official Gazette of RS, No. 32/10)
- Regulation on general and special food hygiene requirements at any stage of production, processing and transport (Official Gazette of RS, No. 72/10, 62/18)

- Regulation on the content of the documentation to be submitted with the application for the issuance of a permit for the import, export, and transit of waste (Official Gazette of RS, No. 60/09, 101/10, 48/17, 80/17, 98/17, 38/18, 6/21)

A gap analysis between the relevant Serbian EIA legislation and applicable WB ESSs are provided in the end of this Chapter. These gaps are fulfilled within the ESIA study and provided in the ESIA report. Among the additional measures and actions required in the scope of ESIA studies in order to fulfil the requirements of the applicable WB ESSs on top of the national legislation requirements are the development of SEP, Grievance Mechanism and ESMP. The description of the national legislation related to the Sub-project is provided in Appendix-B to the ESIA report.

4.3 International Standards

4.3.1 Requirements by the World Bank Group

The ESIA will be prepared in accordance with the requirements of World Bank Group. These include World Bank's ESF as detailed below:

WB's Environmental and Social Framework (ESF)

The WB adopted a new set of environment and social policies called the ESF in 2016 after the review of the Safeguard Policies with the objective of creating better long-term development outcomes. As of 2018, the ESF began to be applied to all new WB investment project financing. Thus, the Environmental and Social Standards (ESSs) of the WB ESF have been taken into consideration in the ESIA studies and development of the relevant mitigation measures and monitoring plan. ESSs given in ESF have a more comprehensive approach to environmental and social risk, particularly on social issues. The list of the WB's ESSs relevant to the Project are given in Table 4-1.

Table 4-1. WB Environmental and Social Standards Related to the Project

Standard
ESS1: Assessment and Management of Environmental and Social Risks and Impacts
ESS2: Labour and Working Conditions
ESS3: Resource Efficiency and Pollution Prevention and Management
ESS4: Community Health and Safety
ESS6: Biodiversity Conservation and Sustainable Management of Living Natural Resources
ESS8: Cultural Heritage
ESS10: Stakeholder Engagement and Information Disclosure

ESS5 Land Acquisition, Restrictions on Land Use and Involuntary Resettlement is not relevant to the Sub-project and out of scope of the ESIA since no land acquisition is expected within the scope of the Sub-project. Also, ESS7 Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities is not triggered and out of scope since there are

no indigenous communities identified by WB guidelines in the Sub-project impact area. ESS9 Financial Intermediaries is also out of scope since no financial intermediaries are involved.

The World Bank Group (WBG) Environmental, Health, and Safety (EHS) Guidelines, WHO Guidelines related to health care facilities which are benchmark International Good Practice Standards, including IFC EHS guideline for Health Care Facilities, and where applicable Sectoral Guidelines have been considered in the ESIA. More specifically, the WHO Laboratory Biosafety Manual (4th edition, 2020) is directly applicable as international best practice requirements to the proposed BSL-3 laboratory Sub-project. For the impact assessment and development of mitigation measures the performance levels and measures in the EHS Guidelines and WB's Pollution Prevention and Abatement Handbook are taken into consideration in addition to the national legislative requirements. Furthermore, as required by WB's ESF and ESS1 when the national regulations differ from the levels and measures presented in the EHS Guidelines, the more stringent threshold or standard will apply to the Sub-project.

Below are the applicable documents of World Bank Group and Good International Industry Practice (GIIP):

- World Bank Environmental and Social Framework (ESF) and Guidance Notes for Loan Beneficiaries;
- World Bank Group (WBG) Environmental, Health and Safety Guidelines (EHS);
- World Bank Group EHS Guidelines for Health Care Facilities;
- World Bank Group EHS Guidelines applicable to Water and Sanitation;
- World Bank Group EHS Guidelines applicable to Electric Power Transmission and Distribution;
- World Bank Group EHS Guidelines applicable to Gas Distribution Systems;
- World Bank Group EHS Guidelines applicable to Pharmaceuticals and Biotechnology Manufacturing;
- World Bank Group Gender-Based Harassment and Abuse Guidelines;
- WHO Laboratory Biosafety Manual, 3rd edition 2004, and 4th edition, 2020;
- WHO Biorisk Management: Laboratory Biosecurity Guidance, 2006, WHO/CDS/EPR/2006.6;
- UN Model Regulations for the Transport of Dangerous Goods.

4.3.2 International Reference Documents

Several international standards are available and can be applied for the Sub-project in addition to national and international regulations and laws:

- ISO 35001: 2009 Bio-risk Management for Laboratories;
- CEN/CWA 15793 Laboratory Bio Risk Management Standard;
- DIN 1946 Ventilation and Air Conditioning (for the healthcare sector);
- DIN EN 1886 Ventilation for Buildings – Air Handling Units – Mechanical Performance or ANSI/ASHRAE/ASHE Standard 170-2017, Ventilation of Health Care Facilities;
- EUROVENT Certification (third party product performance certification for Heat Ventilation Air Conditioning and Refrigeration products);
- TS 12124 EN ISO 14644 Clean Rooms and Related Controlled Environments;
- FAO, 2018. Biosafety Primer 2018. Bangkok. 120 pp.;
- WHO Good Manufacturing Practices for Biological Products, Annex 2;
- WHO White Paper-Establishing Manufacturing Capabilities for Human Vaccines, 2017;
- CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition, 2020;
- NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (DRM), 2019;
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), 2016;
- NIH Biosafety Level 3 Laboratory Certification Requirements, 2006;
- ANSI Z9.14: Testing and performance verification methodologies for ventilation systems for Biological Safety Level 3 (BSL-3) and animal Biological Safety Level 3 (ABSL-3) facilities;
- Industry Standards and Best Practices;
- US GMP requirements for the manufacturer of Biological Product 21 CFR Part 600;
- FDA Vaccine and Related Biological Product Guidances,
- FDA CMC and GMP Guidances (ex.: Process Validation: General Principles and Practices, Guidance for Industry);
- US cGMP Guide Biologics 21 CFR 610 – General Biological Products Standards;
- US 21 CFR Part 200 & 210 Current Good Manufacturing Practice;
- Transport of Biological Materials, OIE Terrestrial Manual Chapter 1.1.3., 2018,

- ICAO-Technical Instructions for The Safe Transport of Dangerous Goods by Air (Annex 18) IATA-Dangerous Goods (63rd 2022);
- Biological Weapon Convention, 1975;
- General requirements for the competence of testing laboratories are contained in the standard ISO / IEC 17025.

5 SCOPE AND METHODOLOGY

5.1 Overview

The ESIA assists in ensuring environmentally and socially sound management of the Sub-project during its entire lifetime (construction, operation, decommissioning). The Environmental and Social Impact Assessment presented in this section will be limited to the construction and operation phases only due to the unavailability of sufficient relevant information on the decommissioning phase activities.

The basic approach for the ESIA is adopted for conducting the environmental and social impact study for the proposed Sub-project to assess the existing baseline in the AoI, where the components and activities of the Sub-project having potential environmental and social impacts. Environmental and Social impact assessments are framed with the prevailing institutional and legislative setup provided in Chapter 4 Institutional and Regulatory Framework.

The main approaches for the assessment covers:

1. Identification and analysis of potential positive and negative impacts, direct and indirect impacts, and short-term and long-term impacts likely to result from project implementation.
2. Identification of feasible and cost-effective mitigation measures to avoid or to minimize negative impacts, and to provide technical guidance to the engineering design for the implementation of proposed mitigations.
3. Identify potential opportunities for environmental enhancement;

   Preparation of Environmental and Social Management Plan (ESMP) and Environmental and Social Monitoring Plan as a part of ESMP for effective implementation of environmental mitigation measures at different stages of the project.

5.2 Scoping of the Impacts

The potential environmental and social impacts of the Sub-project are summarized below:

- The Construction Phase activities, which comprises pre-construction including detailed design, and construction phases. In this respect, this phase covers all detailed design and construction activities as well as decommissioning of the temporary construction facilities such as construction management office, sanitary facilities (dressing rooms, toilets).

- The Operational Phase considers all operational activities including:
    - Operation of the Sub-project, which may potentially result in impacts such as the generation of waste, occupational health and safety risks as well as community health and safety risks;
    - Maintenance activities of the Sub-project which may potentially result in impacts such as on the occupational health and safety and public safety during the maintenance.

The potential impacts (adverse and positive) of all planned Sub-project activities have been identified and the interaction between the project activities in all these phases and the natural, physical environment and social-economic aspects are addressed.

The scoping study has identified potential impacts which are discussed in relation to the topics listed in Table 5-1 below. This study has defined the scope of the ESIA process and indicated issues to be considered, including those described below:

Table 5-1. Potential Impacts Considered for Environmental and Social Impacts

Topic	Potential Impacts		Evaluation Criteria
Air quality	**Construction Phase**	Fugitive dust and PM emissions due to: soil/earth movements, transport of excavated soils outside the Sub-project Area, excavations, vehicle movements, stockpiles, unpaved surfaces. Exhaust emissions from the construction machinery and vehicles.	WB ESF/ESS1/ESS3 WB EHS Guidelines National Legislation Directive 2008/50/EC Directive 2004/107/EC
	Operation Phase	Emissions from heating system Emissions from lab ventilation	WB ESF/ESS1/ESS3 WB EHS Guidelines National Legislation Directive 2010/75/EU
Climate	**Construction Phase**	Greenhouse Gases (GHGs) Emissions from the construction machinery and vehicles.	WB ESF/ESS1 WB EHS Guidelines National Legislation Directive 2008/50/EC c 2004/107/EC
	Operation Phase	Greenhouse Gases (GHGs) Emissions from the vehicles. GHGs emissions due to heating system	WB ESF/ESS1 WB EHS Guidelines National Legislation Directive 2010/75/EU
Acoustics (Noise and vibration)	**Construction Phase**	Noise from the construction machinery and vehicles. No significant vibration impact is expected from construction because there will not be any blasting operations involved.	WB ESF/ESS1 WB EHS Guidelines National Legislation Directive 2002/49/EC
	Operation Phase	Potential noise generating equipment (depending on location of ventilation system, type of generator etc.)	WB ESF/ESS1 WB EHS Guidelines National Legislation Directive 2002/49/EC

Topic	Potential Impacts		Evaluation Criteria
Geology, soil	**Construction Phase**	Excavation works during construction. Disturbance of topsoil during site clearance and potential degradation of topsoil quality due to improper management of topsoil. Potential accidental releases or leaks of fuel or chemicals from construction equipment, hazardous chemicals and waste storage areas.	WB ESF/ESS1/ESS3 WB EHS Guidelines Law on Environmental Protection The Law on Waste Management Directive 2006/118/EC Directive 2008/98/EC
	Operation Phase	Potential accidental releases or leaks of chemicals, wastewater and due to project traffic.	WB ESF/ESS1/ESS3 WB EHS Guidelines Law on Environmental Protection The Law on Waste Management Directive 2006/118/EC Directive 2008/98/EC
Water resources and quality	**Construction Phase**	Settled dust and sediment transport from construction site. Potential accidental releases or leaks. Water use for construction activities and at camps (if to be built) during construction phase.	WB ESF/ESS1/ESS3 WB EHS Guidelines Law on Environmental Protection The Law on Waste Management Directive 2006/118/EC Directive 2008/98/EC
	Operation Phase	Potential accidental releases or leaks of chemicals, wastewater and due to project traffic.	WB ESF/ESS1/ESS3 WB EHS Guidelines Law on Environmental Protection The Law on Waste Management Directive 2006/118/EC Directive 2008/98/EC
Wastewater	**Construction Phase**	Management of the additional wastewater generated from the construction workers.	WB ESF/ESS1/ESS3 WB EHS Guidelines Regulation on the removal and purification of atmospheric and wastewater on the territory of Belgrade

Topic	Potential Impacts		Evaluation Criteria
	Operation Phase	Bypass of untreated or insufficiently treated wastewater due to under design or equipment failure in the institute. Failure to meet the effluent discharge standards due to improper management of the healthcare unit. Failure to meet the effluent discharge standards due to risks of illegal discharges (regarding quality of wastewater discharged to sewer system particularly).	WB ESF/ESS1/ESS3 WB EHS Guidelines Regulation on the removal and purification of atmospheric and wastewater on the territory of Belgrade
Waste management	**Construction Phase**	Excavated soil and overburden. Solid wastes (including domestic and packaging wastes). Construction wastes (such as steel, cables, other types of construction materials). Hazardous wastes (including waste oil, oily rags, waste batteries and accumulators and similar). Packaging wastes	WB ESF/ESS1/ESS3 WB EHS Guidelines Law on Environmental Protection The Law on Waste Management Directive 2008/98/EC
	Operation Phase	Solid wastes (including domestic and packaging wastes). Hazardous wastes (including chemical residuals, waste oil, oily rags, waste batteries and accumulators and similar). Medical wastes (pathological, infectious, biological, blood, sharps, pharmaceutical etc.) Contaminated wastes Toxic waste	WB ESF/ESS1/ESS3 WB EHS Guidelines Law on Environmental Protection The Law on Waste Management Rulebook on medical waste management Directive 2008/98/EC
Material resources	**Construction Phase**	Use of large quantities of construction materials. Transportation of construction materials. Consumption of fuel by vehicles and machinery. Water and energy usage during construction.	WB ESF/ESS1/ESS3 WB EHS Guidelines
	Operation Phase	Additional electricity (and also water) requirement during the operation phase Supply of chemicals and laboratory equipment	WB ESF/ESS1/ESS3 WB EHS Guidelines UN Model Regulations for the Transport of Dangerous Goods Directive 2008/68/EC
Terrestrial and aquatic ecology	**Construction Phase**	Habitat loss Clear-cut of trees within Sub-project Area	WB ESF/ESS6 WB EHS Guidelines Law on Nature Protection Council Directive 92/43/EEC

Topic	Potential Impacts		Evaluation Criteria
			Council Directive 2009/147/EC
	Operation Phase	No major impact is expected.	WB ESF/ESS6 WB EHS Guidelines Law on Nature Protection Council Directive 92/43/EEC Council Directive 2009/147/EC
Cultural heritage	**Construction Phase**	Possible damage or loss of artefacts if any	WB ESF/ESS8 WB EHS Guidelines European Convention on the Protection of the Archaeological Heritage Convention concerning the Protection of the World Cultural and Natural Heritage
	Operation Phase	No major impact is expected.	WB ESF/ESS8 WB EHS Guidelines European Convention on the Protection of the Archaeological Heritage Convention concerning the Protection of the World Cultural and Natural Heritage
Traffic and transport	**Construction Phase**	Increased traffic load Impacts on roads due to transport of constructions materials.	WB ESF/ESS4 WB EHS Guidelines Law on Planning and Construction
	Operation Phase	No major impact is expected.	WB ESF/ESS4 WB EHS Guidelines Law on Planning and Construction
Visual impacts	**Construction Phase**	Visual impacts from the construction and excavation works and changes in the landscape. Nuisances due to potential, dust, wastes and temporary storage areas.	WB ESF/ESS1 WB EHS Guidelines
	Operation Phase	Change in the landscape and visual impacts from the institute.	WB ESF/ESS1 WB EHS Guidelines
Socio-economic impacts	**Construction Phase**	<u>Positive potential impacts:</u> Employment opportunities;	WB ESF/ESS1 WB ESF/ESS4

Topic	Potential Impacts		Evaluation Criteria
		Local procurement. Adverse potential impacts: Nuisances to the nearby communities and nearby businesses due to potential odour, dust, and noise; Potential impacts on vulnerable/disadvantaged groups/individuals; Potential impacts on community perception, health, safety and security.	WB ESF/ESS 10 WB EHS Guidelines
	Operation Phase	Positive potential impacts: Increase in diagnostics capacity. Adverse potential impacts: Potential impacts on vulnerable/disadvantaged groups/individuals (disrupted participation in consultation processes and greater vulnerability to potential adverse impacts); Potential impacts on community, health, safety and security.	WB ESF/ESS1 WB EHS Guidelines WB Directive on disadvantaged and Vulnerable Groups
Labour and Working Conditions	**Construction Phase**	Non-compliance with national and international labour and working conditions such as child labour, forced labour and unregistered employment Inadequate workers health and safety conditions Potential SEA/SH induced impacts.	WB ESF/ESS2 WB EHS Guidelines
	Operation Phase	Non-compliance with national laws and LMP.	WB ESF/ESS2 WB EHS Guidelines
Occupational health and safety	**Construction Phase**	Activities with increased risks during the construction phase (working with machinery, noise, extreme weather conditions, etc.). Exposure to hazardous chemicals and wastes Life and fire safety during construction. Improper sub-contractor management.	WB ESF/ESS2 WB EHS Guidelines Law on Occupational Safety and Health Council Directive 89/391/EEC
	Operation Phase	Health risks to the workers and personnel, including infection during biologic tests in the institute. Exposure to hazardous chemicals and wastes Potential exposure to diseases during laboratory studies Impacts associated insufficient decontamination of BSL3 LaboratoryPotential exposure to diseases due to improper maintenance operations such as filter changes, waste disposal. Health and safety risks due to potential in-situ accidents involving chemicals/wastes/infectious agents	WB ESF/ESS2 WB EHS Guidelines Rulebook on preventive measures for safe and healthy work related to exposure to biological hazards Council Directive 89/391/EEC Council Directive 2010/32/EU Council Directive 2013/59/Euratom

Topic	Potential Impacts		Evaluation Criteria
		Life and fire safety. Lack of training of laboratory staff and maintenance personnel	Directive 2002/98/EC Directive 2004/23/EC Directive 2003/94/EC Directive 2005/28/EC
Community health, safety, and security	**Construction Phase**	Community nuisances arising from the dust, noise, odour generation. Increased risks from the increased traffic by construction machinery and workers. Construction waste management. Adequacy of Emergency Preparedness and Response Local community and general public misperception due to Insufficient communication or limited availability of information about the Sub-project. (ESS10)	WB ESF/ESS4 and ESS10 WB EHS Guidelines Law on Public Health
	Operation Phase	Risks to the community from the operational failures of Institute after the commissioning of the Project such as inadequate modifications in facility design. Life and fire safety during operation. Biosafety and biosecurity failure due to accidents, unexpected events (flood, sabotage, fire etc.). Impact of escaping of infectious agents from BSL-3 containment. Impacts associated insufficient decontamination of BSL3 Laboratory. Potential exposure to diseases due to improper maintenance operations such as filter changes, waste disposal. Public reactions in case of non-transparent communication sharing, such as health and safety concerns expressed to government, media, etc. fear or panic, public unrest. Adequacy of Emergency Preparedness and Response. Exposure to hazardous chemicals and wastes Lack of training of laboratory staff and maintenance personnel	WB ESF/ESS4 and ESS10 WB EHS Guidelines Law on Public Health WHO Laboratory Bio-Safety Manual (LBM) WHO Biorisk Management: Laboratory Biosecurity Guidance Directive 2001/83/EC Directive 2002/98/EC Directive 2004/23/EC Directive 2003/94/EC Directive 2005/28/EC
Cumulative impacts/risks	**Construction Phase**	Added impacts from the construction phases (dust, noise, traffic, etc.) or operations of other projects around the Sub-project Area and in the same district.	WB ESF/ESS4 WB EHS Guidelines
	Operation Phase	The potential cumulative impacts of the project -generated wastewater and waste on the AoI. Increased stress on waste collection network and final disposal facilities	WB ESF/ESS4 WB EHS Guidelines

5.3 Key Steps of the ESIA Process

This subsection presents the methodology used to conduct the impact assessment. The overall ESIA approach is illustrated in Figure 5-1. The ESIA Process consists of a multi-stage iterative approach in order to predict and evaluate the potential effects the Sub-project could have on the physical, biological, social and cultural environment. Measures are then identified that the Sub-project will take to avoid, minimize, mitigate or compensate for any adverse impacts; and to enhance positive impacts where possible. Results continue to be revisited and modified as the assessment progresses and as Sub-project effects are monitored.

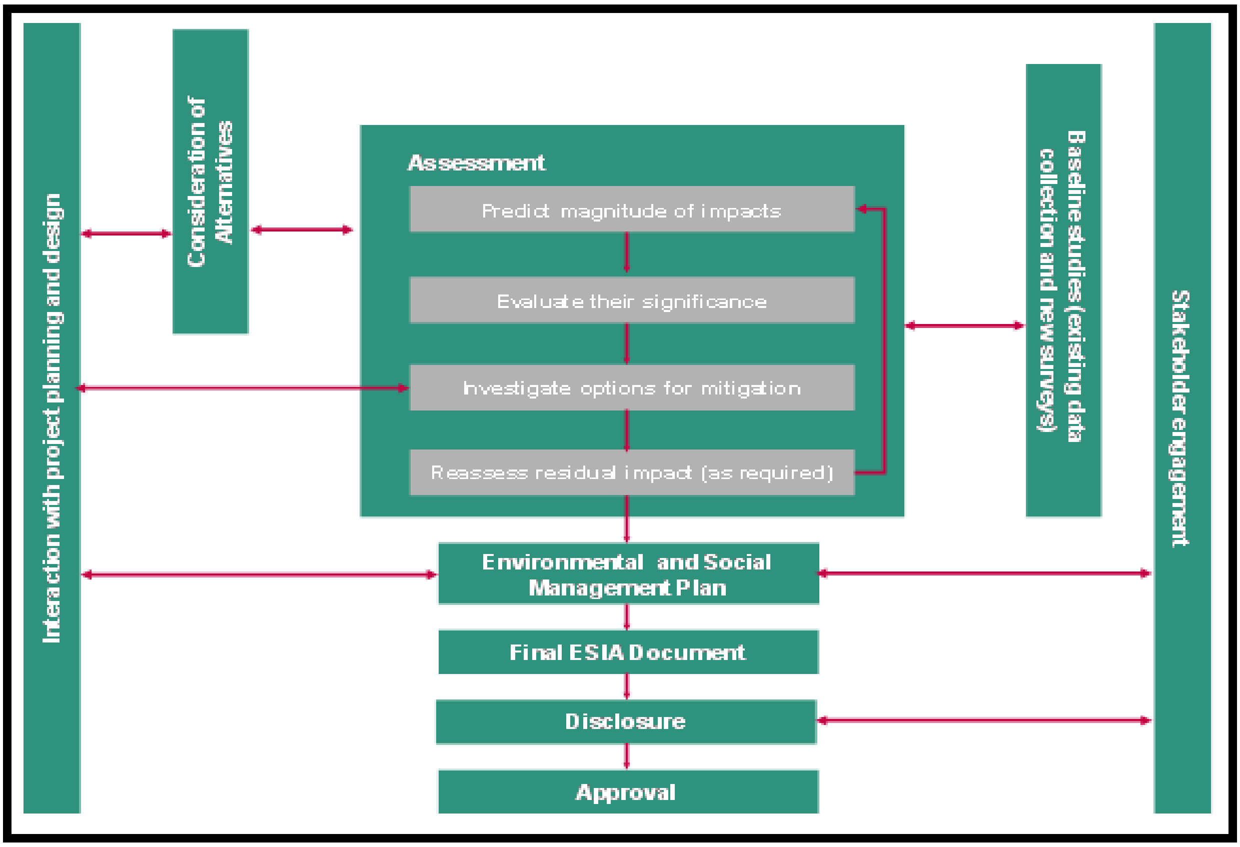


Figure 5-1. ESIA Methodology

5.3.1 Screening

The first step in the ESIA process is the screening stage which determines whether an impact assessment is required to be undertaken for a specific project. As the Sub-project will be financed under the one of its subcomponents as the Subcomponent 1.1 of the Serbia Emergency COVID-19 Response Project (SECRP) financed by the World Bank, there is a need to undertake an ESIA study to meet the requirements of the lenders.

Screening step of the Project has already been finalized and the environmental and social risks of the construction and operation of the Torlak Institute BSL-3 Subproject Project were rated as “Substantial”, in accordance with the WB ESF and revised ESMF of SECRP. Therefore, it is a requirement for comprehensive ESIA as per WB requirements.

5.3.2 Scoping

Scoping is a crucial step in an ESIA process that:

- defines the limits of what is included in the ESIA and what it is not necessary to include;
- gives a clear focus which environmental and social issues will be addressed in the ESIA;
- starts the process of understanding regulations and standards and their context for the ESIA;
- provides provisional identification of the impacts;
- provides an indication of what additional baseline information is required and how to get it;
- provisionally describes the assessment methods to be used;
- includes a preliminary identification of alternatives which should be investigated.

Scoping is the stage at which consultations with stakeholders are initiated, which is an important part of the ESIA process. At the initial phase of the Sub-project, Scoping Report was prepared.

Following the scoping step, baseline studies were conducted, available information on the current environmental and social baseline conditions were gathered including up-to-date and secondary data, social surveys, ecological surveys, baseline field surveys.

After preparation of Scoping Report, Public Participation Meeting for the disclosure of Scoping Report before ESIA preparation process were conducted. The engagement and consultations with stakeholders have not been limited by the disclosure and consultations on this Scoping Report but will also be held by MoH throughout the entire stages of the Sub-project.

All studies to be conducted were in line with WB Environmental and Social Standards requirements, GIIP, relevant international standards and guidelines and Serbian legal requirements. EIA Report has not been prepared according to Serbian regulation. For the financing of the Sub-project, ESIA report was prepared in line with WB ESSs.

5.3.3 Identification Sub-Project's Area of Influence (AoI)

The relevant environmental AoI for the Sub-project can be divided into two main parts. The first part covers the followings:

1. The Sub-project and activities defined as the part of Sub-project at the Chapter 2 as well as the areas or activities required for construction works such as mobilization area, temporary top soil and excavated storage sites;

2. Within the scope of the Sub-project, there has been no identified potential associated facility as per WBG Policies[14];
3. The extended AoI of the Sub-project, including access roads.

For the intense and direct impacts associated with the Sub-project activities in construction and operational phases, the immediate vicinity of the Sub-project covering above mentioned items are considered to be a buffer of 150 m which is the major impact zone of the construction activities. In addition, the following areas compose the second part of the Environmental AoI since there can be impacts (e.g., handling of wastes and transportation of the supply materials to the site from a long distance) associated with the activities in relation to the Sub-project:

- Material supply locations; (e.g., quarries, concrete batching plants, and the roads associated with transport of such materials);
- Excess excavated material dumpsites;
- Waste disposal facilities and the roads associated with waste management (e.g., sanitary landfills, waste recycling facilities);

Information about the type of the land use on the construction site of the Sub-project can be also found in Chapter 6 of the ESIA Report. In addition to this discussion, in particular, considering the constructional activities' environmental impacts, regarding air emissions and noise are the important factors to determine the AoI. Such impacts are assessed within a distance of 250 m.

It should be also noted that the Project Owner will not open any new quarry or borrow pit and it commits to use the operational quarries which will be audited with respect to the E&S selection criteria set out in the ESIA, prior to use. Those quarries will be among the ones which possess all needed environmental permit in addition to the other legal requirements.

The Social AoI has been also identified for the Sub-project due to the nature of social impacts. The Social AoI is described in detail is Chapter 6 and Chapter 7.

5.3.4 Baseline Data Collection

The next step of the ESIA process is the collection of data to establish the existing baseline conditions (i.e., conditions in the absence of the proposed development), which the impacts of construction and operation of the Sub-project can be assessed against. In undertaking the ESIA study, information on the current environmental and social baseline conditions was gathered using, among others, the following sources:

[14] Facilities or activities that are not funded as part of the project and, in the judgment of the Bank, are: (a) directly and significantly related to the project; and (b) carried out, or planned to be carried out, contemporaneously with the project; and (c) necessary for the project to be viable and would not have been constructed, expanded or conducted if the project did not exist. For facilities or activities to be Associated Facilities, they must meet all three criteria.

- technical reports prepared by the Sub-project Company and its consultants;
- secondary data sources (published materials and documents, maps by government agencies, research organizations and other relevant organizations);
- review of aerial photographs of the Sub-project site and its surroundings;
- interviews with specialists, field surveys and consultation with experts and community consultation;
- field study results.

Baseline data for the Sub-project is collected via various field studies and desktop reviews according to the subject to be assessed. Details of the studies are given in Chapter 6 and the summary of the baseline data collection studies is given in Table 5-2.

Table 5-2. Summary of Baseline Data Collection Studies

Subject	Baseline Data Collection Studies
Land Use, Zoning and Visual	Site visits, review of topographic maps, land use plans, and zoning regulations
Geology	Site visit, geological maps, geological and geotechnical reports
Soil Quality	Site visit, The Serbian National Soil Inventory, Relevant scientific literature on soil quality assessment
Climate and Meteorology	Database review-the Republic Hydro-meteorological Service of Serbia
Air Quality	Serbian Environmental Protection Agency (SEPA)-operational air quality monitoring station database, background PM10 and PM2.5 measurements at 2 locations-EN 12341:2015 standard
Noise	Background noise measurements at 2 sensitive locations in line with WB General EHS Guideline
Hydrology and Hydrogeology	Site visit, Sava River Basin Management Report
Waste Management	Site visit, Serbian Environmental Protection Agency (SEPA) data review, Torlak Waste Materials and Waste Management Policy,
Biodiversity	Review of pertinent literature and previous works, websites, Field studies carried out in the Sub-project Area, Satellite image interpretation, Communication with the inhabitants in the study area Data review: CITES, Bern Convention and IUCN Red List Database, Bird Directive and Habitat Directive
Traffic	Site visit, traffic count at 3 locations
Biosafety and Biosecurity	Related manuals and guidelines review, meeting with PCU and Torlak Institute personnel
Social Baseline Conditions	Site visit, DevInfo database, Surveys with Torlak Institute Employees, interview with local people, local community and Municipality representatives, focus group discussions with professionals (academicians) and NGOs, meetings with PCU and Torlak personnel, Public Consultation Meeting

Baseline data collection started during the scoping phase and continued to support the assessment process. Baseline studies and findings are described in the relevant chapters of the ESIA Report.

5.3.5 Method to Assess Environmental and Social Impacts

Impact Types and Definitions

Impacts may occur as positive, negative, direct, indirect and cumulative. Determination of the type of impact is the important step of the assessment process. The determination of the impact type is based on geographical size, sensitivity of receptor, duration, significance and likelihood of the impact. Impact types are provided in Table 5-3.

Table 5-3. Impact Types and Definitions

Impact Type	Definition
Positive	Impacts that make positive changes over the current conditions.
Negative	Impacts that lead to new and undesirable changes over the current conditions.
Direct	Direct impacts occur through direct interaction of an activity with an environmental, social, or economic component.
Indirect	Impacts which are not a direct result of the project, often produced away from or as a result of a complex impact pathway.
Cumulative	Impacts that consist of an impact that is created as a result of the combination of the project evaluated in the current project together with other projects causing related impacts.

Assessment

The impact assessment process predicts and describes impacts that are expected to occur for different phases of the Project. Where possible, impacts are quantified to the extent practicable, which may include size of land affected; increase in noise or air pollution levels above acceptable standards; volume of waste or water discharged, number of households affected, etc. For each impact, its significance is evaluated by defining and evaluating two key aspects:

- The magnitude of the impact; and
- The sensitivity of the feature or receptor that will be impacted.

Impact Magnitude

Impact magnitude essentially describes the intensity of the change that is predicted to occur in the resource/receptor as a result of the impact. Magnitude rating tends to reflect a combination of the size of an area that may be affected, the duration over which the aspect may be altered, and the size, degree or scale of that change. In essence, magnitude is a descriptor for the degree of change that is predicted to occur in the resource or receptor.

For positive impacts (which are mostly socio-economic impacts) magnitude is generally categorised as ‘Positive’ unless sufficient information is available to support a more robust characterisation. For instance, if the number of jobs to be assigned to local community members is confirmed or if the size or value of the contribution to the national, regional or district economy is known then a magnitude rating can be assigned. If not, then the significance rating is assigned based on the sensitivity of the feature impacted by a specific activity or change.

The term 'magnitude' therefore encompasses all the characteristics of the predicted impact including:

- Geographic Extent;
- Duration;
- Intensity;
- Frequency; and
- Likelihood (only for unplanned events).

The definitions for characteristics of magnitude used during the impact assessment are summarized in Table 5-4.

In the case of intensity and frequency, these characteristics are not assigned fixed designations, as they are typically numerical measurements (e.g., number of acres affected, number of times per day, etc.).

The terminology and designations are provided to ensure consistency when these characteristics are described in an impact assessment deliverable. However, it is not a requirement that each of these characteristics be discussed for every impact identified.

For unplanned events (e.g., accidental release of hazardous materials) the likelihood of the impact occurring is taken into consideration in deriving the magnitude rating. The likelihood of an impact occurring as a result of an unplanned event is expressed as a probability and is designated using a qualitative scale (or semi-quantitative, where appropriate data are available), according to the attributes described in Table 5-4.

Likelihood is estimated on the basis of experience and/or evidence that such an outcome has previously occurred. It is important to note that likelihood is a measure of the degree to which the unplanned event is expected to occur, not the degree to which an impact or effect is expected to occur as a result of the unplanned event.

In the case of impacts resulting from unplanned events, the same resource/receptor-specific approach to concluding a magnitude designation is utilised, but the 'likelihood' factor is considered, together with the other impact characteristics, when assigning a magnitude designation. There is an inherent challenge in discussing impacts resulting from (planned) Project activities and those resulting from unplanned events. To avoid the need to fully elaborate on an impact resulting from an unplanned event prior to discussing what could be a very low likelihood of occurrence for the unplanned event, this methodology incorporates likelihood into the magnitude designation (i.e., in parallel with consideration of the other impact characteristics), so that the "likelihood- factored" magnitude can then be considered with the resource/receptor sensitivity/vulnerability/importance in order to assign impact significance.

Rather than taking a prescriptive (e.g., matrix) approach to factoring likelihood into the magnitude designation process, it is recommended that this be done based on professional judgment, and assisted by quantitative data (e.g., modelling, frequency charts) where available.

Once the impact characteristics are understood, these characteristics are used (in a manner specific to the resource/receptor in question) to assign each impact a magnitude. In summary, magnitude is a function of the following impact characteristics:

I. Geographical Extent (G);
II. Duration (D);
III. Intensity (I);
IV. Frequency or Likelihood (F or L);
V. Reversibility (R).

Impact Magnitude = (G+D+I+F (or L)) x R

The magnitude can also be defined as the severity of the potential impact. It indicates whether such an impact is irreversible or reversible. If the adverse effect of a project can not be mitigated then the magnitude of the impact is considered as very high.

Magnitude essentially describes the degree of change that the impact is likely to impart upon the resource/receptor. As in the case of extent and duration, the magnitude designations themselves (i.e., negligible, low, medium, high and very high) are universally used and across resources/receptors, but the definitions for these designations will vary on a resource/receptor basis, as is discussed further below. The universal magnitude designations are:

- Negligible;
- Low;
- Medium;
- High; and
- Very High

The magnitude of impacts takes into account all the various dimensions of a particular impact in order to make a determination as to where the impact falls on the spectrum (in the case of adverse impacts) from negligible to large. Some impacts will result in changes to the environment that may be immeasurable, undetectable or within the range of normal natural variation. Such changes can be regarded as essentially having no impact, and should be characterised as having a negligible magnitude.

Table 5-4. Criteria for Determining Impact Significance

Aspect	Score	Definition
Geographic Extent (G) is the area within which the impact occurs.	**1**	**Project Site:** (i.e. the impact is confined within the facilities owned or exclusively controlled by the project)
	2	**Local** (i.e. the impact extends to areas or communities around the project site)
	3	**Regional** (i.e. the impact extends to an area beyond the surroundings of the project site and to regional physical (airshed, watershed, etc) or administrative boundaries)
	4	**National:** (i.e. the impact extends throughout several regions or to the entire country)
	5	**International:** (*i.e the impact is transboundary*)
Duration (D) is the duration of the impact and can vary from short to long terms.	**1**	**Very Short** (<1 Month)
	2	**Short** (1 Month - 1 year)
	3	**Medium** (1-2 years)
	4	**Long** (2-5 years - the impact will cease after the operational life span of the project)
	5	**Very Long** (over 5 Years - no mitigation measure of natural process will reduce the impact after construction)
Intensity (I) is a measure of the physical, economic or social severity of the impact.	**1**	**Negligible**: the impact cannot be easily detected or perceived and is unlikely to cause detectable change in environmental or social components.
	2	**Low**: the impact can be detected or perceived but the effects are unlikely to cause tangible changes in environmental or social components
	3	**Medium**: the impact are well within legal standards or accepted practices and/or are likely to cause tangible changes in environmental or social components.
	4	**High**: the impact is near the limit of legal standards or accepted practices and/or are likely to cause serious impairment of environmental or social components.
	5	**Very high:** the impact may result in exceedances of legal standards or accepted practices and/or is likely to cause very serious to catastrophic damage to environmental or social components.
Frequency (F): is the frequency of the impact (not the activity causing the impact).	**1**	**Single event**
	2	**Infrequent:** a few events evenly or randomly distributed over time
	3	**Recurrent:** numerous events evenly or randomly distributed over time
	4	**Frequent:** a high number of events evenly or randomly distributed over time
	5	**Continuous:** no interruption over time.

Aspect	Score	Definition
Likelihood (L) (unplanned events)	**0**	**Improbable:** The event is extremely unlikely to occur during implementation (construction and operation) of the Project. (Probability; less than 1%).
	1	**Unlikely:** The event is unlikely but may occur at some time during implementation (construction and operation) of the Project. (Probability; less than 5%, greater than 1%)
	3	**Likely:** The event is likely to occur at some time during implementation (construction and operation) of the Project. (Probability; less than 50%, greater than 5%)
	5	**Probable:** The event will occur during implementation (construction and operation) of the Project (i.e., it is essentially inevitable). (Probability; greater than 50%)
Reversibility (R)	**1**	**short term:** if the initial condition of the component can be restored within weeks or months after the cessation of the impact source and/or with restoration activities.
	2	**short/mid-term:** if the initial condition of the component can be restored within a few months to one year after cessation of the impact source and/or with restoration activities.
	3	**mid-term:** if the initial condition of the component can be restored within one to five years after cessation of the impact source and/or with restoration activities.
	4	**long term:** if the initial condition of the component can be restored within five to 25 years after cessation of the impact source and/or the restoration activities.
	5	**Irreversible:** if it is not possible to achieve restoration of the initial conditions.

Sensitivity

In addition to characterising the magnitude of impact, the other principal step necessary to assign significance for a given impact is to define the sensitivity/vulnerability/importance of the impacted resource/receptor to the type of activity proposed (e.g., habitat clearance, topsoil removal, etc.) or the impact of a Project activity (e.g., dust, noise, water pollution, or induced population influx). This requires a range of physical, biological, cultural or human factors to be taken into account and may also need to include other factors such as legal protection, government policy, stakeholder views and economic value.

Characterisation of sensitivity for a physical or biological resource or receptor (e.g., a water feature or parameter, cliff, vegetation type) will take into account its conservation status and importance (on a local, national and international scale), its vulnerability to disturbance, and its resilience to recover or withstand a specific impact or type of impact. Where the receptor is human or cultural, the value of that social and cultural heritage receptor/s and its vulnerability to the impact is considered, taking into account the receptor's resilience, including ability to adapt to change or use alternatives where available.

As in the case of magnitude, the sensitivity/vulnerability/importance designations themselves are universally consistent, but the definitions for these designations will vary on a resource/receptor basis. The universal sensitivity/vulnerability/importance designations are:

- Low;
- Medium; and
- High.

Receptor sensitivity definitions are provided in Table 5-5.

Table 5-5. Receptor Sensitivity

Receptor Sensitivity (S)[15] describes the ability of the receptor to withstand adverse impacts. It takes into consideration not only activity-impact-receptor pathways, but also social and environmental characteristics of the receptor that might make it more or less resilient to change.	**1**	**Low:** Local community and/or environment is fully equipped/has the tools to manage changes of life quality: • Species and/or population has high capacity to absorb or adapt to change (i.e. has capacity to move away from or adapt to the project impact), and is potentially unaffected or marginally affected; • People being least vulnerable to change or disturbance (i.e. ambient conditions such as air quality are well below applicable legislation and international guidance,); • Individuals who are able to quickly adapt to temporary disruption in their living conditions, livelihood status or a change in the status of public infrastructure.

[15] Receptors may be humans, ecological and physical components of the environment. Receptor sensitivity considers how a particular receptor may be more or less susceptible to a given impact. More sensitive receptors may experience a greater degree of change, or have less ability to deal with the change, compared with less sensitive receptors that may be more resilient or adaptable.

	3	**Medium:** Local community and/or environment is partially equipped/has the tools to manage changes of life quality. For example: • Internationally threatened species /protected area within the area impacted by the project activities outside of period of high sensitivity or during routine or reliably predictable peak presence; • Species and/or population which has moderate capacity to absorb or adapt to change (i.e. has capacity to move away from or adapt to the project impact), leading to potential temporary but sustainable effect which does not substantially alter character or result in significant loss of ecological functionality; • People being vulnerable to change or disturbance (i.e. ambient conditions such as air quality are below adopted standards; • Negative change in livelihood status, household assets/income or living conditions. Temporary disruption to businesses resulting in a small drop in business revenue; • Increased risk to public health that can be controlled using detailed mitigation measures; and • Disruption to public infrastructure that results in an inconvenience to other users.
	5	**High:** Sensitive local community and/or environment not equipped or prepared to cope with social and environmental impacts such as changes of life quality. For example: • Internationally threatened species /protected area within the area impacted by the project activities during period of high sensitivity (e.g. during breeding, spawning or nesting) and during routine or reliably predictable peak presence; • Species and/or population which has little or no capacity to absorb or adapt to change (i.e. little or no capacity to move away from or adapt to the project impact), leading to potential for substantial change of character and/or loss of ecological functionality; • Most vulnerable groups (i.e. ambient conditions such as air quality are at or above adopted standards; • People /citizens who may misinterpret the Lab3 operation work; • Individuals with a marginal livelihood, low socio-economic income or poor quality living conditions; • Individuals who are vulnerable due to their age, disability or other reason and who may require special assistance during engagement activities; and • Businesses with a marginal economic existence which are not able to easily adapt to change.

Determination of the Overall Impact

For impacts resulting from unplanned events (typically accidents, such as a major oil spill or other event that cannot be reasonably foreseen), the above methodology is applied but likelihood is also considered when assigning the magnitude designation.

The Impact significance is calculated by multiplying the Impact magnitude by the Sensitivity Score:

Impact Significance = Impact magnitude x S

Table 5-6. Description of the Impact Significance

Score of the Impacts		
Value	**Score**	**Definition**
4-25	**Negligible**	An impact of "**Negligible**" significance is one where a resource/receptor (including people) will essentially not be affected in any way by a particular activity or the predicted effect is deemed to be 'imperceptible' or is indistinguishable from natural background variations.
26 - 75	**Low**	An impact of "**Low**" significance is one where a resource/receptor will experience a noticeable effect, but the impact magnitude is sufficiently small (with or without mitigation) and/or the resource/receptor is of low sensitivity/ vulnerability/ importance. In either case, the magnitude should be well within applicable standards.
75 - 150	Medium	An impact of "**Medium**" significance has an impact magnitude that is within applicable standards, but falls somewhere in the range from a threshold below which the impact is minor, up to a level that might be just short of breaching a legal limit. Clearly, to design an activity so that its effects only just avoid breaking a law and/or cause a major impact is not best practice. The emphasis for moderate impacts is therefore on demonstrating that the impact has been reduced to a level that is as low as reasonably practicable (ALARP). This does not necessarily mean that impacts of moderate significance have to be reduced to minor, but that moderate impacts are being managed effectively and efficiently.
150 - 250	**High**	An impact of "**High**" significance is one where an accepted limit or standard may be exceeded, or large magnitude impacts occur to highly valued/sensitive resource/receptors. An aim of impact assessment is to get to a position where the Project does not have any major residual impacts, certainly not ones that would endure into the long term or extend over a large area. However, for some aspects there may be major residual impacts after all practicable mitigation options have been exhausted (i.e. ALARP has been applied). An example might be the visual impact of a facility. It is then the function of regulators and stakeholders to weigh such negative factors against the positive ones, such as employment, in coming to a decision on the Project.
250 - 500	**Very High**	An impact of "**Very High**" significance after all feasible mitigation measures have been identified and assessed warrants the highest level of attention and concern. As with residual impacts of major significance, the regulators and stakeholders will need to closely evaluate whether the positive impacts of the project outweigh residual negative impacts of very high significance. In many cases residual critical impacts can be considered as a potential fatal flaw of the project.

Development of Mitigation Measures Plans

One of the aims of an Environmental and Social Impact Assessment consists of suggesting mitigation measures in order to limit any potential negative impacts affecting all physical, biological and socioeconomic resources as well as receptors due to Project activities. Mitigation measures are defined against each significant adverse impact by making use of avoidance, minimization, restoration and remediation as appropriate. Mitigation measures provided in each impact assessment table are also grouped under each project phase such as design, pre-construction, post construction and operation. In general, mitigations suggested for operation phase are directly related to the Project design, in this respect these mitigations are also grouped under design phase.

A hierarchy of mitigation options is considered, with avoidance at the source of the impact as a priority and compensatory measures or offsets to reduce the impact significance as a last resort. The mitigation hierarchy that is utilised in identification of mitigation measures are presented in Table 5-7 below.

Table 5-7. Hierarchy of Options for Mitigation

Options	Explanation
Avoid	Anticipate and avoid risks and impacts
Minimize or Reduce	Where avoidance is not possible, minimize or reduce risks and impacts to acceptable levels
Mitigate	Once risks and impacts have been minimized or reduced, mitigate
Compensate	Where significant residual impacts remain, compensate for or offset them, where technically and financially feasible

The aim of the mitigation measures is to prevent or reduce the importance of negative impacts whilst optimizing the feasibility and potential benefits of the Project for project affected people/stakeholders. Impact mitigation objectives are often established on the basis of legal standards or by referring to best practice. In the absence of any existing benchmarks, objectives specific to the project are established. Mitigation activities are supported with management plans linked to potential impacts, and they include monitoring requirements detailing what will be monitored, the method of monitoring, frequency, and measurable targets. Steps for determination of mitigations in line with “Mitigation Hierarchy” provided below:

- Avoid at Source, Reduce at Source: avoiding or reducing at source through the design of the Project (e.g., avoiding by siting or re-routing activity away from sensitive areas or reducing by restricting the working area or changing the time of the activity). For this purpose, Constraint Maps regarding no-go areas and sensitive locations are prepared to serve as a Guiding document for the detailed design as well as Sub-management and monitoring plans;
- Abate on Site: add something to the design to abate the impact (e.g., pollution control equipment, traffic controls, perimeter screening and landscaping);

- Abate at Receptor: if an impact cannot be abated on-site then control measures can be implemented off-site (e.g., noise barriers to reduce noise impact at a nearby residence or fencing to prevent unauthorized access to the site);
- Repair or Remedy: some impacts involve unavoidable damage to a resource (e.g. forestry due to creating access, materials storage areas) and these impacts can be addressed through repair, restoration or reinstatement measures;
- Compensate in Kind, Compensate Through Other Means: where other mitigation approaches are not possible or fully effective, then compensation for loss, damage and disturbance might be appropriate (e.g., planting to replace cut down trees).

The priority in mitigation is to first apply mitigation measures to the source of the impact (i.e., to avoid or reduce the magnitude of the impact from the associated Project activity), and then to address the resultant effect to the resource/receptor via abatement or compensatory measures or offsets (i.e., to reduce the significance of the effect once all reasonably practicable mitigations have been applied to reduce the impact magnitude).

Taking into account how mitigation will reduce a predicted impact, receptor sensitivity and significance of the after-mitigation impacts, residual impacts are identified. Some mitigation measures may directly address the impact on the predicted receptors, in which, the overall impact after applying the mitigation measures will result in reducing the impact on the sensitive receptors.

Where significant residual impacts or risks remain, further options for mitigation are evaluated and impacts are re-assessed until they are considered to be low and technically and financially feasible for the Project and would be deemed to be within acceptable levels.

The effectiveness of the mitigation measures defined in the ESIA are assessed using expert judgement and the findings from the previous application of the measures to similar projects. The definitions of the mitigation effectiveness are:

- Low: the measures can reduce the impacts by less than 20% of the expected magnitude;
- Medium low. the measures can reduce the impacts by 20% - 40% of the expected magnitude;
- Medium: the measures can reduce the impacts by 40% - 60% of the expected magnitude;
- Medium high: the measures can reduce the impacts by 60% - 80% of the expected magnitude;
- High: the measures can reduce the impacts by more than 80% of the expected magnitude.

The Mitigation effectiveness is measured on a scale 1 – 0.2 (1=minimum effectiveness; 0.2=maximum effectiveness). Residual impacts will be identified by taking into account the mitigation effectiveness.

Residual Impact Assessment

Once mitigation measures are declared, the next step in the impact assessment process is to assign residual impact significance. This is essentially a repeat of the impact assessment steps discussed above, considering the assumed implementation of the additional declared mitigation measures.

5.3.6 Cumulative impacts

Torlak Institute and Faculty of Pharmacy were identified as existing facilities close to the Sub-project site that have the potential to be considered as part of the cumulative impact assessment scope.

5.3.7 Environmental and Social Management and Monitoring Plans

Environmental and Social Management Plan and Monitoring Plan have been developed as part of the ESIA study including the description of the mitigation measures for each impact during construction and operation phases of the Sub-project, responsible parties for the implementation of the mitigation measures, the timing, monitoring and audit requirements. The environmental and social management and monitoring plans focus on the avoidance of impacts, and where this is not possible, presents technically and financially feasible and cost-effective mitigation measures to minimize or reduce potential impacts to acceptable levels. The environmental and social management and monitoring plans of the Sub-project are presented in Appendix C of this ESIA report. The ESMP should be kept up to date with any required additional mitigation throughout the Sub-project lifecycle.

Implementation of the environmental and social management and monitoring plans will be accomplished within the framework of a project-specific Environmental and Social Management System (ESMS) to be developed by the Project owner in accordance with the national and international standards (i.e., WB’s ESF, WB’s EHS guidelines).

6 ENVIRONMENTAL AND SOCIAL BASELINE

This chapter serves as a comprehensive assessment of the current conditions of the Sub-project area and its surroundings, including the physical, biological, and social aspects that may be affected by the Sub-project's activities.

It provides a vital understanding of the current state of the environment and social context in which the Sub-project operates, enabling decision-makers to assess potential impacts and identify appropriate mitigation measures. The report is based on a robust and transparent methodology, using a combination of field assessments, stakeholder engagement, and secondary data analysis. The environmental and social baseline report forms a fundamental component of the Environmental and Social Impact Assessment (ESIA) process, and its findings will inform the development of the Sub-project's environmental and social management plans.

6.1 Land Use, Zoning and Visual

6.1.1 Methodology and Data Source

To assess the land use, visual impact, and zoning aspects of the Sub-project, ESIA consultants team (Enacta Ltd. (Serbia), 2U1K Engineering and Consultancy Inc. (Türkiye) and 2U1K International Ltd.) conducted site visits and reviewed available data sources, including topographic maps, land use plans, and zoning regulations.

6.1.2 Baseline Conditions

Land Use and Zoning

The Sub-project location is in settlement Jajinci on the southern edge of Belgrade. The Sub-project area is a state-owned land already within the existing Torlak Institute and there will be no land acquisition and/or restriction to lands/assets and resources use within the scope of the Sub-project. Land use map of the Sub-project is provided in Figure 6-1.

Figure 6-1. Sub-Project Location on the Regional Map

The Torlak Institute in a fenced area includes an administrative building and four national reference laboratories for diagnostics. The complex is located in an urban area, surrounded by commercial and residential buildings. The Sub-project will be located on the north side of the institute within the fenced area. The Sub-project Area landcover is discontinuous urban fabric as can be seen from the Figure 6-2.

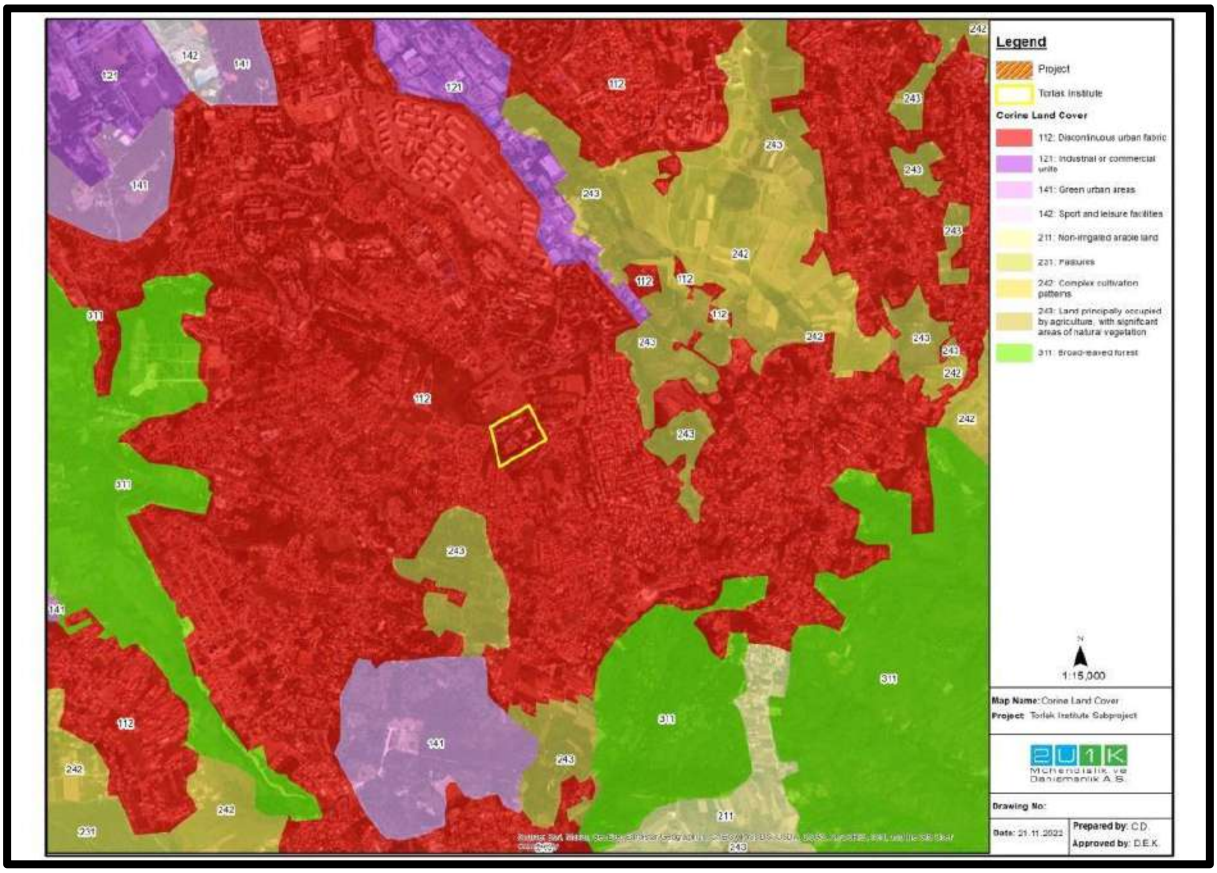


Figure 6-2. Corine Land Cover Map

Currently, the Sub-project Area is within the premises of existing Torlak Institute and the parcel on which the Sub-project is planned is not used by any formal or informal user. Within the Sub-project Area there are concrete structures with vent-holes and chimneys that are the existing infrastructures of Torlak Institute. Also, the existence of an underground gas pipeline in a part of the Sub-project Area has been verified by the Sub-project representative.

During the site visit, no legacy environmental issues that potentially require additional analysis and/or remediation have been identified. Besides that, soil quality sampling during excavation works will be conducted in the construction phase of the Sub-project in case any contamination is identified. If any contamination is detected during construction works, soil sampling studies will be conducted and remediation plan will be prepared according to the sampling study results in line with type of the contaminants.

Visual

The proposed Sub-project will be within an existing Institute complex. Therefore, the visual impact of the proposed Sub-project is expected to be minimal due to the location of the site within an existing complex and ’he building's design.

6.1.3 Sensitive Receptors

Sensitive receptors near the Sub-project site include the Torlak Institute complex, which houses medical research facilities, and several residential areas. The construction and operation of the proposed Sub-project could potentially impact the quality of life of the nearby residents and the staff working at the Torlak Institute complex. Mitigation measures such as noise barriers and dust suppression measures during construction and proper waste management and air filtration systems during operation can minimize the potential impacts on sensitive receptors.

6.2 Geology

The geology baseline provides a comprehensive understanding of the geological characteristics of the Sub-project site. This information is essential to assess the potential environmental impacts of the proposed Sub-project and develop effective mitigation measures.

6.2.1 Methodology and Data Source

The geology section of the ESIA was developed using desktop study including a review of available literature and maps, as well as geological and geotechnical reports of the surrounding area.

The methodology for geological mapping was based on the guidelines provided by the International Union of Geological Sciences (IUGS), which involves the identification and description of rock formations and the characterization of the geological structure of the area.

The data sources for the geology section include geological maps, geological and geotechnical reports, and data collected from the field investigation. These data sources were reviewed and analyzed to develop a comprehensive understanding of the geology and geotechnical conditions of the Sub-project area.

6.2.2 Baseline Conditions

6.2.2.1 General Geology

The Sub-project site is located in the central part of Serbia, which is predominantly composed of three geological units: the Dinarides, the Pannonian Basin, and the Serbo-Macedonian massif. The Dinarides are predominantly composed of Mesozoic and Tertiary rocks, while the Pannonian Basin is composed of Quaternary deposits. The Serbo-Macedonian massif consists of Precambrian rocks and their metamorphic derivatives (Pantić, 2015).

Serbia belongs to the Pannonian and particularly Peri-Pannonian regions in the scope of geological classification (Marovic, Djokovic, Pesic, Radovanovic, Toljic, & Gerzina, 2002). According to Horvath, et al. (2006), the Pannonian Basin is located in Eastern Europe. The Alpine, Carpathian and Dinaric Mountain belts environ the extensional basin of Neogene-

Quaternary age. The basin is a wide zone of convergence between the Eurasian and African plates, the territory of Serbia can be defined in five geologic group that are Pannonian Basin, Dinarides, Vardar Zone, Serbo-Macedonian Massif, Carpatho-Balkanides.

Belgrade, the capital of Serbia, is located in Southeast Europe, on the Balkan Peninsula, at the confluence of the Sava and the Danube Rivers. It covers an area of 3,227 km^2 of which almost 276.6 km^2 includes rivers and riparian land. Belgrade city area includes the southern margin of the Pannonian Basin, northern parts of the Vardar Zone and the Serbo-Macedonian Massif (MAROVIĆ et al., 2007).

Morphologically, two distinct units are clearly recognized in Belgrade:

a) Southern part of the Pannonian Plain that represents vast plain and low land area located north of the Sava and Danube rivers; and

b) Mountainous/hilly area (Mts. Šumadija, Avala and Kosmaj) located south of the Sava and Danube rivers.

The primary morphological relief of the Belgrade area (see. Figure 6-3) results from the tectonic movements that occurred during the Palaeogene and early Neogene. During the Oligocene Miocene, a few horsts (Mt. Avala, Mt. Kosmaj) and a large-scale tectonic basin (Pannonian Basin) were created, as well as small tectonic depressions south of the Pannonian Basin. The turbulent tectonic activity was accompanied by volcanism, which lasted until the end of the Miocene. Volcanic landforms created during this period are not preserved in the territory of Belgrade, instead igneous rocks from that period (Mt. Avala, Mt. Kosmaj) and pyroclastic material can be observed.

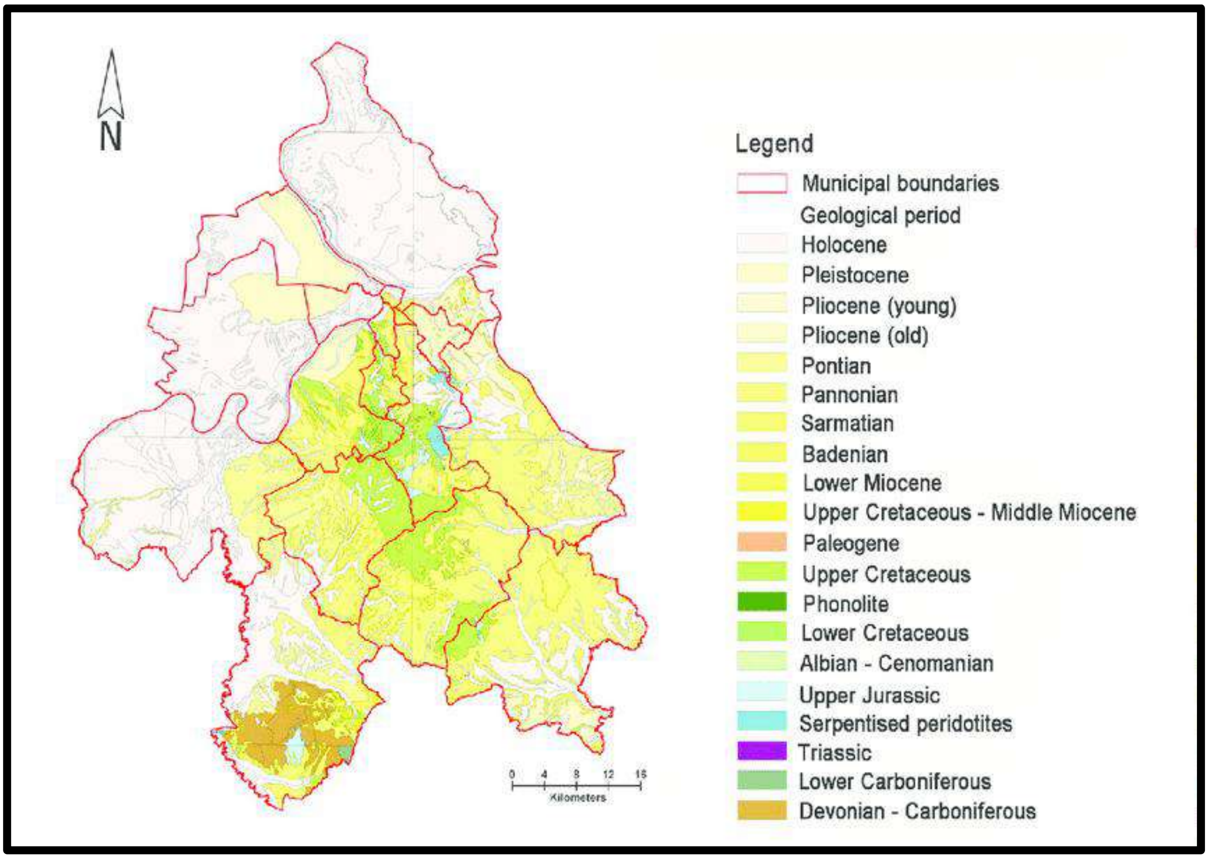


Figure 6-3. General Geological Map of Belgrade

The geology of the Sub-project site is mainly controlled by the Dinarides, which are composed of a thick sequence of limestones, dolomites, and marls. These rocks were deposited in a shallow marine environment during the Jurassic and Cretaceous periods. The sedimentary sequence is interrupted by several faults that are part of the North-South trending Serbian-Macedonian tectonic zone. The Sub-project site is located on the northern margin of this zone, which is characterized by a high degree of tectonic activity.

6.2.2.2 Lithology

The Sub-project site is underlain by a sequence of sedimentary and metamorphic rocks. The sedimentary rocks consist of sandstones, siltstones, and shales of the Paleozoic age, while the metamorphic rocks are represented by gneisses and schists of the Precambrian age. The sediments were deposited in a marine environment, and the metamorphic rocks resulted from regional metamorphism of the sediments (Vasiljevic & Stankovic, 2016).

The limestone at the Sub-project site is predominantly composed of micritic limestone, which is finely crystalline and homogeneous. The micrite is composed of calcite and is interbedded with marl layers. The marl is composed of clay minerals and calcite, and is characterized by a higher porosity than the limestone. The limestone and marl are both susceptible to karstification, which is a common process in the Dinaric karst. Karstification can result in the formation of sinkholes and underground caves, which can pose a risk to structures built on the surface (Milojević, Miljković, & Ćalić, 2017).

The lithology of the Sub-project site and its surroundings are presented in the Table 6-1.

Table 6-1. Lithology of the Sub-project site and surrounding areas

Formation	Lithology
Quaternary	Gravel, sand, silt, clay
Tertiary	Clay, silt, sand, lignite
Cretaceous	Sandstone, shale, limestone
Jurassic	Limestone, marl, sandstone
Triassic	Limestone, dolomite, sandstone, shale
Permian	Sandstone, shale
Carboniferous	Sandstone, shale, limestone, coal
Devonian	Sandstone, shale, limestone
Silurian	Sandstone, shale, limestone
Ordovician	Sandstone, shale, limestone
Precambrian	Gneiss, schist, granite

6.2.3 Sensitive Receptors

Since no groundwater resources were determined within and around Torlak Institute, sensitive receptors are determined as the Sub-project footprint.

6.3 Soil Quality

This Section starts with the general information on Serbia's soil type and quality and focuses on detailed information of the baseline conditions of the AoI.

6.3.1 Methodology and Data Source

The soil quality baseline was carried out through a desktop study that involved a review of relevant documents related to soil quality in the study area. The documents reviewed include:

- The Serbian Law on Soil Protection ("Official Gazette of RS" No. 43/2011 and 36/2013);
- The Regulation on the Conditions for Soil Monitoring and Soil Quality Requirements (Official Gazette of RS, No. 11/10 and 75/10, Amend 63/13);
- The Serbian National Soil Inventory;
- Relevant scientific literature on soil quality assessment; and
- Site visit.

The desktop study aimed to identify the baseline conditions of soil quality in the study area based on the available data. The documents reviewed provided information on soil type, land use, and potential sources of soil contamination, as well as relevant soil quality standards and guidelines.

The soil type in the study area is predominantly chernozem, which is a fertile soil that supports agriculture. The land use in the study area includes agriculture, urban areas, and industrial areas. The potential sources of soil contamination in the study area include agricultural practices, waste disposal, and industrial activities.

The documents reviewed provided information on the relevant soil quality standards and guidelines, including the Serbian Law on Soil Protection and the Regulation on the Conditions for Soil Monitoring and Soil Quality Requirements. These documents provide criteria for assessing the quality of soil based on physical, chemical, and biological parameters.

Overall, the methodology and data source used in the soil quality baseline were based on a desktop study that reviewed relevant documents related to soil quality in the study area. The results of the desktop study provide a baseline for further environmental impact assessment of the Sub-project.

6.3.2 Baseline Conditions

The Soil Map of Serbia (see. Figure 6-4) consists of a large number of soil types and subclasses, each with a unique set of morphological, chemical and water-physical properties, each with different production characteristics (Licina, et al., 2011).

According to the census of agriculture (in 2012), 73.1% of the land in agricultural areas is cultivated. 20.7% of these areas consist of pastures and meadows. 4.8% of this area is used for fruit cultivation, 0.6% for vineyard and 0.7% for the garden (Pavlovic, Costic, Karadzic, & Mistrovi, 2017).

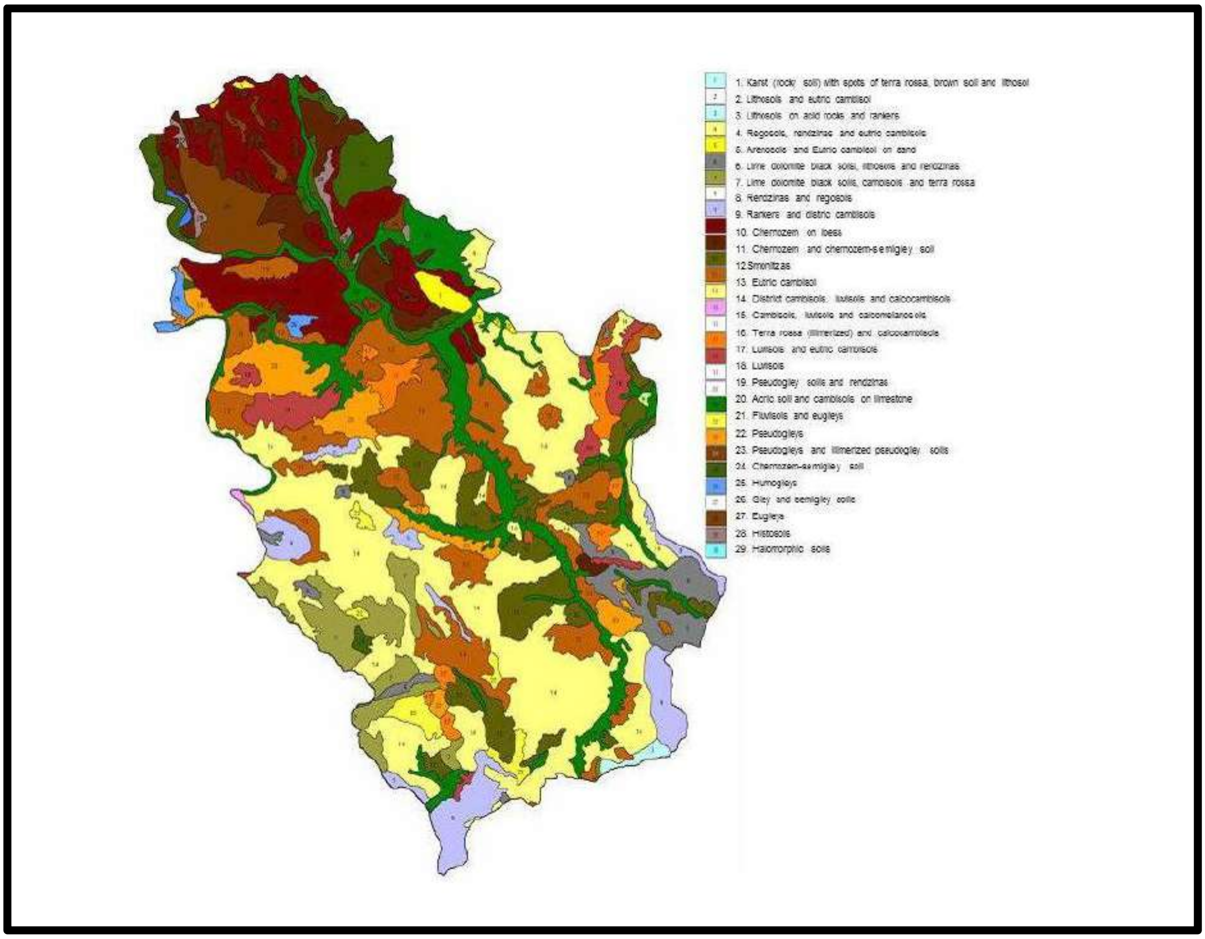


Figure 6-4. Soil Map of Serbia (Serbian Environmental Protection Agency, 2015)

The territory of Belgrade Figure 6-4 includes two regions. The first pedogeographical area, north of the Sava and the Danube, is the steppe and forest-steppe region of the Pannonian Plain. The second pedogeographical area extends south of the Sava and the Danube rivers. In the Pannonian Plain, the alluvial deposits on river terraces host fluvisols, gleysol, chernozems, and solonchaks (IUSS WORKING GROUP WRB, 2006). There are also loess plateaus with chernozems and salt marshes soils. South of the Sava and the Danube, Neogene sediments prevail. Overlying the sediments, eutric cambiosols developed, which dominate in the sequence: regosol–leptosol (rendzinas)–eutric cambisol– luvisol while the heavy sediments predominately contain clays (vertisol). In the areas of significant soil erosion there are many colluvial soils, and on the lower river terraces there are fluvisols, fluvic cambiosols and gleysols. Within Belgrade specifically in the urban area, technosols are common, especially in the area north of the Sava and the Danube rivers (Ilic, Rundić, & Calic, 2016).

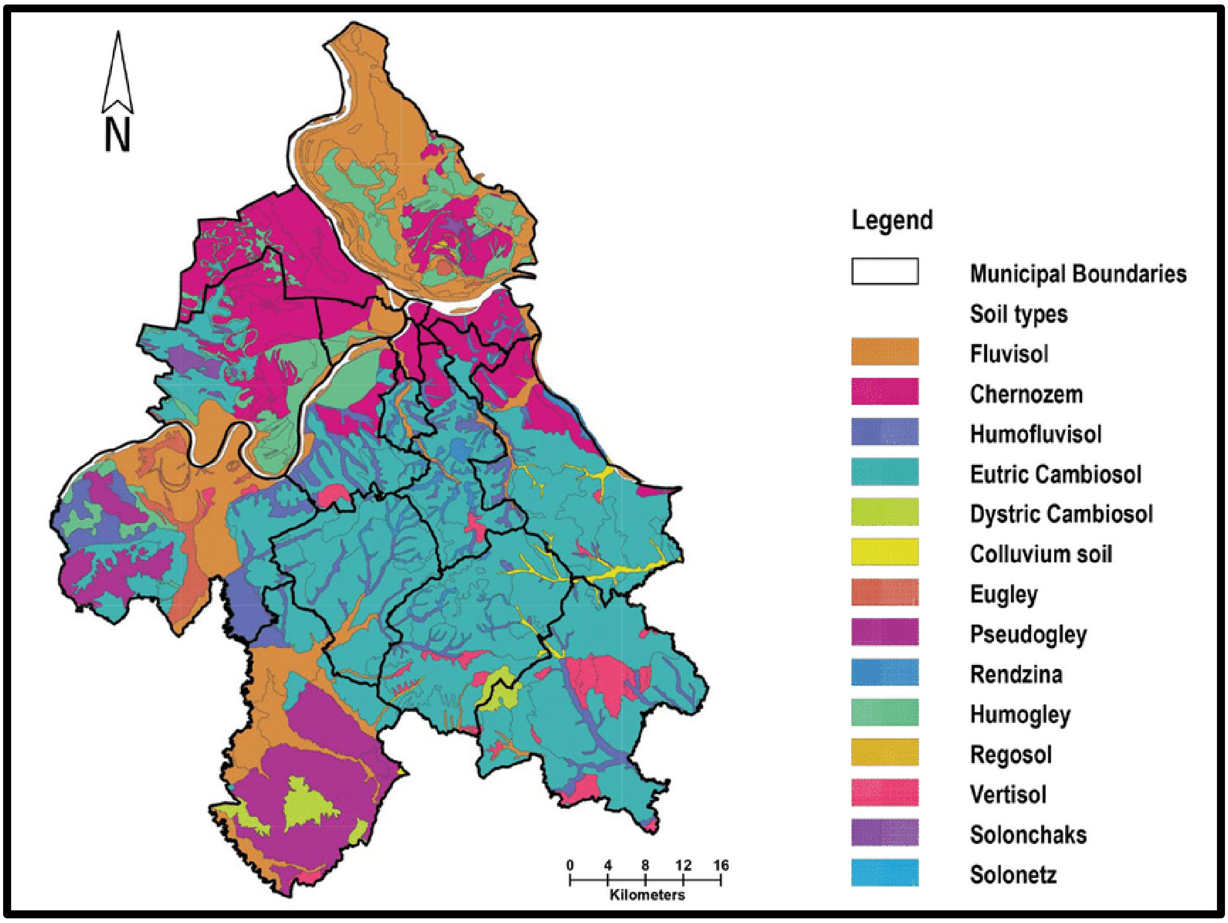


Figure 6-5. Soil Map of Belgrade

Vojvode Stepe Street is located in the Pannonian Basin, which is characterized by alluvial deposits and loess. The soil in this area is derived from various parent materials, including alluvial deposits, loess, and colluvium (Andjelkovic, Petrovic, & Pocuca, 2012). According to the Soil Atlas of Europe, the soil types in the area can be classified as Udalfs, Ustolls, and Ustalfs, which are all types of Mollisols. These soils are characterized by a high level of organic matter and a thick, dark surface layer, which makes them highly fertile and suitable for agricultural use (Jones, Hiederer, & Rusco, 2005).

Soil texture is an important factor that influences soil quality. According to the Soil Atlas of Europe, the soil texture in Vojvode Stepe Street ranges from sandy loam to clay loam (Jones, Hiederer, & Rusco, 2005). The texture of the soil influences nutrient availability and plant growth. In general, soils with higher clay content tend to retain more water and nutrients than sandy soils, while soils with more sand tend to be well-drained (Brady & Weil, 2008).

Soil structure also plays an important role in soil quality. The structure of the soil influences the movement of water and air through the soil, which in turn affects nutrient availability and plant growth. The soils in Vojvode Stepe Street are generally well-structured, with good water-holding capacity and soil structure (Radovic & Markovic, 2006). According to the results of a study conducted in Vojvode Stepe Street, the soils have a high level of essential nutrients, including nitrogen, phosphorus, and potassium (Varga, Glusac, & Bekavac, 2013).

Quality parameters according to Serbian Law on Soil Protection and The Regulation on the Conditions for Soil Monitoring and Soil Quality Requirements are presented in Table 6-2.

Table 6-2. Serbian Law on Soil Protection and The Regulation on the Conditions for Soil Monitoring and Soil Quality Requirements

Quality Parameter	Serbian Law on Soil Protection	Regulation on the Conditions for Soil Monitoring and Soil Quality Requirements
pH	Not specified	5.5 - 8.5
Organic matter content	Not specified	≥ 2%
Total nitrogen content	≥ 0.1%	≥ 0.1%
Available phosphorus content	Not specified	≥ 15 mg/kg
Available potassium content	Not specified	≥ 100 mg/kg
Exchangeable magnesium content	Not specified	≥ 50 mg/kg
Exchangeable calcium content	Not specified	≥ 200 mg/kg
Heavy metals (e.g. lead, cadmium, mercury)	Not specified	≤ Maximum permissible concentrations (MPCs) as specified in the regulation
Polycyclic aromatic hydrocarbons (PAHs)	Not specified	≤ MPCs as specified in the regulation
Polychlorinated biphenyls (PCBs)	Not specified	≤ MPCs as specified in the regulation

During the site visit, no legacy environmental issues that potentially require additional analysis and/or remediation have been identified. Besides that, soil quality sampling during excavation works will be conducted in the construction phase of the Sub-project in case of any contamination is identified.

6.3.3 Sensitive Receptors

Sensitive receptors were determined as the Sub-project footprint.

6.4 Climate and Meteorology

This Section starts with the general information on Serbia's climate and focuses on detailed information of the baseline conditions of the AoI.

6.4.1 Study Area

The climate of Serbia can be described as moderate continental, featuring four seasons. Compared to spring, autumn is a longer season with more extended periods of warmth and sunshine.

Between 1961-1990, the average yearly temperature for areas up to 300 m in altitude in Belgrade was 10.9 ºC. The areas at 300 to 500m altitude had an average yearly temperature of around 10.0 ºC, while areas above 1000m had an average yearly temperature of 6.0 ºC.

From July to September, the maximum temperature measured in lower regions ranged from 37.1 to 42.3 ºC, while in mountainous regions, it ranged from -35.6 to -20.6 ºC.

In order to determine meteorological characteristics of the AoI, observation data of the nearest meteorology station were used. Belgrade-Vračar meteorology station is 6.4 km to the northwest of the Sub-project Area.

Belgrade-Vračar meteorology station is the closest station and it can represent the AoI better than other stations because of the change of meteorological parameters with regard to distance, topography and vegetation. Therefore, in order to identify meteorological characteristics, Belgrade-Vračar meteorology station observation data were used.

6.4.2 Methodology and Data Source

Meteorological data (from 1981 to 2010) of Belgrade-Vračar meteorology station is given in Table 6-3:

Table 6-3. Average Values of Climate Parameters from 1981 to 2010

	Jan.	Feb.	March	Apr.	May	June	July	Ags.	Spt.	Oct.	Nov.	Dec.	Annual Avg.
Tsr(ºC)	1.4	3.1	7.6	12.9	18.1	21	23	22.7	18	12.9	7.1	2.7	12.5
Tx(ºC)	4.6	7	12.4	18	23.5	26.2	28.6	28.7	23.9	18.4	11.2	5.8	17.4
Tn(ºC)	-1.1	-0.1	3.7	8.3	13	15.8	17.5	17.6	13.5	9	4.2	0.2	8.5
ApsTx(ºC)	20.7	23.9	28.8	32.2	34.9	37.4	43.6	40	37.5	30.7	28.4	22.6	43.6
ApsTn(ºC)	-18.2	-15.4	-12.4	-3.4	2.5	6.5	9.4	6.7	4.7	-4.5	-7.8	-13.4	-18.2
U (%)	78	71	63	61	61	63	61	61	67	71	75	79	68
SS (h)	72.2	101.7	153.2	188.1	242.2	260.9	290.8	274	204.3	163.1	97	64.5	2111.9
N	14	10	9	8	6	5	4	3	6	7	11	15	99
RR(mm)	46.9	40	49.3	56.1	58	101.2	63	58.3	55.3	50.2	55.1	57.4	690.9
maxRR(mm)	33.2	39.1	36.8	64.2	56.4	94	80.1	75.6	41.9	43.7	51.8	39.9	94

T_{sr} : Mean air temperature (ºC)
T_x : Average Maximum Air Temperature (ºC)
T_n : Average Minimum Air Temperature (ºC)
$A_{ps}T_x$: Absolute Maximum Air Temperature (ºC)
$A_{ps}T_n$: Absolute minimum air temperature (ºC)
U : Relative humidity (%)
SS : Sunset in hours total
N : Cloudiness in 10/10
RR : Precipitation (mm)
maxRR : Daily maximum rainfall (mm)

Precipitation

Depending on the atmospheric processes and relief characteristics of Serbia's territory, precipitation amount varies depending on the temperature and space. The general annual precipitation amount in the Country is 896 mm. The annual amount of precipitation increases with altitude. Annual precipitation over the Country ranges from 600 mm to 1,000 mm.

The majority part of Serbia has a higher amount of continental precipitation during warmer times of the year. Precipitation usually occurs in June and May. 12-13% of total annual precipitation falls in June. The least amount of precipitation occurs in February and October with 5-6% of total annual precipitation. On the other hand, southwestern part of Serbia has Mediterranean precipitation regime based on relief, Mediterranean climate influence and mountain ranges' slopes and maximum precipitation occurs in November, December, and January while minimum precipitation occurs in August.

Data from the website of the Republic Hydro-meteorological Service of Serbia have been reviewed during the desktop study of the Sub-project:

6.4.3 Baseline Conditions

6.4.3.1.1 Temperature and Sunshine

Monthly average values of surface air temperature based on data collected for a period of 30 years (1981-2010) are provided in Table 6-4.

Table 6-4. Monthly climatological means for temperature and sunshine in Belgrade (based on 30 years of monitoring data between 19819-2010)

Temperature parameters	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	Oct	Nov	Dec
Mean temp. (°C)	1.4	3.1	7.6	12.9	18.1	21	23	22.7	18	12.9	7.1	2.7
Mean max. temp. (°C)	4.6	7	12.4	18	23.5	26.2	28.6	28.7	23.9	18.4	11.2	5.8
Mean low temp. (°C)	-1.1	-0.1	3.7	8.3	13	15.8	17.5	17.6	13.5	9	4.2	0.2
Max. recorded temp.(°C)	20.7	23.9	28.8	32.2	34.9	37.4	43.6	40	37.5	30.7	28.4	22.6
Min. recorded temp. (°C)	-18.2	-15.4	-12.4	-3.4	2.5	6.5	9.4	6.7	4.7	-4.5	-7.8	-13.4
Sunset in hours total (hrs)	72.2	101.7	153.2	188.1	242.2	260.9	290.8	274	204.3	163.1	97	64.5

The climatological annual mean temperature, annual mean maximum temperature and annual mean minimum temperature observed in Belgrade are 12.5 ºC, 17.4 ºC and 8.5 ºC, respectively. The minimum and maximum temperatures measured in the city during the last 30 years are -18.2 ºC in January and 43.6 ºC in July, respectively.

Average monthly temperature data at Belgrade Meteorology Station are presented at Figure 6-6. The average maximum monthly temperature and the average minimum monthly temperature are approximately 30 and -2 °C, respectively.

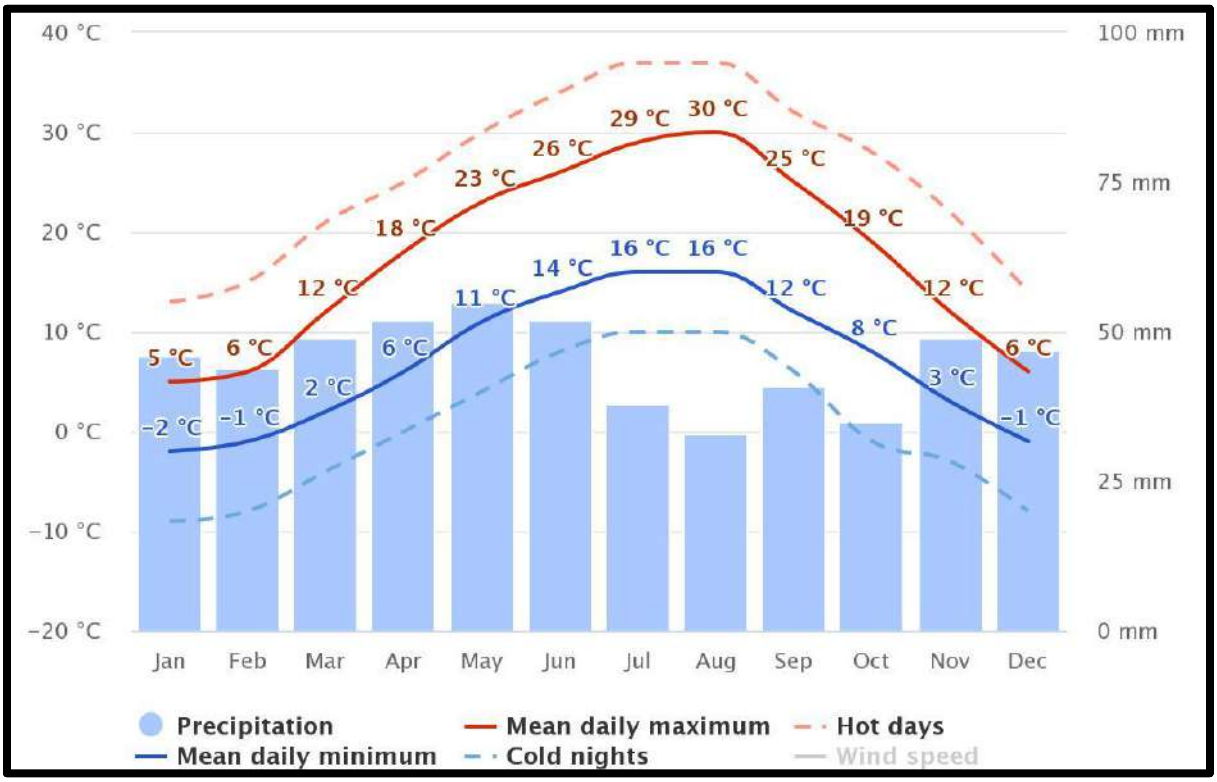


Figure 6-6. Average Daily Precipitation and Temperature

6.4.3.1.2 Precipitation

Depending on the atmospheric processes and relief characteristics of Serbia's territory, precipitation amount varies depending on the temperature and space. The general annual precipitation amount in the Country is 896 mm. The annual amount of precipitation increases with altitude. Annual precipitation over the Country ranges from 600 mm to 1,000 mm.

The majority part of Serbia has a higher amount of continental precipitation during warmer times of the year. Precipitation usually occurs in June and May. 12-13% of total annual precipitation falls in June. The least amount of precipitation occurs in February and October with 5-6% of total annual precipitation. On the other hand, southwestern part of Serbia has Mediterranean precipitation regime based on relief, Mediterranean climate influence and mountain ranges' slopes and maximum precipitation occurs in November, December, and January while minimum precipitation occurs in August.

Based on the meteorological data obtained from the Belgrade-Vračar meteorology station between 1981 and 2010, the highest climatological mean of monthly total precipitation is 101.2 mm for June, while the lowest climatological mean of monthly total precipitation is 40 mm for

February. The climatological mean of total annual precipitation is 690.0 mm, as calculated for 30-years period (see. Table 6-5).

Table 6-5. Precipitation climatology in Belgrade (based on 30 years of monitoring data between 1981 and 2010)

Precipitation parameters	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sep	Oct	Nov	Dec
Mean of total monthly precipitation (mm)	46.9	40	49.3	56.1	58	101.2	63	58.3	55.3	50.2	55.1	57.4
Maximum of total daily precipitation (mm)	33.2	39.1	36.8	64.2	56.4	94	80.1	75.6	41.9	43.7	51.8	39.9

6.4.3.1.3 Humidity

Based on the meteorological data obtained from the Belgrade-Vračar meteorology station for a period of 30 years (1981-2010), the climatological monthly mean of humidity in the region ranges from 61% to 79% in December (see. Table 6-6).

Table 6-6. Climatology for relative humidity and air pressure in Belgrade (based on 30 years of monitoring data between 1981-2010)

Humidity Parameter	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Relative humidity (%)	78	71	63	61	61	63	61	61	67	71	75	79

6.4.3.1.4 Wind Characteristics

The characteristic of Belgrade climate is the southeast-east wind. The average wind speed is 25-43 km/h, but certain strokes can reach up to 130 kmh.

6.4.4 Sensitive Receptors

Climate has a global feature and the **AoI** has been considered as sensitive receptor.

6.5 Air Quality

This section initially provides an overview of the air quality in Serbia. It then proceeds to provide more detailed information on the baseline conditions for air quality in the specific area where the Sub-project is located, after first specifying the methodology and data sources used for this purpose.

6.5.1 Study Area

There is no site-specific air quality data publicly available for the Sub-project Area nor any background air quality assessment has been conducted or provided by the Project Owner within the scope of the Sub-project. Therefore, to determine the current air quality within the AoI, PM measurements was carried out in the AoI of the Sub-project. For PM_{10} and $PM_{2.5}$

parameters, measurements were made at 2 different points, coordinates and map of the air quality measurement points are presented in the Table 6-7 and Figure 6-7, respectively and measurement report is given in Appendix F.

Table 6-7. Coordinates of the Air Quality Measurements

Measurement Location	X (WGS 1984 UTM Zone 34N)	Y (WGS 1984 UTM Zone 34N)
Measuring Point 1 PM_{10} and $PM_{2.5}$-1	459935	4954819
Measuring Point 2 PM_{10} and $PM_{2.5}$-2	460068	4954870

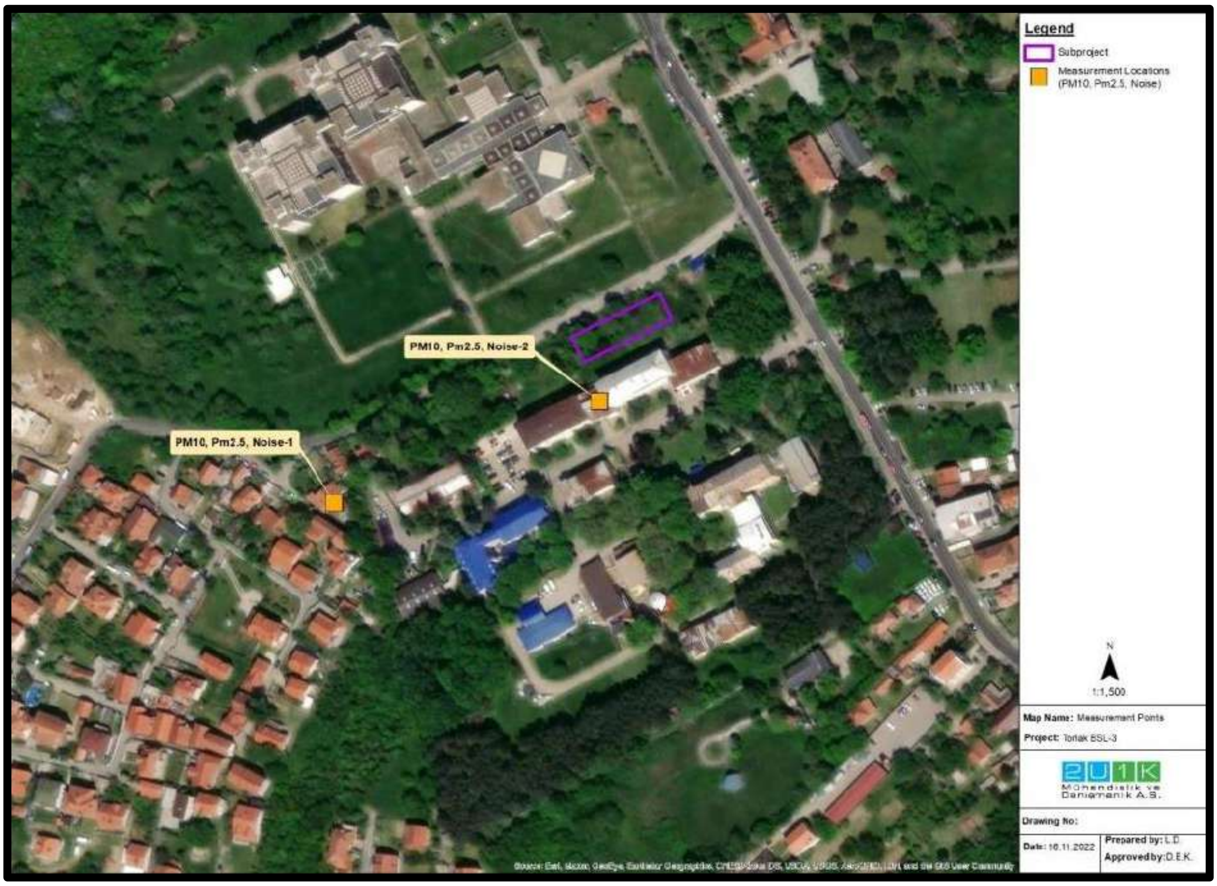


Figure 6-7. PM_{10} and $PM_{2.5}$ Measurement Points

6.5.2 Methodology and Data Source

Measurements were carried out by a laboratory with national and international competence (see Appendix-2 for certificate of competence). The measurements were conducted in line with Regulation on the Conditions for Monitoring and Air Quality Requirements (Official Gazette of RS, No. 11/10 and 75/10, Amend 63/13).

Measuring air quality to determine background concentrations of air pollutants is based on the usage of passive sampling equipment which is internationally acceptable technique based on EN ISO/IEC 17025:2005 standard.

Ambient air - Standard gravimetric measurement method is used for the determination of the PM10 and PM2.5 mass concentration of suspended particulate matter which is internationally acceptable technique based on EN 12341:2015 standard.

Following documents have been reviewed during the desktop study of the Sub-project as;

- WHO Global Air Quality Guidelines;
- Law on Air Protection ("Official Gazette of RS" No. 36/2009 and 10/2013);
- Regulation on the Conditions for Monitoring and Air Quality Requirements (Official Gazette of RS, No. 11/10 and 75/10, Amend 63/13).

6.5.3 Baseline Conditions

Overall, the air quality situation in Serbia has been a significant cause for concern, as evidenced by various measurement studies carried out for different purposes in the past. One such study was conducted in 2013, and its findings indicate that the air quality is harmful to human health due to the high levels of PM2.5 and PM10, which exceed the limits set by the EU and the World Health Organization (WHO) to protect health ((HEAL), 2014).

Serbian Environmental Protection Agency (SEPA) has operational air quality monitoring stations in the national network for air quality monitoring in the Republic of Serbia since 2006. According to articles 13 and 67 of Law on Air Protection, SEPA is mandated by law to use the national network to monitor and to publish an annual report on air quality in Serbia.

There are two continuous monitoring stations near to the Sub-project area, Belgrade Zeleno brdo monitoring station is 4.9 km to the northeast and Belgrade Vračar monitoring station is 5.9 km to the northwest of the Sub-project area. Information related to the monitoring stations are given in Table 6-8.

Table 6-8. Information on Air Quality Monitoring Stations[16]

Monitoring Station	Latitude (DMS)	Longitude (DMS)	Distance to the Project Area	Monitoring Parameters
Belgrade Vračar	44° 47' 49" N	20° 28' 31" E	5.9 km	SO_2, NO_2, O_3, CO, PM_{10}, $PM_{2.5}$
Belgrade Zeleno brdo	44° 47' 11" N	20° 31' 18" E	4.9 km	SO_2, NO_2, O_3, CO, PM_{10}, $PM_{2.5}$

According to data from monitoring stations managed by national authorities, air quality assessments indicate that levels of air pollutants, particularly PM, frequently exceed the levels

[16] http://www.amskv.sepa.gov.rs/index.php

that protect human health. The most recent estimation from the World Health Organization (WHO) indicates that the country has an annual mean concentration of $PM_{2.5}$ of 19.4 µg/m^3, with urban areas having a slightly higher concentration of 21.0 µg/m^3 compared to rural areas at 19.4 µg/m^3. These figures are significantly higher than the average annual mean concentration of $PM_{2.5}$ calculated by WHO for the European Region, which is 14.0 µg/m^3 ((WHO, 2019). According to WHO, 20% of deaths from stroke and ischaemic heart disease are caused by air pollution in Serbia (WHO - Serbia Health and Environment Scorecard, 2022).

Regarding the baseline air quality conditions in relation to the AoI of the Project, baseline air quality assessment for PM_{10} and $PM_{2.5}$ parameters was provided by using the results of the extensive air quality measurements conducted by 2U1K (see Appendix-F for air quality measurements report). Measurement results of the air quality tests for PM_{10} and $PM_{2.5}$ and comparison with limit value given in WHO Global Air Quality Guidelines are given in Table 6-9.

Table 6-9. Measurement Results for PM_{10} and $PM_{2.5}$ Parameters

Measuring Point	Parameter	Sampling Date	Result of Measurement (µg/m^3)	National Limit Value (µg/m^3)	WHO Global Air Quality Guidelines 2021 (µg/m^3)
Measuring Point 1 (PM10, PM2.5-1)	PM_{10}	December 7-8, 2022	29.6 ± 17%	50[17]	45
		December 8-9, 2022	33.9 ± 17%		
		December 9-10, 2022	39.2 ± 17%		
		December 10-11, 2022	29.1 ± 17%		
		December 11-12, 2022	30.4 ± 17%		
		December 12-13, 2022	49.2 ± 17%		
		December 13-14, 2022	38 ± 17%		
	$PM_{2.5}$	December 7-8, 2022	34.6 ± 17%	25[18]	15
		December 8-9, 2022	33.7 ± 17%		
		December 9-10, 2022	23 ± 17%		
		December 10-11, 2022	22.4 ± 17%		
		December 11-12, 2022	30.7 ± 17%		
		December 12-13, 2022	47.6 ± 17%		
		December 13-14, 2022	31.4 ± 17%		
Measuring Point 2 (PM10, PM2.5-2)	PM_{10}	December 14-15, 2022	23.5 ± 17%	50	45
		December 15-16, 2022	36.1 ± 17%		
		December 16-17, 2022	40.8 ± 17%		
		December 17-18, 2022	96 ± 17%		
		December 18-19, 2022	72 ± 17%		
		December 19-20, 2022	30 ± 17%		
		December 20-21, 2022	47.5 ± 17%		
	$PM_{2.5}$	December 14-15, 2022	24.4 ± 17%	25	15
		December 15-16, 2022	18.1 ± 17%		
		December 16-17, 2022	18.6 ± 17%		

[17] Limit value referring to the 1 - day averaging period
[18] Limit value referring to the calendar year averaging period

Measuring Point	Parameter	Sampling Date	Result of Measurement (µg/m^3)	National Limit Value (µg/m^3)	WHO Global Air Quality Guidelines 2021 (µg/m^3)
		December 17-18, 2022	31.6 ± 17%		
		December 18-19, 2022	51.7 ± 17%		
		December 19-20, 2022	38 ± 17%		
		December 20-21, 2022	65.7 ± 17%		

Comparing results of concentrations of suspended PM10 particles to the national limit value (Degree on monitoring conditions and air quality requirements, "Off. Gazette of RS" No. 11/2010, 75/2010 and 63/2013, Attachment X, Part B) can be concluded that at Measuring Point 1, the measured values of PM10 particles do not exceed the limit value and at Measuring Point 2, the measured values of PM10 particles exceed the limit value on 2 of 7 days.

For PM2.5 particles, no limit value was defined for the one - day averaging period. The above limit value refers to the averaging period for the calendar year. Comparing results of concentrations of PM2.5 particles with that limit values (Degree on monitoring conditions and air quality requirements, "Off. Gazette of RS" No. 11/2010, 75/2010 and 63/2013, Attachment X, Part B) can be concluded that at Measuring Point 1, measured values of PM2.5 particles exceed the limit value on 5 of 7 days and at Measuring Point 2, the measured values of PM2.5 particles exceed the limit value on 4 of 7 days.

6.5.4 Sensitive Receptors

Since the results of the measurements for PM2.5 exceed the limit values on both measuring points, both measurement locations within the AoI, are determined as sensitive receptors and the impact assessment will be carried out accordingly.

6.6 Noise

In this section, at first, the methodology and data sources used to write the baseline conditions is specified, and then background noise information about the area where the Sub-project is located is given more specifically.

6.6.1 Study Area

The existing noise level of the AoI was determined at the Sub-project Area and closest residential unit.

6.6.2 Methodology and Data Source

Definitions of basic acoustical terms and concepts related to the study are given below.

Sound: Sound is a vibrational disturbance, stimulating human aural sensory response, transmitted in a predictable manner determined by the medium through which it propagates.

To be audible, the disturbance must fall within the frequency range 20 Hz to 20,000 Hz. Sound levels are expressed in decibels (dB) on a logarithmic scale, where 0 dB is nominally the "threshold of hearing" and 120 dB is nominally the "threshold of pain".

Noise: Noise is typically defined as "unwanted sound".

Background (Baseline) noise: Prevailing noise in a specified environment measured in the absence of the noise being studied.

Decibels (dB): It is the unit describing the amplitude of the sound. The human hear responds to sound logarithmically. The bel is the logarithm of the ratio of the two powers and decibel is 1/10 bel.

Frequency: The measure of the rapidity of alterations of a periodic signal, expressed in cycles per second or Hz.

Sound pressure level (L_p): It is a logarithmic measure of the effective sound pressure of a sound relative to a reference value. It is measured in decibels (dB) above a standard reference level. The commonly used "zero" reference sound pressure in air is 20 µPa RMS (root mean square), which is usually considered the threshold of human hearing (at 1 kHz).

Sound power level (L_w): Ten times the logarithm of the ratio of the sound power under consideration of the standard reference power of 1 pW (10^{-6} W). The quantity obtained is expressed in decibels.

Equivalent Sound Level (Leq): Quantifies the noise environment as a single value of sound level for any desired duration. Leq correlates well with the effects of noise on people. Leq is also sometimes known as Average Sound Level.

L10: Sound pressure level that is exceeded 10% of the time of measurement.

L90: Sound pressure level that is exceeded 90% of the time of measurement.

A-Weighting: A-weighting is the most commonly used method of characterizing sound as it is experienced through human hearing. It provides a measure of sound pressure level designed to reflect the response of the human ear, which does not respond equally to all frequencies, by giving greater weight to the frequencies of sound to which the human ear is most sensitive. The resultant sound level is said to be A-weighted, and the units are in decibels (dBA).

C-Weighting: A measure of sound pressure level designed to reflect the response of the human ear, for higher levels above 100 dB when the human ear's response is flatter.

LAeq: A-weighted equivalent sound pressure level.

LAmax: The maximum A weighted sound pressure level detected in the measurement time domain.

LCeq: C weighted equivalent sound pressure level.

Point Source: A source of sound which is concentrated to a point.

Area Source: A source of sound which is distributed over an area.

Line Source: A source of sound emanating from a linear geometry.

Noise Barrier: A physical obstruction that is constructed between the highway noise source and the noise sensitive receptor(s) that lowers the noise level, including standalone noise walls, noise berms (earth or other material), and combination berm/wall systems.

Noise Berms: Noise barriers constructed from natural earthen materials such as soil, stone, rock, rubble, etc. in a natural, unsupported condition are termed, noise berms.

Noise Walls: Noise barrier systems that are manufactured according to a technical design and assembled on-site to obstruct the noise propagating from the noise source to receptors.

The threshold of perception of the human ear is approximately 3 dB and a 5 dB change is considered to be clearly noticeable to the ear. This is primarily due to the logarithmic measuring metric typically associated with decibels. The perceived change with regard to decibel levels is shown below:

Table 6-10. The perceived change with regard to decibel levels

Change in sound level	Perceived Change to the Human Ear
± 1 dB	Not perceptible
± 3 dB	Threshold of perception
± 5 dB	Clearly noticeable
± 10 dB	Twice as loud
± 20 dB	Four-fold change

Following documents have been reviewed during the desktop study of the Sub-project;

- Degree on noise indicators, limit values, methods for evaluating of noise indicators, disturbance and harmful effects of environmental noise (Official Gazette of RS, no. 75/10)
- WHO Noise Guideline.

In order to determine the current situation along the Sub-project Area, 24 hours of background noise measurements was carried out by Anahem at the Sub-project Area and closest residential unit which was determined as the sensitive receptor in close proximity to the noise sources of the Sub-project.

Instrument (Type I noise measurement instruments i.e., Brüel & Kjær model) was used for noise measurements. The equipment was calibrated by the technician before each measurement (see Appendix-F for noise measurements report).

Ambient noise sources such as traffic, human and animal sounds, natural events, etc. will be observed and recorded for the measurement. The noise measurement methodology is described below;

- Noise measurement locations was minimum 2 m away from reflective surfaces the buildings, walls, stone blocks, etc.
- The weather conditions observed by the measuring personnel were recorded for reporting and in case of rainfall or heavy storm/strong winds, measurements or the recorded results are cancelled.
- The measurement equipment automatically saves the measurements in its memory.

6.6.3 Baseline Conditions

In order to assess the contribution of the proposed Sub-project's effect on the sensitive receptors, background noise levels at the closest sensitive receptor have been measured. The background noise measurements were conducted at the Sub-project Area and closest residential unit. Coordinates and map of the measurement points are presented in the Table 6-11 and Figure 6-8, respectively.

Table 6-11. Coordinates of the Noise Measurements

Measurement Location	X (WGS 1984 UTM Zone 34N)	Y (WGS 1984 UTM Zone 34N)
MT-1 (Noise-1)	459935	4954819
MT-2 (Noise-2)	460068	4954870

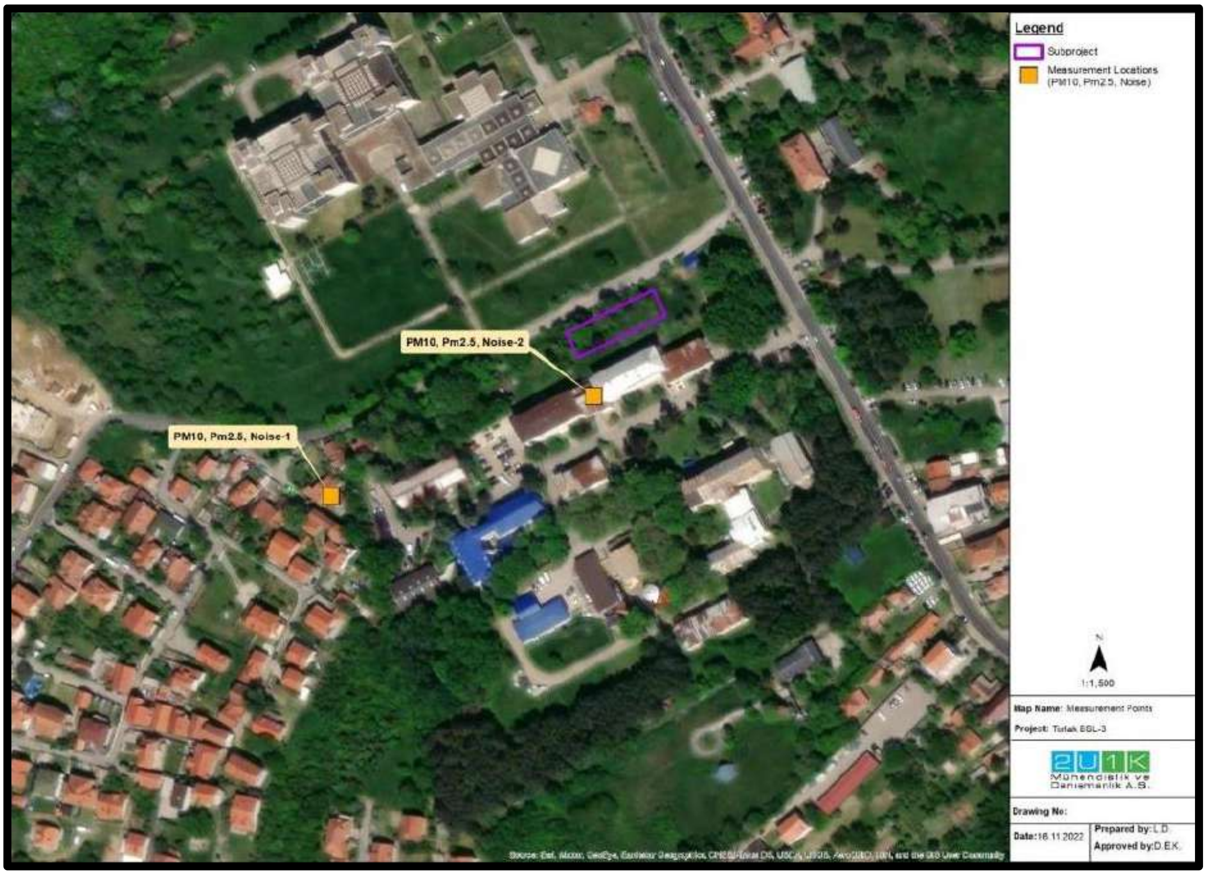


Figure 6-8. Noise Measurement Points

Noise survey was conducted per WB General EHS Guidelines for Noise. Daytime and night-time measurements were taken over one-hour intervals at each location.

The WB General EHS Guideline suggests that any increase in background noise levels should be limited to a maximum of 3 dBA where background noise levels already exceed WB guideline values.

The results of noise level measurements conducted within the scope of ESIA studies are provided in Table 6-12.

Table 6-12. Noise Measurement Results

Measurement Point	Date	Measurement Time Scale	Measurement Results (dBA)			National Limit Values and WHO Limit Value Residential Areas dB (A)
			L_{Req}	L90	LCmax	
MT-1 (Noise-1)	09.12.2022	Day	49	42.4	70.4	55
		Evening	45	41.6	63.3	
		Night	42	40.5	54.7	45
	10.12.2022	Day	47	41.1	71.8	55
		Evening	49	42.1	64.3	
		Night	44	40.0	65.7	45
MT-2 (Noise-2)	09.12.2022	Day	57	54.5	74.3	55
		Evening	57	54.0	76.8	
		Night	55	54.3	61.1	45
	10.12.2022	Day	56	53.4	71.5	55
		Evening	56	54.0	64.6	
		Night	55	53.3	64.0	45

Noise sources nearby Measurement Point 1 are transformer station and parking lot; and noise sources nearby Measurement Point 2 are gas vent, two ventilation outlets, cooling chiller and traffic in Vojvode Stepe Street.

As shown in Table 6-12, at Measurement Point 1, the measurement results do not exceed the limit values which is given according to WHO Noise Guideline and at Measurement Point 2, the measurements results are over the national and WHO Noise Guideline limits. In the Guideline and Degree, as shown in the table above, limit values are given as 55 dBA (daytime) and 45 dBA (nighttime) for residential areas.

6.6.4 Sensitive Receptors

Sensitive receptors were determined as the closest residential units to the Sub-project Area because locals who live in the close vicinity are the ones affected mostly from noise pollution, considering that the measurement results.

6.7 Hydrology and Hydrogeology

6.7.1 Methodology and Data Source

To conduct the hydrological and hydrogeological baseline assessment desktop studies were carried out. The desktop study involved the analysis of geological and hydrological data from published reports, maps, and databases.

6.7.2 Water Resources

The Sub-project site is located within the Mesozoic and Tertiary sedimentary rocks of the Dinarides geological unit. The area is characterized by complex geology, including multiple rock types with different permeability and porosity properties. The dominant aquifer in the Sub-project site is the karstic limestone aquifer, which is characterized by a high degree of heterogeneity and anisotropy. The aquifer is recharged by precipitation, and the water flow is controlled by the karstic features, such as sinkholes, springs, and underground rivers. The karstic aquifer is susceptible to contamination due to the rapid transport of pollutants through the interconnected network of conduits and fractures.

The main sources of water in the Sub-project site are groundwater and surface water. The groundwater resources are derived from the karstic limestone aquifer, which is the most productive and reliable aquifer in the area. The surface water resources are derived from the local streams, which are tributaries of the Sava River. The Sava River is the largest river in the region and is located approximately 5 km to the north of the Sub-project site. The river is an important source of water for domestic, agricultural, and industrial purposes.

The Sub-project Area is located within the boundaries of the Sava River Basin. The Sava River Basin (Figure 6-9) is a major drainage basin of South-eastern Europe with a total area of 97,713.20 km^2 and is one of the most significant sub-basins of the Danube River Basin, comprising 12 % of this basin.

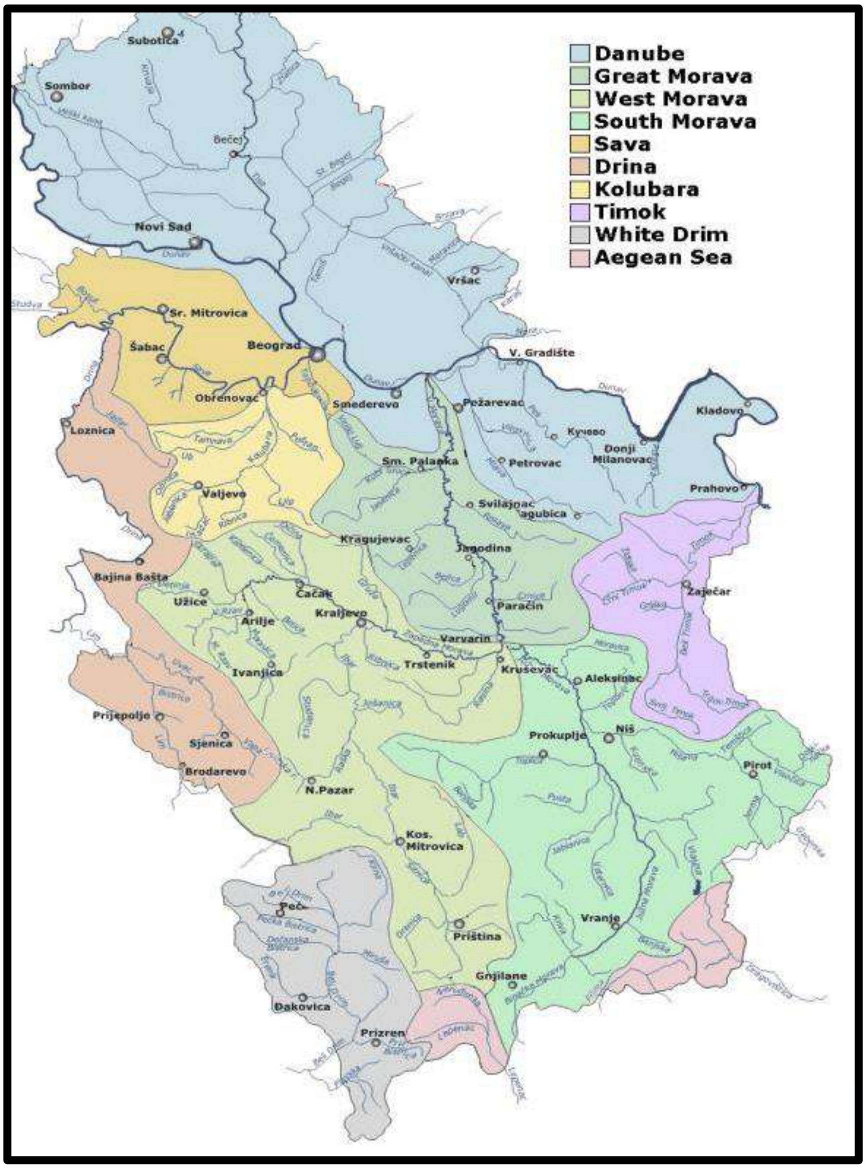


Figure 6-9. River Basins in Serbia (Sava River Basin Management Report, 2014)

As in 2005 the Serbia reported the following major water uses of Sava River:

- Thermal power plants
- Public water supply
- Agricultural water use (Irrigation and Fish farms)
- Industry

Groundwater is the main source of drinking water in the Sava River Basin and an important water supply source for industry and agriculture (80-95 % of water is used for this purpose) (Sava River Basin Management Report, 2014).

6.7.3 Surface and Groundwater Water Quality

There are two main categorization of the surface water bodies in Serbia. The first categorization is defined as Water Quality Classes and the second categorization is the type of surface water bodies. The parameters which define the class, and the type of the water body are presented in Appendix-4 of the Decree.

According to the Decree on Water Classification (Official Gazette of RoS, 05/68), all surface waters are classified between I, II, IIa, IIb, III and IV river class. This Decree provides division of waters into 4 main classes (i-IV, with IIa and IIb subclasses), according to the degree of pollution and purpose. Class I rivers are the best quality (could be used for drinking in natural condition or after disinfection) surface waters while class IV surface waters are the worst (could be used after special treatment).

Decree on Water Classification (Official Gazette of RoS, 05/68) adopted specific water quality characteristics to define four classes of surface water quality, and these are provided in the table below.

Table 6-13. Classes of Surface Water Quality

Class	Description
I	Water bodies that are in their natural state or after disinfection can be used or exploited for supplying settlements with potable water, food industry and for breading of some certain species of fish (salmonids).
II	Water bodies that are suitable for swimming, recreation, water sports and for breeding some certain species of fish (cyprinids) and waters which are subject to normal methods of processing, and which, after processing, can be used to supply settlements with potable water and the food industry.
III	Water bodies that can be used for irrigation and industry, except the food industry.
IV	Water bodies that can be used or exploited for other purposes only after special treatment.

According to the Decree on Water Classification, water quality classes of the Sava River is given in Table 6-14.

Table 6-14. Classification of Surface Water Bodies According to the Decree on the Categorization of Watercourses

RIVER NAME	QUALITY CLASS (Official Gazette of the SFRY, No. 5/68)
The Sava River	II b

In addition to this classification stated above, water bodies are divided into six (6) types. According to the Regulation on Parameters of Ecological and Chemical Status of Surface Waters and Parameters of Chemical and Quantitative Status of Groundwater (Official Gazette of RoS, No. 74/11), thresholds for ecological status and class limits for ecological potential of surface water are prescribed for six (6) types of waters, which are even more described through the Regulation on Determination of Surface and Groundwater Water Bodies (Official Gazette of RoS, No. 96/10). Types are valid only for Class I and Class II of surface watercourses due to the fact that excellent and good ecological status can only exist in these classes of watercourses.

The definitions of type classification are given below (The Republic of Serbia, 2015):

Table 6-15. Types of Surface Water Quality

Type	Description
1	Large lowland rivers dominated by fine sediments (the Danube River, the Sava River, the Great Morava River, the Tisza (Tisa or Tyza) River, the Tamiš River, the Begej River and the Stari Begej River):
2	Large rivers dominated by medium sediments, excluding rivers in the Pannonian Plain
3	Small and medium watercourses up to 500 m.s.l. (mean sea level) dominated by coarse sediments
4	Small and medium watercourses above 500 m.s.l. dominated by coarse sediments
5	Watercourses in the Pannonian Plain (excluding type 1 watercourses)
6	Small watercourses outside of the Pannonian Plain not included in other types and watercourses not included in the rulebook that regulates this area

According to the Rulebook on Parameters of Ecological and Chemical Status of Surface Waters, and Quantitative and Chemical Status of Ground Waters ("Official Gazette RS" No. 74/11), types of water bodies is given in Table 6-16;

Table 6-16. Type Classification of Main Water Bodies

RIVER NAME	QUALITY CLASS (Official Gazette of RoS, No. 74/11)
The Sava River	Type 1

Table 6-17. Limit Values of Pollutants in Wastewater Discharged

Parameter	Regulation on Limit Values of Pollutants in Wastewater Discharged into Water (Official Gazette of the Republic of Serbia, No. 13/2010)
pH	6.5-9.5
TDS	-
EC	-
Turbidity	<5
Nitrate	11
Phosphate	1
Cadmium	0.003
Chromium	0.05
Copper	1
Lead	0.01
Mercury	0.0001
Zinc	5
Total organic carbon	-

6.7.4 Wastewater Management

At present, urban wastewater from Belgrade is partially discharged into the Sava River and partially into the Danube River. It is apparent that a high proportion of urban wastewater in the Sava River Basin is discharged via the sewerage system into surface water without treatment.

The wastewater pollution load for the Sava River represents approximately 30-40% of the load generated from the central part of Belgrade. All discharge points on the Sava River are located near the confluence of the Sava and Danube (not more than 2 km or in the mixing zone) and therefore these discharges do not have a significant impact on the water quality of the upstream parts of the Sava River.

In the future, all urban wastewater from Belgrade will be treated at Veliko Selo WWTP and discharged into the Danube (Sava River Basin Management Report, 2014).

On the other hand, the Sub-project as BSL-3 laboratory is intended to be constructed as dry-lab. However, it has been stated by the project representatives liquid waste per day are expected to be approximately five (5) litres and chemical decontamination of liquid waste is foreseen during the operation phase of the Sub-project. Hence, there is no expected wastewater discharge to the receiving environment except for domestic wastewater. The ESIA report will include the disposal methods for the generated limited amount of liquid waste as well as the generated domestic wastewater.

6.7.5 Sensitive Receptors

The sensitive receptors in the Sub-project site include the karstic limestone aquifer, the local streams, and the Sava River. These water resources are important for domestic, agricultural, and industrial purposes and are also home to various aquatic species. The karstic aquifer is particularly sensitive to contamination due to its high permeability, which allows pollutants to rapidly travel through the subsurface. Therefore, it is important to ensure that the Sub-project activities do not have any adverse impacts on the water resources in the Sub-project site.

6.8 Waste Management

According to a report by the Serbian Environmental Protection Agency (SEPA) on waste management between 2011-2017, a total of 2.15 million metric tons of waste was generated, of which 1.80 million metric tons, or 83.7%, was collected by municipal public utilities. The median daily amount of municipal waste landfilled per capita was 0.84 kg, and the annual figure was 0.30 metric tons. This does not include some 20% of generated municipal waste which ends up in illegal dump sites. The Public Utility Company “Gradska čistoća” is the only provider of municipal solid waste services, e.g., collection, transportation, and disposal. The waste collection service of the company is organized in ten functional units located on correspondent municipality (Popović, Filipović, & Božanić, 2012).

On the other hand, on basis of data collected, it has been concluded that with a population of just over seven million, Serbia generates between 4,500 and 5,000 tons of infectious waste on an annual basis in the public healthcare sector. 20% of these quantities of infectious waste originated from the treatment of out-patients, 75% from the treatment of in-patients and 5% from micro-biological laboratory tests. The Institute for Public Health “Dr. Milan Jovanovic Batut” is collecting data on infectious waste generation and treatment from the Central Treatment Points (CTPs) and Local Treatment Points (LTPs). On the basis of these data approximate waste generation rates per out-patient visit, per bed day and per microbiological test can be determined. The data are presented in Table 6-18.

Table 6-18. Waste Generation Rates per out-patient visit, per bed day and per micro-biological test

Occurrence	Amount	Unit
Out-patient visit	0.01	kg/visit
Waste generation in Primary Healthcare Facility	12	kg/day
In patient treatment	0.26	kg/bed/day
Micro-biological test	0.004 to 0.4	kg/test
Waste Generation in micro-biology	From 250 to 14,000	kg per laboratory per year

As for the classification of medical waste management, according to the data of *the Waste Management in the Republic of Serbia in the period 2011-2020; Environmental Protection Agency, 2021*, medical waste management in Serbia is detailed in Table 6-19 and Table 6-20.

Table 6-19. Medical Waste of Category 18 01, Generated in The Period 2017-2020. year, (in tons)

Index Number	Description of Waste	2017	2018	2019	2020
18 01 01	Sharp instruments (excl. 18 01 03)	154.98	150.82	152.69	160.29
18 01 02	Body parts and organs including blood bags and blood products (excl. 18 01 03)	44.17	42.49	49.5	42.42
18 01 03*	Waste whose collection and disposal is subject to special requirements to prevent infection	2,641.11	2,993.23	2,868.35	3,181.30
18 01 04	Waste whose collection and disposal is not subject to special requirements to prevent infection	38.69	39.16	68.02	59.26
18 01 06*	Chemicals consisting of or containing hazardous substances	19.03	19.98	20.5	14.94
18 01 08*	Cytotoxic and cytostatic drugs	31.44	40.27	57.3	43.36
18 01 09	Medicines other than those mentioned in 18 01 08	9.15	7.3	9.36	7.38
18 01 10*	Waste amalgam from dentistry	0.03	0.07	0	0
	TOTAL 18 01	**2,938.58**	**3,293.32**	**3,225.73**	**3,509.45**

Table 6-20. Medical Waste Treated in 2020

Index Number	Description of Waste	Quantity of waste treated (tons)
18 01 01	Sharp instruments (excl. 18 01 03)	64.95
18 01 02	Body parts and organs including blood bags and blood products (excl. 18 01 03)	2.82
18 01 03*	Waste whose collection and disposal is subject to special requirements to prevent infection	3,377.69
18 01 04	Waste whose collection and disposal is not subject to special requirements to prevent infection	21.9

Index Number	Description of Waste	Quantity of waste treated (tons)
18 01 08*	Cytotoxic and cytostatic drugs	0.63
18 01 09	Medicines other than those mentioned in 18 01 08	23.78
18 02 02*	Waste the collection and disposal of which is subject to special requirements to prevent infection	17.9
	TOTAL	**3,509.67**

The existing facility as Torlak institute has an in-house developed “Waste Materials and Waste Management Policy” for the waste management in line with Serbian legislation. The concerned policy is defined including waste management plan for wastes with or without special treatment (waste material handling, storage and finally care), who is responsible for waste management and her/his duties. These wastes are as follows.

Wastes without special treatment

- Municipal waste: disposed of in garbage containers without any special treatment.
- Recycable waste: paper, glass, plastic, metals, electronic waste, etc.

Wastes with special treatment

- Chemical waste: chemicals that have expired or are not approved for use, oils and lubricants, substances that can be harmful to human health and the environment.
- Medical waste: used needles, syringes, cotton wool, gauze, microbiological substrates and the like. Medical waste also includes:
  - Biological waste: dead or sacrificed animals, body and tissue parts, tissue samples, secretions and excreta, blood products that cannot be used, etc.
  - Pharmaceutical waste: Pharmaceutical waste - live and inactivated vaccines, serums and expired medicines expired or otherwise unusable, etc.
- Technical waste: generated during the work of the service for technical and other similar tasks. It includes waste generated during construction or demolition too.

Detailed information on how and where wastes including medical, hazardous, and toxic wastes in the existing facility are disposed are provided in Chapter 7 of the ESIA report. On the other hand, the Sub-project as BSL-3 laboratory is intended to be constructed as dry-lab. All the laboratory consumables are planned to be for single use. Solid waste per day is expected to be 20 kg and decontamination of solid waste is planned to be on site by autoclaving during the operation phase of the Sub-project.

In this context, in Serbia health care and other institutions are responsible for medical waste management. Medical and pharmaceutical waste is subject to a separate system of separate collection. This system has been established in all healthcare institutions in the Republic of Serbia. Producers are obliged to either treat the waste themselves in accordance with the applicable legal provisions, or to conclude a contract with the operator of the plant for the treatment of this waste. The medical waste generated at the Sub-project will be autoclaved and sent to a licenced landfill after sterilization according to the national legislation. There are 11 sanitary and 138 unsanitary landfill areas in Serbia. Also in 2021, a sanitary landfill named "Beocista Energija" in Belgrad started operating according to EU Directives.

6.9 Resource Efficiency

The construction materials will be provided from close vicinity of the Sub-project Area. There will be no need for borrowing pits/quarries within the scope of the Sub-project since the need will be met by the existing licensed quarries in the region.

Worker accommodation area will not be established at any phase of the Sub-project. However, if a worker accommodation area or container is constructed for the Sub-project, it will meet the standards for worker accommodation prepared by International Finance Corporation (IFC) and approved by the WB[19]. Since the Sub-project Area is accessible through the existing road, construction of any access/service road is not required. All equipment and machines expected to be used for the construction and operation phases of the Sub-project will be provided from the existing roads and off-peak hours will be preferred by prioritizing the main road route.

In this respect, as the impacts on resource efficiency of the Sub-project during both phases of the Sub-project is anticipated to be negligible, it is omitted in the concerned impact assessment section of this ESIA report.

6.10 Biodiversity

Biological environment was investigated which included habitat structures of the AoI, Nationally Protected Areas, and Internationally Recognized Areas (such as Key Biodiversity Areas). For this purpose, desktop studies and field surveys were carried out. Also, site visits were conducted on 07.12.2022 and 14.12.2022.

6.10.1 Study Area

The Sub-project is located on the southern edge of Belgrade. The moderate continental climate is dominant in the Sub-project area, which is located in the South-eastern Europe, on the Balkan Peninsula, at the crossroads of Eastern and Western Europe.

Due to the intense anthropogenic impact observed in the Sub-project area, the distribution of flora and fauna is highly suppressed. The flora and fauna species that can be observed in the area comprise cosmopolitan species that have adapted themselves to the conditions of the settlement area. In terms of flora species, especially the cultural species are distributed. On the other hand, the fauna distributed in the Sub-project area consists of species that are highly tolerant of the effects of settlements, such as intense human presence and noise. General view of the Sub-project Area is shown in Figure 6-10 and Figure 6-11.

[19] https://documents1.worldbank.org/curated/en/604561468170043490/pdf/602530WP0worke10Box358316B01PUBLIC1.pdf

Figure 6-10. General View of The Sub-Project Area-1

Figure 6-11. General View of The Sub-Project Area-2

6.10.2 Methodology and Data Source

Methodology was determined and fieldwork was performed by local field team consisting of Milos Zbillijic (Botanist), Stefan Skorić (Fauna Expert) and Aleksa Vukicevic (Ornithologist). In addition, literature research was also carried out by Celal Denizli (Biologist) and Şevval Kurt (Biologist).

The information gathered included data on the followings:

- Biological components on terrestrial environment,
  - Terrestrial habitats and ecosystems
  - Terrestrial flora and ecosystems,
    - Flora species
  - Terrestrial fauna components
    - Amphibians and reptiles,
    - Aves,
    - Mammals,
- Key biodiversity areas,
- Important Bird Areas,
- Important Wetlands (Ramsar Sites),
- Potential sensitive areas.

The methodology to determine the baseline conditions included the following:

- Review of pertinent literature and previous works.
- Field studies carried out in the Sub-project Area.
- Satellite image interpretation, as available.
- Communication with the inhabitants in the study area during the field studies.

The data review included an extensive review of published scientific literature, websites and other sources. General aspects of the baseline studies are provided below:

I. Within the scope of the field studies, a review of the existing information was undertaken and ecological composition of the Sub-project area in terms of terrestrial flora and fauna elements; potential sensitive areas and sensitive species were identified.

II. Distribution, population, ecology and reproductive biology of the threatened and endemic plant species that are likely to occur within study area of interest were studied. The literature surveys were intended to give information on identification of endemic, endangered, and rare species and species defined under the national and international conservation status. Accordingly, species that are under the risk of being affected due to the Sub-project and therefore, require special attention and protection measures were determined.

III. A species inventory for the baseline conditions are established as well as description of the habitats, having been recorded in a systematic way. Also, Endemic, restricted-range, CR, EN and VU category flora and fauna species were determined as the target species within the scope of the study.

6.10.2.1 Terrestrial Flora and Ecosystems

In this section, terrestrial flora and ecosystem structures and habitat features were identified at the AoI. Within the scope of the terrestrial flora studies, the flora and vegetation types within the study area were identified to serve as a basis for determination of the impacts of the Sub-project on biological resources and to develop appropriate mitigation measures, where necessary. The aim of the baseline studies for terrestrial flora species and vegetations were to collect data throughout the field surveys for explanation of the environmental conditions of in the study area through selected sensitivity elements. In this context, floristic studies were conducted including both desktop and field studies to determine the baseline conditions in the study area.

The objectives of the desktop study were to review and organize the existing information on terrestrial flora, habitats and ecosystems within the study area. Terrestrial flora studies were carried out light on the following key baseline issues:

- Determining the species of terrestrial flora present in the AoI, their distribution and conservation status (such as critically endangered species, endangered species, as well as any endemic species),
- Defining natural and critical terrestrial habitats and ecosystems present in the AoI, their distribution and the list of species associated to each habitat.

The baseline data/information collection provide an overall picture of the conditions and sensitivities in the areas that were considered in assessment of potential impacts and development of relevant mitigation measures for design, construction, and operation phases of the Sub-project. Terrestrial flora and ecosystem studies were investigated in the following two parts:

- Terrestrial habitats and ecosystems,
- Terrestrial flora.

Terrestrial Habitats and Ecosystems

Terrestrial habitats within baseline study area are categorized as modified, natural or critical habitats, as the definition of critical habitats is dependent on the presence of endemic, threatened, restricted-range species. As a result, distribution of the endemic, threatened, restricted-range species and EUNIS habitat distribution within the Sub-project Area were obtained and mapped.

The habitat classification is completed following the EUNIS habitat type classification, a comprehensive pan-European system that facilitates the harmonized description and collection of data across Europe, through the use of habitat identification criteria. The preliminary habitat distribution in the study area is determined based on EUNIS habitat classification. A variety of habitat types were determined by analyzing appropriate satellite imagery and aerial photos (most of the territory of the Republic of Serbia is covered by satellite imagery available through Google Earth). Since there are different habitat types within the study area, the EUNIS habitat classification is used to determine the number of different habitat types.

The habitats within the Sub-project Area determined with desktop studies according to EUNIS Habitat Classifications used satellite imagery. After the field studies, habitat types were verified by expert observations.

Terrestrial Flora

Sampling points were selected by the Sub-project botanist in different habitats during the field study. The best sampling points were selected using a varied array of datasets such as topographical maps and satellite images. At these selected sampling points, the existing plant types have been identified. The dominant plant species were identified by taking photographs of the sampling points studied.

The coordinates of the sampling point were taken according to UTM, the general photograph of habitat, and the pictures of the plants in the study area were taken. During the field study, data were generated for the report stage by taking notes according to the characteristics of the sampling points studied.

6.10.2.2 Terrestrial Fauna

The main objectives of fauna studies are i) to identify the fauna elements (amphibians, reptiles, birds and mammals) of the study area, ii) to define the habitats that these fauna elements inhabit, and iii) to make evaluations on faunal and ecological characteristics of the study area. During the terrestrial fauna field studies, two different experts investigated and reported each fauna groups as amphibian-reptiles, birds and mammals.

Beside these above stated main goals, objectives of the terrestrial fauna survey within the study area can be described as follows;

- To determine the characteristics and importance of the AoI in terms of terrestrial fauna species,
- To determine the important and sensitive habitats and critical fauna species,
- To determine the protection status of the fauna species according to national and international conventions, decisions, and requirements.
- To determine population densities of these species according to project sub-areas,

Fauna studies include mammals (Mammalia), birds (Aves), reptiles (Reptilia) and amphibian (Amphibia) groups.

Habitats at each point determined during the field study were examined in detail, species of fauna were recorded. The species list where fauna species are given was prepared according to the observations during the survey.

The species lists were systematically prepared based on the names of the order, family species names. Common names of species, hazard and protection categories in IUCN, Bern Convention, CITES and nationally protected species are also given in detail in the tables.

- Direct observation was made in determining the species, as well as traces and signs (nests, nestlings and tracks of species, excrete and food wastes; horn and bone remains, feathers, pellets, etc.) of suitable fauna species.
- No hunting-gathering-killing was done during the identification of species in the area during field work in line with ethical rule. Observations made directly (using advanced optical instruments) have been utilized for species identification of fauna species.
- For the identification of fauna species in the identification of fauna elements, no trapping by using nets or other kind of trapping was used.
- Manual bat detector (Echo Meter Touch 2 Pro) was utilized to detect the bat species at the Sub-project site.
- Maps and satellite images have been used for field studies.

Methodologies applied for each fauna class during the faunal studies are summarized below.

Amphibians and Reptiles

A detailed literature study was conducted to present potential amphibian and reptile species at the AoI. In line with this literature research, before the start of field study, expert determined the general habitat types in the area by evaluating the habitats in terms of seasonality and depending on the habitat types and season of the field survey, amphibians and reptiles likely to be present in each habitat type was identified. In this respect, field studies regarding amphibian species (salamanders and frogs), have been carried out at suitable habitats for these species. These field survey locations comprise suitable areas for feeding, sheltering and breeding of the amphibians.

During the field survey, underneath the plants and rocks, which are the potential locations for nests, tadpoles and adult individuals of salamanders and frogs, were checked. Individuals were identified through direct observation or caught with a net and released back after being identified and photographed.

Habitat-based assessment was also used to identify the filed study locations. In this respect, field studies on reptiles mainly were mainly focused on rocky part of the habitats and tree hollows. These areas were searched for nests, eggs, and adult individuals of reptiles. As part of the amphibian field survey methodology, underneath of the plants and rocks at the Sub-project site were checked, and individuals were identified through direct observation or caught by catcher sticks and released back after being identified and photographed.

Birds

A detailed literature study was conducted to present potential bird species at the AoI. As a result of the literature survey, suitable habitats for the bird species in the AoI were identified as field survey locations. Field survey locations were studied in terms of potentiality for presence of nests, offspring, and adult individuals. Observed individuals were photographed whenever possible. All identified birds seen or heard were recorded.

The transects are already clustered into four groups according to general habitats. Moreover, at each transect the habitats were recorded to make a habitat specific analysis of bird communities.

Mammals

A detailed literature study was conducted to present potential mammal species at the AoI.

In each survey locations for bat species, all cracks, space between wooden beams and any other hole that could potentially be a roost for bats were inspected. During the inspection, a flashlight was used, as well as a manual bat detector (Echo Meter Touch 2 Pro). Also, an inspection of the floors in the attics was carried out to determine the existence of bat droppings as an indirect indicator of their presence. For identification of small mammals’ baits and burrows were used.

6.10.3 Nationally Protected Areas and Internationally Recognized Areas in and around the Sub-Project Area

The map showing the national protected areas and internationally recognized areas in the Sub-project area, or its immediate surroundings is given in Figure 6-12. International recognized areas investigated as KBA (Key Biodiversity Area), IBA (Important Bird Area) and AZE (the Alliance for Zero Extinction).

Serbia’s KBAs have been identified on a national scale by Institute for Nature Conservation of Serbia.

The Sub-project Area does not include Nationally Protected Areas and Internationally Recognized Areas of high biodiversity value, such as World Heritage Natural Sites, Biosphere Reserves, Ramsar Wetlands of International Importance, Important Bird Areas, and Alliance for Zero Extinction Sites. Neither of these areas is located in the AoI. The area to be Torlak Institute BSL-3 Subproject is relatively poor in terms of biodiversity. Therefore, the Sub-project area is not considered to reflect the characteristics of the protected areas in the environment.

The closest protected area to the Sub-project area is the "Bajfordova Suma Natural Monument", which is approximately 2 km away by bird flight. The distances of protected areas to the Sub-project Area are given in the Table 6-21 and Figure 6-12.

Table 6-21. Nationally Protected Areas

Nationally Protected Area	Distance
Bajfordova Suma Natural Monument	2 km
Miljakovacka Suma Natural Monument	2.5 km
Suma Kosutnjak Natural Monument	3.9 km
Avala Landscape of Outstanding Qualities	4.9 km

Bajfordova Suma Natural Monument is 2.3 km long, up to 300 m wide. It covers an area of 39,61 hectares. Most common trees are pedunculate oak, red maple, silver maple and boxelder maple. The common birds are nightingale, blackcap, great_tit, magpie, woodpigeon and great spotted woodpecker. Mammals include hedgehog, moles, shrews, bats, the local brown subspecies of the red squirrel and least weasel.

Miljakovacka Suma is a protected natural monument since 2010. 105 plant species were recorded in the forest, such as rose, cherry, licorice, plane tree, ash, elm, linden, red and white hawthorn and cranberry. There are several insect species on the world list of endangered species found in this forest.

Suma Kosutnjak Natural Monument is declared protected due to significant spatial functions and bioecological values of the complex under forest vegetation and to preserve the habitat of diverse fauna of mammals, birds, insects, reptiles and amphibians, as well as signs of geological discovery.

Avala Landscape of Outstanding Qualities is extremely rich in vegetation and floristic elements. A large number of plant species, such as *Laburnum anagyroides* Medik., *Lilium martagon* L., *Prunus laurocerasus* L. and others are protected as natural rarities. Numerous bird species occur in oak, premontane and beech forests. The most important are *Falco tinnunculus, Strix aluco, Otus scops*, *Sitta europaea, Buteo buteo* and others. Of the total Avala flora, 15% are recognized and known medicinal plants.

There is an Internationally Recognized Area 8 km away from the Sub-project area named as *Usce* Save u Dunav Key Biodiversity Area (KBA) (Figure 6-12). Key Biodiversity Areas (KBAs) are the most significant areas considering their characteristics in terms of supporting biological components.

Usce Save u Dunav KBA, comprises of 10 km of the Sava River and 39 km of the Danube within the cities of Belgrade and Pančevo. It connects several vast flood areas (Beljarica, Kožara, Veliko i Malo Ratno ostrvo) as well as river islands (Forkontumac, Čakljanac, Štefanac etc). An important part of the area is also the car fishpond "Mika Alas". The bordering forest are mainly comprised of industrial poplar species, with some patches of natural riparian forests.

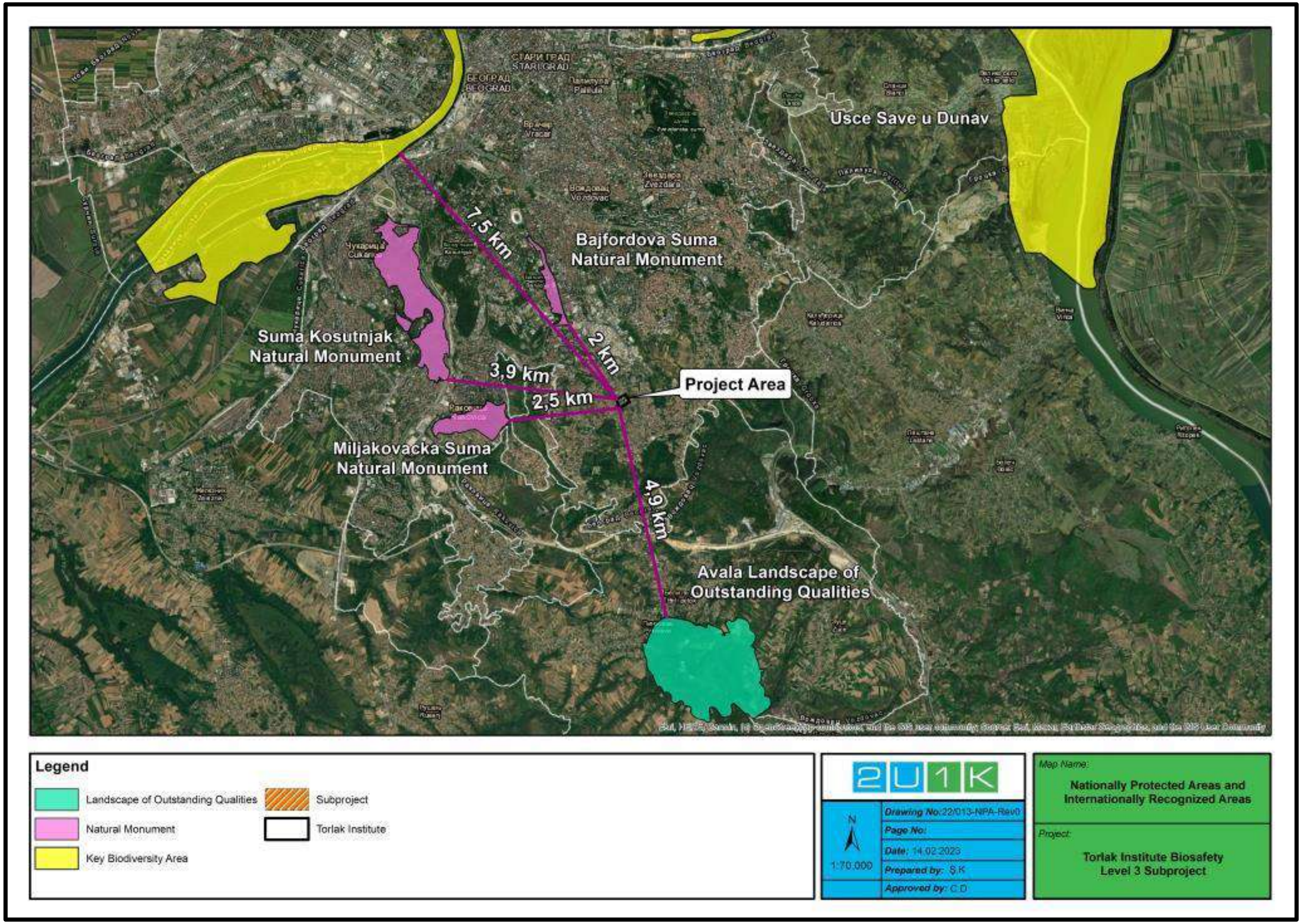


Figure 6-12. Nationally Protected Areas and Internationally Recognized Areas

6.10.4 Baseline Condition

6.10.4.1 Habitats

All components of the Sub-project cover poor vegetation features and modified habitat. Flora species of these habitats are widespread and adapted to human pressure. Habitat types of the Sub-project area are described as follow:

In the field study conducted 07.12.2022 and 14.12.2022, According to European Nature Information System (EUNIS) a total of 7 different habitat types have been determined in the Sub-project area and surroundings. All the habitats determined in the Sub-project area are modified. The descriptions of habitat and vegetation found in this area are given in Table 6-22.

Table 6-22. List of EUNIS Habitat Types

Habitat Code	Habitat Type
FB	Shrub plantations
G1.C	Highly artificial broadleaved deciduous forestry plantations
G3.F	Highly artificial coniferous plantations
G5.2	Small broadleaved deciduous anthropogenic woodlands
I2.2	Small-scale ornamental and domestic garden areas
J1.2	Residential buildings of villages and urban peripheries
J1.3	Urban and suburban public buildings

I2.2 Small-scale ornamental and domestic garden areas: Cultivated areas of ornamental gardens and small parks beside houses or in city squares. This habitat covers the Sub-project area and contains ruderal species (see. Figure 6-13).

Figure 6-13. I2.2 Small-scale ornamental and domestic garden areas

FB Shrub plantations: Plantations of dwarf trees, shrubs, espaliers or perennial woody climbers, mostly cultivated for fruit or flower production, either intended to have permanent cover of woody plants when mature, or else for wood or small tree production with a regular whole-plant harvesting regime. The fenced area occupied with shrub vegetation close to Torlak Institute (see. Figure 6-14).

Figure 6-14. FB Shrub plantations

G1.C Highly artificial broadleaved deciduous forestry plantations: Cultivated deciduous broad-leaved tree formations planted for the production of wood, composed of exotic species, of native species out of their natural range, or of native species planted in clearly unnatural stands, often as monocultures. There are linden trees in the Sub-project area part of this habitat (see. Figure 6-15).

Figure 6-15. G1.C Highly artificial broadleaved deciduous forestry plantations

G5.2: Small broadleaved deciduous anthropogenic woodland: Plantations and small intensively-managed woods of deciduous broadleaved trees less than about 0.5 ha in area. There are oaks and maples in the Sub-project area part of this habitat (see. Figure 6-16).

Figure 6-16. G5.2 Small broadleaved deciduous anthropogenic woodland

G3.F: Highly artificial coniferous plantations: Plantations of exotic conifers or of European conifers out of their natural range, or of native species planted in clearly unnatural stands, typically as monocultures in situations where other species would naturally dominate. There are pines in the Sub-project area part of this habitat (see. Figure 6-17).

Figure 6-17. G3.F Highly artificial coniferous plantations

J1.2: Residental buildings of villages and urban peripheries: It consists of residential buildings in suburbs and villages occupied by buildings and other impermeable surfaces. This habitat covers most of the surroundings.

J1.3: Urban and suburban public buildings: Buildings with public access, such as hospitals, schools, churches, cinemas, government buildings, shopping complexes and other places of public resort. This habitat covers most of the study area and its surroundings.

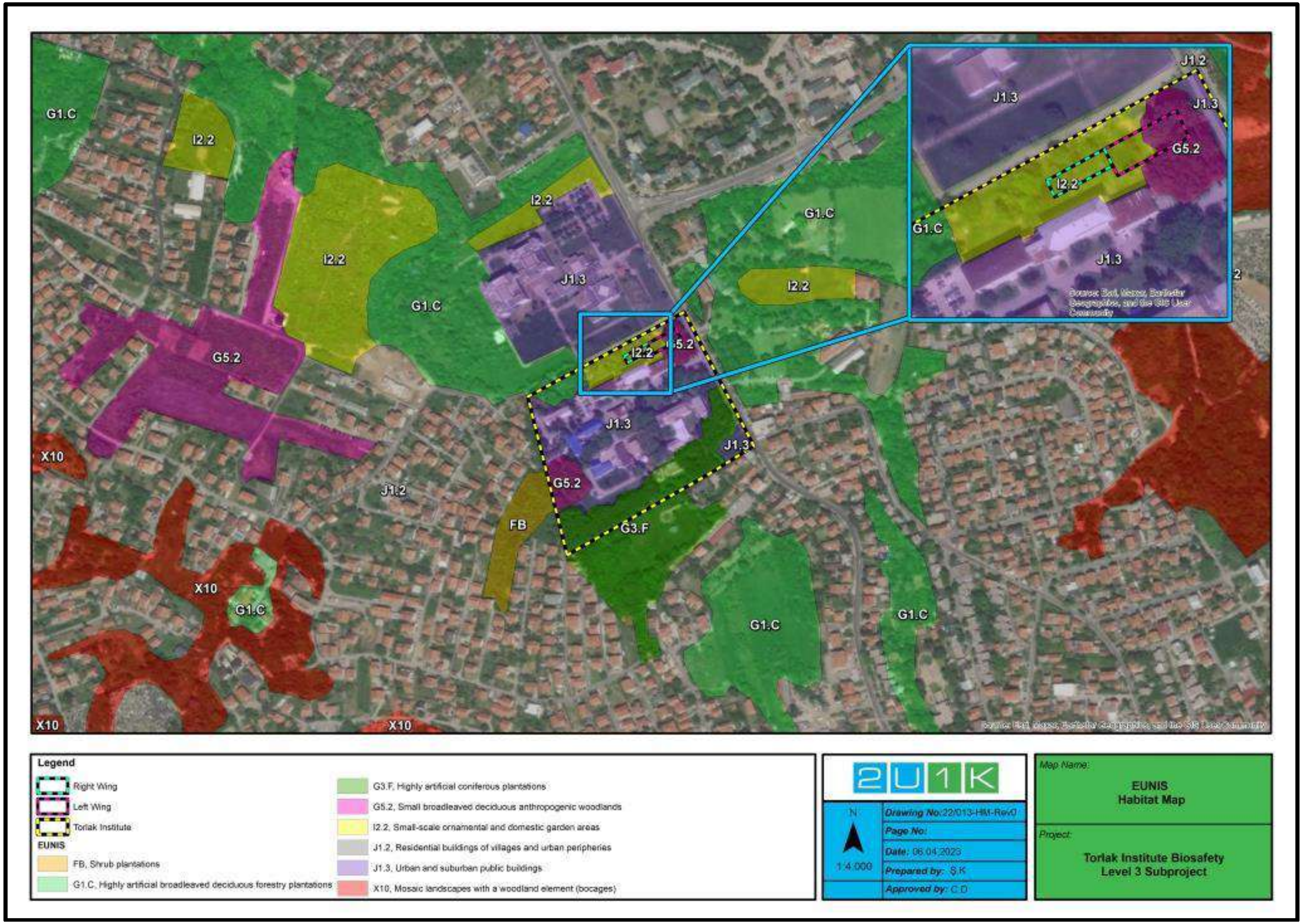


Figure 6-18. Habitats in the Sub-Project Area

6.10.4.2 Flora

Field studies on the Sub-project area were carried out on 07.12.2022 by botanist Miloš Zbiljić. The habitats at each point determined during the field studies were examined in detail and the field notes were recorded in the field book. The habitat-based species in the floristic list were prepared based on the findings obtained during the field study.

A total of 77 species were recorded within the study area. 58 of them were directly identified during the fieldwork carried out at the Sub-project site. None of the species found are threatened or endemic. The recorded flora is typical of anthropogenic habitats such as parks or gardens. A certain number of species do not represent native flora but are cultivated species (e. g. *Mahonia aquifolium, Thuja occidentalis, Pinus sylvestris*). Several highly invasive non-native species, such as *Robinia pseudoacacia, Erigeron annus, Erigeron canadensis*, and *Datura inoxia*, were found within the area of observation.

Within the research area, no natural habitats or vegetation are protected by national or European legislation. Settlements start about 125 m from the Sub-project area and the anthropogenic effect is dominant therefore vegetation of close vicinity of the area has poor vegetation. Ruderal areas are dominant in the area.

A summary table of the conservation status of the flora species identified within the scope of the Sub-project is given in Table 6-23.

Table 6-23. Conservation Status of Flora Species

IUCN							BERN Annexes	CITES Annexes			Habitat Directive Annexes			National Regulation Annexes	
CR	EN	VU	NT	LC	DD	NE	I	I	II	III	II	IV	V	I	II
				31	3		1	1						1	7

Species found or possible to be found in the Sub-project area are listed in the Table 6-24.

Table 6-24. Flora species found and possible to be found in the Sub-project area

	Scientific Name	Common Name	IUCN	BERN	CITES	EU Habitat Directive	National Regulation*	Source**
1	*Abies alba*	Silver Fir	LC	-	-	-		O
2	*Acer platanoides*	Norway Maple	LC	-	-	-		O
3	*Acer pseudoplatanus*	Sycamore Maple	LC	-	-	-		O
4	*Achillea millefolium*	Yarrow	LC	-	-	-	Ann-II	O
5	*Aegilops cylindrica*	Jointed Goat Grass	LC	-	-	-		L
6	*Aegilops neglecta*	Three-awn Goat Grass	-	-	-	-		L
7	*Agrimonia eupatoria*	Agrimony	-	-	-	-		O
8	*Agrostis stolonifera*	Creeping Bentgrass	LC	-	-	-		L
9	*Artemisia vulgaris*	Mugwort	-	-	-	-		O
10	*Ballota nigra*	Black Horehound	-	-	-	-		O
11	*Beckmannia eruciformis*	European Slough-grass	LC	-	-	-	Ann-II	L
12	*Bellis perennis*	Common Daisy	-	-	-	-		O
13	*Betula pendula*	Silver Birch	LC	-	-	-	Ann-II	O
14	*Brachiaria eruciformis*	Giavone Sottile	LC	-	-	-		L
15	*Celtis occidentalis*	Common Hackberry	LC	-	-	-		O
16	*Cirsium acaule*	Dwarf Thistle	-	-	-	-		O
17	*Cirsium arvense*	Canada Thistle	-	-	-	-		O
18	*Clematis vitalba*	Old Man's Beard	-	-	-	-		O
19	*Convolvulus arvensis*	The Field Bindweed	-	-	-	-		O
20	*Dactylis glomerata*	Orchard Grass	-	-	-	-		O
21	*Datura innoxia*	Downy Thorn-appl	-	-	-	-		O
22	*Daucus carota*	Wild Carrot	LC	-	-	-		O
23	*Erigeron annuus*	Eastern Daisy Fleabane	-	-	-	-		O
24	*Erigeron canadensis*	Horseweed	-	-	-	-		O
25	*Fraxinus excelsior*	European Ash	-	-	-	-		L
26	*Galeopsis segetum*	Downy Hemp-nettle	DD	-	-	-		L

	Scientific Name	Common Name	IUCN	BERN	CITES	EU Habitat Directive	National Regulation*	Source**
27	*Galium aparine*	Catchweed Bedstraw	-	-	-	-		O
28	*Geranium molle*	Dove's Foot Geranium	-	-	-	-		O
29	*Glechoma hirsuta*	-	-	-	-	-		O
30	*Gymnadenia odoratissima*	Short Spurred Fragrant Orchid	LC	-	App-II	-	Ann-II	L
31	*Hedera helix*	English Ivy	-	-	-	-		O
32	*Helminthotheca echioides*	Bristly Ox-tongue	-	-	-	-		O
33	*Humulus lupulus*	Common Hop	-	-	-	-		O
34	*Juglans regia*	Common Walnut	-	-	-	-		O
35	*Mahonia aquifolium*	Oregon Grape	-	-	-	-		O
36	*Medicago sativa*	Alfalfa	LC	-	-	-		L
37	*Medicago truncatula*	Barrel Clover	LC	-	-	-		L
38	*Onobrychis viciifolia*	Sainfoin	LC	-	-	-		L
39	*Persicaria maculosa*	Redshank	LC	-	-	-		L
40	*Picea abies*	Norway Spruce	LC	-	-	-		O
41	*Picris hieracioides*	Hawkweed Oxtongue	-	-	-	-		O
42	*Pinus nigra*	Austrian Pine	LC	-	-	-		O
43	*Pinus sylvestris*	Scots Pine	LC	-	-	-		O
44	*Plantago lanceolata*	Ribwort Plantain	-	-	-	-		O
45	*Platanus orientalis*	Oriental Plane-tree	DD	-	-	-		O
46	*Poa pratensis*	Kentucky Bluegrass	-	-	-	-		O
47	*Populus alba*	White Poplar	LC	-	-	-		L
48	*Prunus avium*	Sweet Cherry	LC	-	-	-		O
49	*Prunus cerasifera*	Cherry Plum	-	-	-	-		O
50	*Prunus domestica*	European Plum	-	-	-	-		O
51	*Prunus laurocerasus*	Cherry-laurel	LC	-	-	-	Ann-I	O
52	*Quercus cerris*	Turkey Oak		-	-	-		O
53	*Quercus pubescens*	Downy Oak	LC	-	-	-		L

	Scientific Name	Common Name	IUCN	BERN	CITES	EU Habitat Directive	National Regulation*	Source**
54	*Quercus robur*	European Oak	LC	-	-	-		O
55	*Ranunculus flammula*	Lesser Spearwort	LC	-	-	-	Ann-II	L
56	*Robinia pseudacacia*	Black Locust	-	-	-	-		O
57	*Rosa canina*	Dog-rose	-	-	-	-	Ann-II	O
58	*Rosa pendulina*	Alpen-Rose	LC	-	-	-		L
59	*Rubus candicans*	-	-	-	-	-		O
60	*Rubus ideus*	Red Raspberry	-	-	-	-		O
61	*Rumex crispus*	Curly Dock	-	-	-	-		O
62	*Salix alba*	White Willow	LC	-	-	-		O
63	*Sambucus ebulus*	Dwarf Elder	-	-	-	-		O
64	*Samolus valerandi*	Brookweed	LC	-	-	-		L
65	*Senecio vernalis*	Eastern Groundsel	-	-	-	-		O
66	*Sesleria autumnalis*	Autumn Moor Grass	LC	-	-	-		L
67	*Sonchus oleraceus*	Common Sowthistle	-	-	-	-		O
68	*Sorbus aucuparia*	Rowan	LC	-	-	-		L
69	*Sorghum halepense*	Johnsongrass	-	-	-	-		O
70	*Stellaria media*	Common Chickweed	-	-	-	-		O
71	*Taraxacum officinale*	Common Dandelion	-	-	-	-		O
72	*Thuja occidentalis*	Northern White Cedar	LC	-	-	-		O
73	*Tilia tomentosa*	Silver Linden	-	-	-	-		O
74	*Trifolium pratense*	Red Clover	-	-	-	-		O
75	*Tripleurospermum inodorum*	Scentless False Mayweed	-	-	-	-		O
76	*Ulmus campestris*	Wych Elm	DD	-	-	-		O
77	*Viola odorata*	Sweet Violet	-	-	-	-	Ann-II	O

* Regulation on the proclamation and protection of strictly protected and protected wild species of plants, animals and fungi (Official Gazette of Republic of Serbia, No. 5/2010, 47/2011, 32/2016 and 98/2016)
** O: Observation L: Literature

6.10.4.3 Fauna

Field studies on the Sub-project area were carried out on 13.12.2022-14.12.2022 by Aleksa Vukicevic (ornithologist) and Stefan Skorić (Bat Expert). Since the Sub-project will be constructed within the area of The Torlak Institute of Virology, Vaccines and Sera, it is not expected to have habitat types that will inhabit wildlife. However, as a result of the studies conducted by examining the literature and previous studies, it was possible to make an inventory for the fauna species. The investigations were carried out as reptiles-amphibians, birds and mammals.

6.10.4.3.1 Amphibians and Reptilians

According to the location of the Sub-project site, general habitat types, general distribution of species, literature data and expert experiences, within the Sub-project site 2 probable amphibian and 3 reptilian species were listed for the Sub-project site (see. Table 6-26).

There is no endemic, rare or any amphibian and reptilian species that need to be protected in the study areas, and they consist of cosmopolitan species.

A summary table of the conservation status of the amphibian and reptile species identified within the scope of the Sub-project is given in Table 6-25.

Table 6-25. Conservation Status of Amphibians and Reptiles

	IUCN							BERN Annexes		CITES Annexes			Habitat Directive Annexes			National Regulation Annexes	
	CR	EN	VU	NT	LC	DD	NE	II	III	I	II	III	II	IV	V	I	II
Amphibian	-	-	-	-	2	-	-	2	-	-	-	-	-	1	-	1	-
Reptile	-	-	-	-	3	-	-	3	-	-	-	-	-	-	-	2	-

Table 6-26. Amphibian and Reptilian Species Identified from the Sub-Project Site

Family	Scientific Name	English	END	IUCN	BERN	CITES	EU Habitat Directive	National Regulation	Source
Amphibians									
Bufonidae	*Bufotes viridis*	Green Toad	-	LC	Ann-II	-	-	-	L
Hylidae	*Hyla arborea*	European Tree Frog	-	LC	Ann-II	-	Ann-IV	Ann-I	L
Reptilians									
Colubridae	*Dolichophis caspius*	Large Whip Snake	-	LC	Ann-II	-	-	Ann-I	L
	Zamenis longissimus	Aesculapian Ratsnake	-	LC	Ann-II	-	-	Ann-I	L
Anguidae	*Anguis fragilis*	Slow Worm	-	LC	Ann-III	-	-	-	L

6.10.4.3.2 Birds

As a result of the observations, literature data, survey studies and habitat investigations, it has been determined that 79 bird species belonging to 30 families can presents or visit these areas in the Sub-project area and its immediate surroundings. Some of these species were added to the lists by direct observations, and some of them were added to the lists after the statements of the residents and literature checks (see. Table 6-28).

According to the IUCN red list, *Turdus iliacus* (Redwing) is in the "NT" (=Near Threatened) category and *Falco vespertinus* (Red-footed Falcon) is in the "VU" (=Vulnerable) category while the remaining species are in the "LC" (=Least Concern) category.

There is no endemic, rare or any bird species that need to be protected in the study areas, and they consist of cosmopolitan species.

A summary table of the conservation status of the bird species identified within the scope of the Sub-project is given in Table 6-27.

Table 6-27. Conservation Status of Birds

IUCN							BERN Annexes		CITES Annexes			Bird Directive Annexes		National Regulation Annexes	
CR	EN	VU	NT	LC	DD	NE	II	III	I	II	III	I	II	I	II
-	-	1	1	77	-	-	42	30	-	9	-	9	12	67	11

Possible bird species expected to be seen in the Sub-project area are presented in Table 6-28

Table 6-28. Bird Species Identified from the Sub-Project Area

Family	Scientific Name	Common Name	End	IUCN	BERN	CITES	EU Bird Directive	National Regulation	Source
Accipitridae	*Accipiter gentilis*	Northern Goshawk	-	LC	Ann-III	App-II	-	Ann-II	L
	Accipiter nisus	Eurasian Sparrowhawk	-	LC	Ann-III	App-II	-	Ann-I	L
	Buteo buteo	Buzzard	-	LC	Ann-III	App-II	-	Ann-I	L
Acrocephalidae	*Acrocephalus arundinaceus*	Great-Reed Warbler	-	LC	Ann-III	-	-	Ann-I	L
	Acrocephalus schoenobaenus	Sedge Warbler	-	LC	Ann-III	-	-	Ann-I	L
Aegithalidae	*Aegithalos caudatus*	Long-Tailed Tit	-	LC	Ann-III	-	-	Ann-I	L
Alaudidae	*Galerida cristata*	Crested Lark	-	LC	Ann-III	-	-	Ann-I	L
	Lullula arborea	Woodlark	-	LC	Ann-III	-	App-I	Ann-I	L
Apodidae	*Apus apus*	Common Swift	-	LC	Ann-III	-	-	Ann-I	L
Bombycillidae	*Bombycilla garrulus*	Bohemian Waxwing	-	LC	Ann-II	-	-	Ann-I	L
Ciconiidae	*Ciconia ciconia*	White Stork	-	LC	Ann-II	-	App-I	Ann-I	L
Columbidae	*Columba livia*	Rock Dove	-	LC	Ann-III	-	App-II	Ann-I	O
	Columba oenas	Stock Dove	-	LC	Ann-III	-	App-II	Ann-I	L
	Columba palumbus	Common Woodpigeon	-	LC	-	-	App-II	Ann-II	O
	Streptopelia decaocto	Eurasian Collared Dove	-	LC	Ann-III	-	App-II	Ann-II	O
Coraciidae	*Coracias garrulus*	European Roller	-	LC	Ann-II	-	App-I	Ann-I	L
Corvidae	*Corvus corax*	Common Raven	-	LC	Ann-III	-	-	Ann-II	L
	Corvus frugilegus	Rook	-	LC	-	-	App-II	Ann-II	O
	Corvus monedula	Eurasian Jackdaw	-	LC	-	-	App-II	Ann-II	O
	Garrulus glandarius	Eurasian Jay	-	LC	-	-	App-II	Ann-II	O
	Pica pica	Eurasian Magpie	-	LC	-	-	App-II	Ann-II	O
Cuculidae	*Cuculus canorus*	Common Cuckoo	-	LC	Ann-III	-	-	Ann-I	L
Emberizidae	*Emberiza cirlus*	Cirl Bunting	-	LC	Ann-II	-	-	Ann-I	L
	Emberiza citrinella	Yellowhammer	-	LC	Ann-II	-	-	-	L
	Emberiza hortulana	Ortolan Bunting	-	LC	Ann-III	-	App-I	Ann-I	L
	Emberiza schoeniclus	Reed Bunting	-	LC	Ann-II	-	-	Ann-I	L
Falconidae	*Falco columbarius*	Merlin	-	LC	Ann-II	App-II	-	Ann-I	L

Family	Scientific Name	Common Name	End	IUCN	BERN	CITES	EU Bird Directive	National Regulation	Source
	Falco tinnunculus	Common Kestrel	-	LC	Ann-II	App-II	-	Ann-I	L
	Falco vespertinus	Red-Footed Falcon	-	VU	Ann-II	-	-	Ann-I	L
Fringillidae	*Carduelis carduelis*	European Goldfinch	-	LC	Ann-II	-	-	Ann-I	L
	Chloris chloris	European Greenfinch	-	LC	Ann-III	-	-	Ann-I	L
	Fringilla coelebs	Common Chaffinch	-	LC	Ann-III	-	-	Ann-I	L
	Fringilla montifringilla	Brambling	-	LC	Ann-III	-	-	Ann-I	L
	Serinus serinus	European Serin	-	LC	Ann-II	-	-	Ann-I	L
	Spinus spinus	Eurasian Siskin	-	LC	Ann-III	-	-	Ann-I	L
Hirundinidae	*Delichon urbicum*	Northern House Martin	-	LC	Ann-II	-	-	Ann-I	L
	Hirundo rustica	Barn Swallow	-	LC	Ann-II	-	-	Ann-I	L
	Ptyonoprogne rupestris	Eurasian Crag Martin	-	LC	Ann-II	-	-	Ann-I	L
Laniidae	*Lanius collurio*	Red-Backed Shrike	-	LC	Ann-II	-	App-I	Ann-I	L
	Lanius excubitor	Great Grey Shrike	-	LC	Ann-II	-	-	Ann-I	L
	Lanius minor	Lesser Grey Shrike	-	LC	Ann-II	-	App-I	Ann-I	L
Motacillidae	*Anthus trivialis*	Tree Pipit	-	LC	Ann-II	-	-	Ann-I	L
	Motacilla alba	White Wagtail	-	LC	Ann-II	-	-	Ann-I	L
	Motacilla cinerea	Gray Wagtail	-	LC	Ann-II	-	-	Ann-I	L
	Motacilla flava	Western Yellow Wagtail	-	LC	Ann-II	-	-	Ann-I	L
Muscicapidae	*Ficedula parva*	Red-Breasted Flycatcher	-	LC	Ann-II	-	App-I	Ann-I	L
	Muscicapa striata	Spotted Flycatcher	-	LC	Ann-II	-	-	Ann-I	L
Oriolidae	*Oriolus oriolus*	Eurasian Golden Oriole	-	LC	Ann-II	-	-	Ann-I	L
Paridae	*Cyanistes caeruleus*	Eurasian Blue Tit	-	LC	Ann-II	-	-	Ann-I	L
	Parus major	Great Tit	-	LC	Ann-II	-	-	Ann-I	O
Passeridae	*Passer domesticus*	House Sparrow	-	LC	-	-	-	Ann-II	L
	Passer montanus	Eurasian Tree Sparrow	-	LC	Ann-III	-	-	Ann-II	L
Picidae	*Dendrocopos major*	Great-Spotted Woodpecker	-	LC	Ann-III	-	-	Ann-I	O
	Dendrocopos syriacus	Syrian Woodpecker	-	LC	Ann-III	-	App-I	Ann-I	O

Family	Scientific Name	Common Name	End	IUCN	BERN	CITES	EU Bird Directive	National Regulation	Source
Prunellidae	*Prunella collaris*	Alpine Accentor	-	LC	Ann-II	-	-	Ann-I	L
	Prunella modularis	Dunnock	-	LC	Ann-II	-	-	Ann-I	L
Sittidae	*Sitta europaea*	Wood Nuthatch	-	LC	Ann-II	-	-	Ann-I	L
Strigidae	*Asio flammeus*	Short-Eared Owl	-	LC	Ann-III	App-II	App-I	Ann-I	L
	Athene noctua	Little Owl	-	LC	Ann-III	App-II	-	Ann-I	L
	Strix aluco	Tawny Owl	-	LC	Ann-III	App-II	-	Ann-I	L
Sturnidae	*Sturnus vulgaris*	Common Starling	-	LC	-	-	App-II	Ann-II	L
Sylviidae	*Curruca communis*	Common Whitethroat	-	LC	Ann-II	-	-	Ann-I	L
	Curruca curruca	Lesser Whitethroat	-	LC	Ann-II	-	-	Ann-I	L
	Hippolais icterina	Icterine Warbler	-	LC	Ann-II	-	-	Ann-I	L
	Iduna pallida	Olivaceous Warbler	-	LC	Ann-II	-	-	Ann-I	L
	Phylloscopus collybita	Common Chiffchaff	-	LC	Ann-II	-	-	Ann-I	L
	Sylvia atricapilla	Eurasian Blackcap	-	LC	Ann-II	-	-	Ann-I	L
	Sylvia borin	Garden Warbler	-	LC	Ann-II	-	-	Ann-I	L
Troglodytidae	*Troglodytes troglodytes*	Northern Wren	-	LC	Ann-II	-	-	Ann-I	O
Turdidae	*Cyanecula svecica*	Bluethroat	-	LC	Ann-III	-	-	Ann-I	L
	Erithacus rubecula	European Robin	-	LC	Ann-II	-	-	Ann-I	O
	Luscinia megarhynchos	Common Nigtingale	-	LC	Ann-II	-	-	Ann-I	L
	Phoenicurus ochruros	Black Redstart	-	LC	Ann-II	-	-	Ann-I	L
	Phoenicurus phoenicurus	Common Redstart	-	LC	Ann-II	-	-	Ann-I	L
	Saxicola rubetra	Whinchat	-	LC	Ann-II	-	-	Ann-I	L
	Turdus iliacus	Redwing	-	NT	Ann-III	-	App-II	Ann-I	L
	Turdus merula	Eurasian Blackbird	-	LC	Ann-III	-	App-II	Ann-I	O
	Turdus philomelos	Song Thrush	-	LC	Ann-III	-	App-II	Ann-I	L
Tytoniade	*Tyto alba*	Common Barn-owl	-	LC	Ann-III	App-II	-	Ann-I	L

Figure 6-19. Species Identified in the Sub-Project Area *Dendrocopos major* (Great Spotted Woodpecker)

Figure 6-20. Species Identified in the Sub-Project Area *Corvus frugilegus* (Rook)

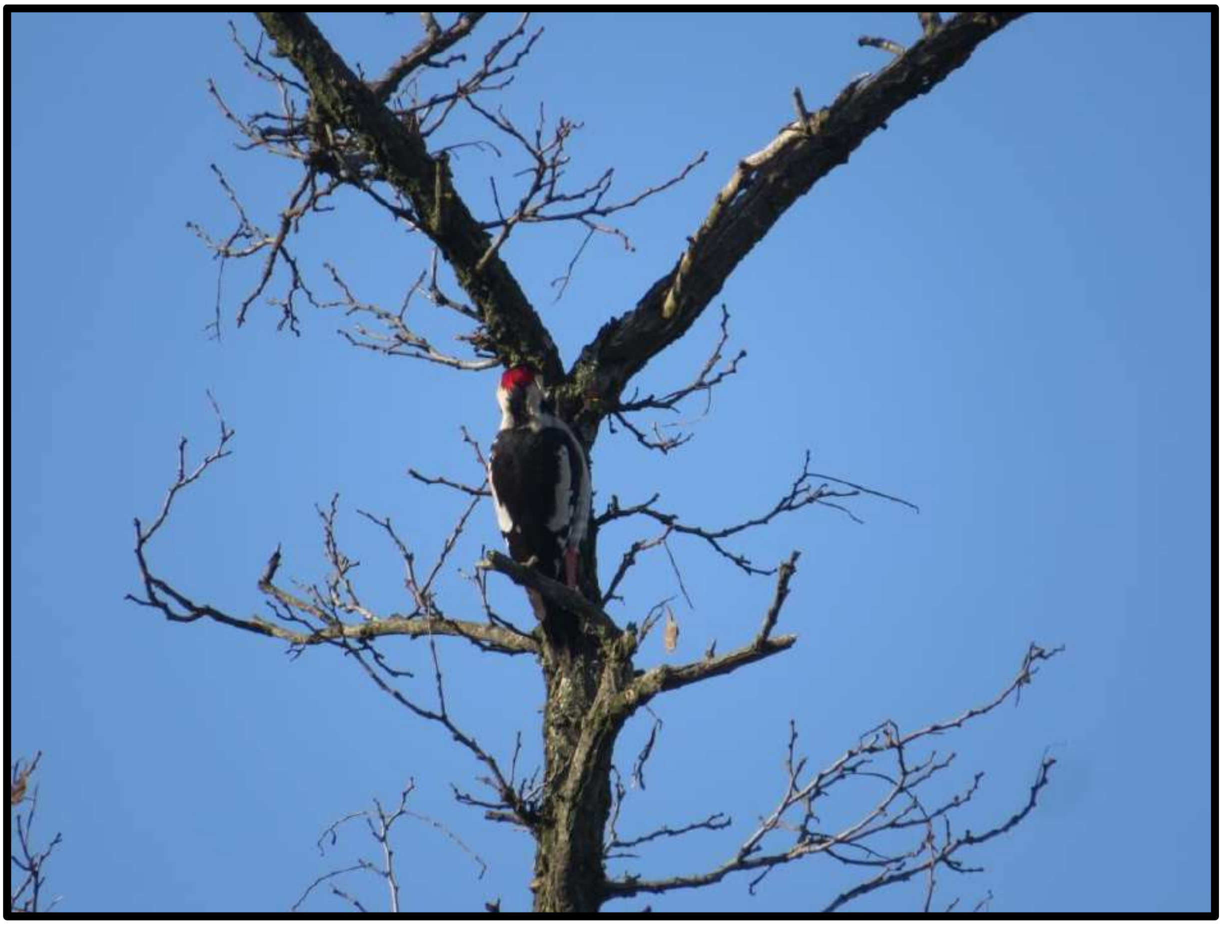


Figure 6-21. Species Identified in the Sub-Project Area *Dendrocopos syriacus* (Syrian woodpecker)

6.10.4.3.3 Mammals

According to the location of the Sub-project site, general habitat types, general distribution of species in Türkiye, literature data and expert experiences, within the Sub-project site 10 probable mammal species were listed for the Sub-project site (see. Table 6-30)

According to the IUCN red list, all of the species are in the "LC" (=Least Concern) category.

According to BERN Convention Appendices, 2 species at the Sub-project site are listed in Ann-II, and 3 species in Ann-III. 5 species in the area have not been listed by BERN convention. There is no endemic, rare or any mammal species in the study areas.

There is no endemic, rare or any mammal species that need to be protected in the study areas, and they consist of cosmopolitan species.

A summary table of the conservation status of the mammal species identified within the scope of the Sub-project is given in Table 6-29.

Table 6-29. Conservation Status of Mammals

IUCN							BERN Annexes		CITES Annexes			Habitat Directive Annexes			National Regulation Annexes	
CR	EN	VU	NT	LC	DD	NE	II	III	I	II	III	II	IV	V	I	II
-	-	-	-	10	-	-	2	3	-	-	-	1	-	-	3	4

A field survey was conducted by Stefan Skorić on the presence of bats in the Sub-project area on 14.12.2022. As a result of the studies, no bats or evidence showing the presence of bats were found. On the other hand, considering the habitat conditions, bat species that can be found in the Sub-project area were included in the study.

Figure 6-22. Potential Bat Roosts-1 (The nearest existing building on the south of the Sub-Project area in Torlak Institute)

Figure 6-23. Potential Bat Roosts-2

Table 6-30. Mammal Species Identified at the Sub-Project Site

Family	Species	Common Name	End	IUCN	Bern	CITES	EU Habitat Directive	National Regulation	Source
Cricetidae	*Microtus subterraneus*	European Pine Vole	-	LC	-	-	-		L
Erinaceidae	*Erinaceus roumanicus*	Northern White-breasted Hedgehog	-	LC	-	-	-	Ann-II	L
Muridae	*Apodemus sylvaticus*	Wood mouse	-	LC	-	-			L
	Mus musculus	House mouse	-	LC	-	-			L
Rhinolophidae	*Rhinolophus ferrumequinum*	Greater Horseshoe Bat	-	LC	Ann-II	-	Ann-II	Ann-I	L
Sciuridae	*Sciurus vulgaris*	Eurasian Red Squirrel	-	LC	Ann-III	-		Ann-II	O
Soricidae	*Crocidura suaveolens*	Lesser Shrew	-	LC	Ann-III	-		Ann-II	L
Talpidae	*Talpa europaea*	European Mole	-	LC	-	-		Ann-II	O
Vespertilionidae	*Nyctalus noctula*	Noctule	-	LC	Ann-II	-		Ann-I	L
	Pipistrellus pipistrellus	Common pipistrelle	-	LC	Ann-III	-		Ann-I	L

6.10.5 Alien Invasive Species

Intentional or accidental introduction of alien, or nonnative, species of flora and fauna into areas where they are not normally found can be a significant threat to biodiversity, since some alien species can become invasive, spreading rapidly, and destroying or out-competing native species.

During the field studies, alien invasive species were identified in the Sub-project site and its immediate surroundings. These are *Robinia pseudoacacia, Erigeron annus, Erigeron canadensis*, and *Datura inoxia*.

Robinia pseudoacacia is a leguminous deciduous tree native to the southeastern United States that has been widely introduced to other parts of North America. It is commonly found in disturbed areas such as old fields, degraded woods, forest edges, and roadsides, but it poses the greatest threat to dry and sand prairies and oak savannas. *R. pseudoacacia* has been planted on reclaimed land to control erosion and has been used for ornamental purposes. It reproduces vigorously by root suckering and stump sprouting to form groves of trees interconnected by a common root system.

Erigeron annus is an annual plant and grows primarily in the temperate biome The native range of this species is Canada to U.S.A., Nicaragua to Panama.

Erigeron canadensis, is an annual plant native throughout most of North America and Central America. This plant has become an invasive weed in Eurasia.

Datura inoxia is a herb with large white flowers, broad leaves and prickly fruits found in the south and central western ranges of California. It is native to Mexico and Central America. It favors dunes and grasslands. It spreads via seed and rhizomes. Seeds are dispersed via ants, birds, animal fur and water.

6.10.6 Habitat Assessment

In accordance with ESS6, habitats are divided into modified, natural and critical habitats.

Habitat condition is classified as either Natural or Modified based on the extent of human modification of the ecosystem. Both Natural and Modified Habitats may contain globally important biodiversity values, thereby qualifying as Critical Habitat

Table 6-31. Habitat Classes

Areas Identified in ESS6		Condition of the Area	
		Natural	Modified
High Biodiversity Values	Present	Critical Habitat	Critical Habitat
	Absent	Natural Habitat	Modified Habitat

6.10.6.1 Habitats Categorization

Modified Habitat

Modified habitats are areas that may contain a large proportion of plant and/or animal species of nonnative origin, and/or where human activity has substantially modified an area's primary ecological functions and species composition. Modified habitats may include, for example, areas managed for agriculture, forest plantations, reclaimed coastal zones, and reclaimed wetlands.

ESS6 applies to those areas of modified habitat that include significant biodiversity value, as determined by the environmental and social assessment required in ESS1. The Borrower will avoid or minimize impacts on such biodiversity and implement mitigation measures as appropriate.

Natural Habitats

Natural habitats are areas composed of viable assemblages of plant and/or animal species of largely native origin, and/or where human activity has not essentially modified an area's primary ecological functions and species composition.

If natural habitats are identified as part of the assessment, the Borrower will seek to avoid adverse impacts on them in accordance with the mitigation hierarchy. Where natural habitats have the potential to be adversely affected by the project, the Borrower will not implement any project-related activities unless:

(a) There are no technically and financially feasible alternatives; and

(b) Appropriate mitigation measures are put in place, in accordance with the mitigation hierarchy, to achieve no net loss and, where feasible, preferably a net gain of biodiversity over the long term. When residual impacts remain despite best efforts to avoid, minimize and mitigate impacts, and where appropriate and supported by relevant stakeholders, mitigation measures may include biodiversity offsets adhering to the principle of “like-for-like or better.

Critical Habitats

Critical habitats can be either modified or natural habitats supporting high biodiversity importance or value, including:

(a) Habitat of significant importance to Critically Endangered or Endangered species, as listed in the IUCN Red List of threatened species or equivalent national approaches.

(b) Habitat of significant importance to endemic or restricted range species.

(c) Habitat supporting globally or nationally significant concentrations of migratory or congregatory species.

(d) Highly threatened or unique ecosystems; and

(e) Ecological functions or characteristics that are needed to maintain the viability of the biodiversity values described above in (a) to (d).

In areas of critical habitat, the Borrower will not implement any project activities that have potential adverse impacts unless all of the following conditions are met:

(a) No other viable alternatives within the region exist for development of the project in habitats of lesser biodiversity value.

(b) All due process required under international obligations or national law that is a prerequisite to a country granting approval for project activities in or adjacent to a critical habitat has been complied with.

(c) The potential adverse impacts, or likelihood of such, on the habitat will not lead to measurable net reduction or negative change in those biodiversity values for which the critical habitat was designated.

(d) The project is not anticipated to lead to a net reduction in the population13 of any Critically Endangered, Endangered, or restricted-range species, over a reasonable time period.

(e) The project will not involve significant conversion or significant degradation of critical habitats. In circumstances where the project involves new or renewed forestry or agricultural plantations, it will not convert or degrade any critical habitat.

(f) The project's mitigation strategy will be designed to achieve net gains of those biodiversity values for which the critical habitat was designated; and

(g) A robust and appropriately designed, long-term biodiversity monitoring and evaluation program aimed at assessing the status of the critical habitat is integrated into the Borrower's management program.

6.10.6.2 Critical Habitat Assessment

6.10.6.2.1 Habitat of Significant Importance to Critically Endangered or Endangered Species, as Listed in the IUCN Red List of Threatened Species or Equivalent National Approaches

There are no any Critically Endangered (CR) or Endangered (EN) flora and fauna species within the Sub-project area and surroundings. Therefore, "Habitat of Significant Importance to Endemic or Restricted Range Species" is scoped out.

In addition, locally protected species according to "*Regulation on the proclamation and protection of strictly protected and protected wild species of plants, animals and fungi (Official*

Gazette of Republic of Serbia, No. 5/2010, 47/2011, 32/2016 and 98/2016)" are given in the table below. Species included in Annex-I (Strictly Protected Species) are considered equivalent to IUCN CR and EN statuses. Therefore, Annex-I species are included in the tables.

Table 6-32. Locally Protected Species Equivalent to IUCN Redlist CR and EN Status

Species	IUCN	National Regulation
Plant		
Prunus laurocerasus	LC	Ann-I
Birds		
Accipiter nisus	LC	Ann-I
Buteo buteo	LC	Ann-I
Acrocephalus arundinaceus	LC	Ann-I
Acrocephalus schoenobaenus	LC	Ann-I
Aegithalos caudatus	LC	Ann-I
Galerida cristata	LC	Ann-I
Lullula arborea	LC	Ann-I
Apus apus	LC	Ann-I
Bombycilla garrulus	LC	Ann-I
Ciconia ciconia	LC	Ann-I
Columba livia	LC	Ann-I
Columba oenas	LC	Ann-I
Coracias garrulus	LC	Ann-I
Cuculus canorus	LC	Ann-I
Emberiza cirlus	LC	Ann-I
Emberiza hortulana	LC	Ann-I
Emberiza schoeniclus	LC	Ann-I
Falco columbarius	LC	Ann-I
Falco tinnunculus	LC	Ann-I
Falco vespertinus	VU	Ann-I
Carduelis carduelis	LC	Ann-I
Chloris chloris	LC	Ann-I
Fringilla coelebs	LC	Ann-I
Fringilla montifringilla	LC	Ann-I
Serinus serinus	LC	Ann-I
Spinus spinus	LC	Ann-I
Delichon urbicum	LC	Ann-I
Hirundo rustica	LC	Ann-I
Ptyonoprogne rupestris	LC	Ann-I
Lanius collurio	LC	Ann-I
Lanius excubitor	LC	Ann-I
Lanius minor	LC	Ann-I
Anthus trivialis	LC	Ann-I
Motacilla alba	LC	Ann-I
Motacilla cinerea	LC	Ann-I
Motacilla flava	LC	Ann-I

Species	IUCN	National Regulation
Ficedula parva	LC	Ann-I
Muscicapa striata	LC	Ann-I
Oriolus oriolus	LC	Ann-I
Cyanistes caeruleus	LC	Ann-I
Parus major	LC	Ann-I
Dendrocopos major	LC	Ann-I
Dendrocopos syriacus	LC	Ann-I
Prunella collaris	LC	Ann-I
Prunella modularis	LC	Ann-I
Sitta europaea	LC	Ann-I
Asio flammeus	LC	Ann-I
Athene noctua	LC	Ann-I
Strix aluco	LC	Ann-I
Curruca communis	LC	Ann-I
Curruca curruca	LC	Ann-I
Hippolais icterina	LC	Ann-I
Iduna pallida	LC	Ann-I
Phylloscopus collybita	LC	Ann-I
Sylvia atricapilla	LC	Ann-I
Sylvia borin	LC	Ann-I
Troglodytes troglodytes	LC	Ann-I
Cyanecula svecica	LC	Ann-I
Erithacus rubecula	LC	Ann-I
Luscinia megarhynchos	LC	Ann-I
Phoenicurus ochruros	LC	Ann-I
Phoenicurus phoenicurus	LC	Ann-I
Saxicola rubetra	LC	Ann-I
Turdus iliacus	NT	Ann-I
Turdus merula	LC	Ann-I
Turdus philomelos	LC	Ann-I
Tyto alba	LC	Ann-I
Mammals		
Rhinolophus ferrumequinum	LC	Ann-I
Nyctalus noctula	LC	Ann-I
Pipistrellus pipistrellus	LC	Ann-I

Sub-project is a building construction project within the existing Torlak Institute of Virology, Vaccines and Sera. Therefore, the Sub-project is not expected to have an impact on the natural habitat. Considering the small size and habitat characteristics of the area, the frequency and probability of using this area by the above species is quite low.

Consequently, triggering of critical habitat for the above-mentioned species cannot be expected.

6.10.6.2.2 Habitat of Significant Importance to Endemic or Restricted Range Species

There is not any endemic or restricted-range flora and fauna species within the Sub-project area and surroundings.

Therefore, "Habitat of Significant Importance to Endemic or Restricted Range Species" is scoped out.

6.10.6.2.3 Habitat Supporting Globally or Nationally Significant Concentrations of Migratory or Congregatory Species

There is a bird migration route above the city of Belgrade, but the Sub-project Area is not directly located on the main migration route of the avifauna species. The Sub-project Area is not considered as gathering area for migratory birds and shelter or a breeding ground for endangered bird species. Some individual species may be seen flying above the area during spring and autumn migrations. The Sub-project site is also not within an IBA or Ramsar site.

Therefore, it does not meet the criteria for critical habitat for "Habitat Supporting Globally or Nationally Significant Concentrations of Migratory or Congregatory Species".

6.10.6.2.4 Highly Threatened or Unique Ecosystems

None of the ecosystems in the AoI has been assessed according to the IUCN's Red List of Ecosystems. None of the habitats identified during the studies are listed as Priority Habitat under Annex 1 of the Habitats Directive.

Therefore, it does not meet the criteria for "Highly Threatened or Unique Ecosystems".

6.10.6.2.5 Ecological Functions or Characteristics that are Needed to Maintain the Viability of the Biodiversity Values

The Sub-project is not substantially different from the surrounding landscape in terms of elevation or moisture gradients, or any other geological, ecological, or evolutionary factors that would suggest that the area is vital for sustaining unique or distinctive evolutionary processes. There is not any isolation, spatial heterogeneity, and wealth of environmental gradients.

Consequently, the Sub-project does not trigger "Ecological Functions or Characteristics that are Needed to Maintain the Viability of the Biodiversity Values".

6.11 Traffic

A traffic impact assessment study was carried out by TM Inženjering for the Sub-project. The study includes site observations, traffic data (counts/assumptions), as well as information provided by the Project Owner.

Vojvode Stepe Street is located in the north-east of the Sub-project area, which has two lanes, the nearest main road being round-trip. Traffic counts were performed on 22.12.2022 from 06.00 to 20.00 o'clock and on 24.12.2022 from 06.00 to 20.00 o'clock in crossroads of Vodice Stepe – Zadoska.

Traffic counts (TC) were conducted at three (3) directions. Combinations are designed as: 1-2, 1-3, 2-1, 2-3, 3-1 and 3-2 (see. Figure 6-24).

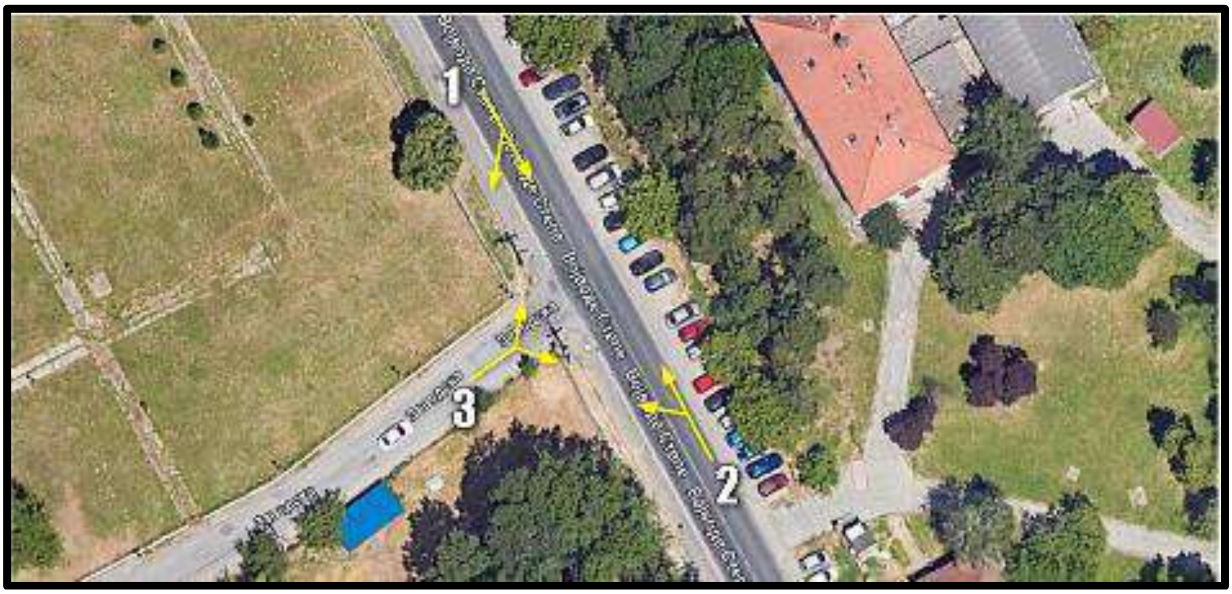


Figure 6-24. Directions of traffic counting

Table 6-33. Distribution of Vehicles in Working Days on Thursday 22.12.2022

Dan	Sat	1 - 2 Number of vehicles	1 - 3 Number of vehicles	2 - 1 Number of vehicles	2 - 3 Number of vehicles	3 - 1 Number of vehicles	3 - 2 Number of vehicles	UCLAS	int.s. (s)
22.12.2022.	[06:00-07:00]	100	15	398	15	27	8	**563**	6,39
22.12.2022.	[07:00-08:00]	136	24	441	24	70	24	**719**	5,01
22.12.2022.	[08:00-09:00]	160	20	333	31	35	12	**591**	6,09
22.12.2022.	[09:00-10:00]	222	39	319	80	92	31	**783**	4,60
22.12.2022.	[10:00-11:00]	247	21	308	33	45	12	**666**	5,41
22.12.2022.	[11:00-12:00]	182	16	275	75	68	26	**642**	5,61
22.12.2022.	[12:00-13:00]	200	14	293	34	49	9	**599**	6,01
22.12.2022.	[13:00-14:00]	195	30	254	56	52	13	**600**	6,00
22.12.2022.	[14:00-15:00]	251	21	337	69	63	18	**759**	4,74
22.12.2022.	[15:00-16:00]	424	33	437	38	31	13	**976**	3,69
22.12.2022.	[16:00-17:00]	404	60	333	16	32	43	**888**	4,05
22.12.2022.	[17:00-18:00]	370	61	363	55	58	24	**931**	3,87
22.12.2022.	[18:00-19:00]	318	17	364	33	21	13	**766**	4,70
22.12.2022.	[19:00-20:00]	312	17	262	13	32	9	**645**	5,58
22.12.2022.	**[06:00-20:00]**	**3.521**	**388**	**4.717**	**572**	**675**	**255**	**10.128**	**4,98**

According to Table 6-33, the density of vehicles of Vodice and Zavodska streets are determined on working day; the distribution of vehicles are 424 at 15.00-16.00 in 1-2 direction, the distribution of vehicles are 61 at 17.00-18.00 in 1-3 direction, the distribution of vehicles are 441 at 07.00-08.00 in 2-1 direction, the distribution of vehicles are 80 at 09.00-10.00 in 2-3 direction, the distribution of vehicles are 92 at 09.00-10.00 in 3-1 direction and the distribution of vehicles are 43 at 16.00-17.00 in 3-2 direction.

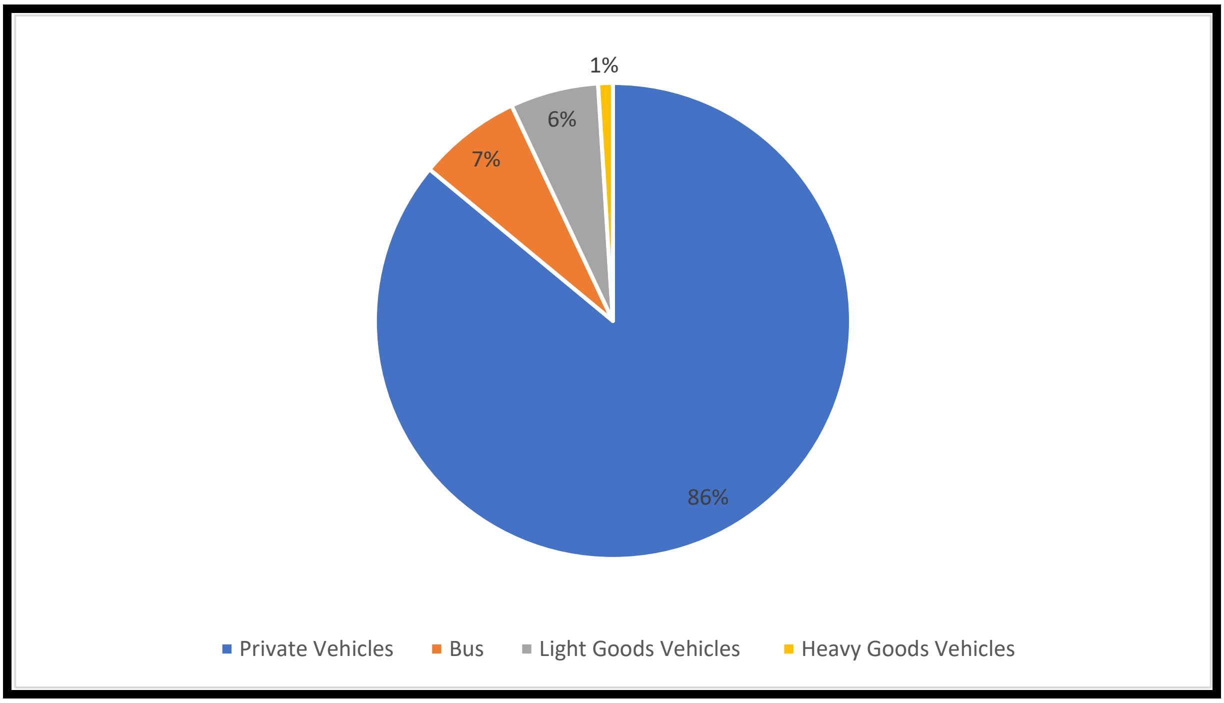


Figure 6-25. Distribution of Vehicle Types in Traffic During the Day

According to Figure 6-25, on 22.12.2022 private vehicles make up %86 of the overall vehicle distribution. Buses and light goods vehicles are following with 7% and 6%.

Table 6-34. Distribution of Vehicles in Non-Working Days on Thursday 24.12.2022

Dan	Sat	1 - 2 Number of vehicles	1 - 3 Number of vehicles	2 - 1 Number of vehicles	2 - 3 Number of vehicles	3 - 1 Number of vehicles	3 - 2 Number of vehicles	UCLAS	int.s
24.12.2022.	[06:00-07:00]	150	13	155	14	4	4	**340**	10,59
24.12.2022.	[07:00-08:00]	62	15	139	32	13	9	**270**	13,33
24.12.2022.	[08:00-09:00]	110	51	135	17	15	18	**346**	10,40
24.12.2022.	[09:00-10:00]	176	8	216	13	5	1	**419**	8,59
24.12.2022.	[10:00-11:00]	85	2	166	10	0	4	**267**	13,48
24.12.2022.	[11:00-12:00]	62	6	160	1	5	5	**239**	15,06
24.12.2022.	[12:00-13:00]	107	12	208	10	9	1	**347**	10,37
24.12.2022.	[13:00-14:00]	135	14	166	2	12	15	**344**	10,47
24.12.2022.	[14:00-15:00]	138	20	192	11	3	15	**379**	9,50
24.12.2022.	[15:00-16:00]	175	5	219	7	2	14	**422**	8,53
24.12.2022.	[16:00-17:00]	112	10	215	9	6	5	**357**	10,08
24.12.2022.	[17:00-18:00]	151	15	224	8	0	16	**414**	8,70
24.12.2022.	[18:00-19:00]	96	15	151	8	2	4	**276**	13,04
24.12.2022.	[19:00-20:00]	137	7	140	2	3	9	**298**	12,08
24.12.2022.	**[06:00-20:00]**	**1.696**	**193**	**2.486**	**144**	**79**	**120**	**4.718**	**10,68**

According to Table 6-34, the density of vehicles of Vodice and Zavodska streets are determined on non-working day; the distribution of vehicles are 176 at 09.00-10.00 in 1-2 direction, the distribution of vehicles are 51 at 08.00-09.00 in 1-3 direction, the distribution of vehicles are 224 at 17.00-18.00 in 2-1 direction, the distribution of vehicles are 32 at 07.00-08.00 in 2-3 direction, the distribution of vehicles are 15 at 08.00-09.00 in 3-1 direction and the distribution of vehicles are 18 at 08.00-09.00 in 3-2 direction.

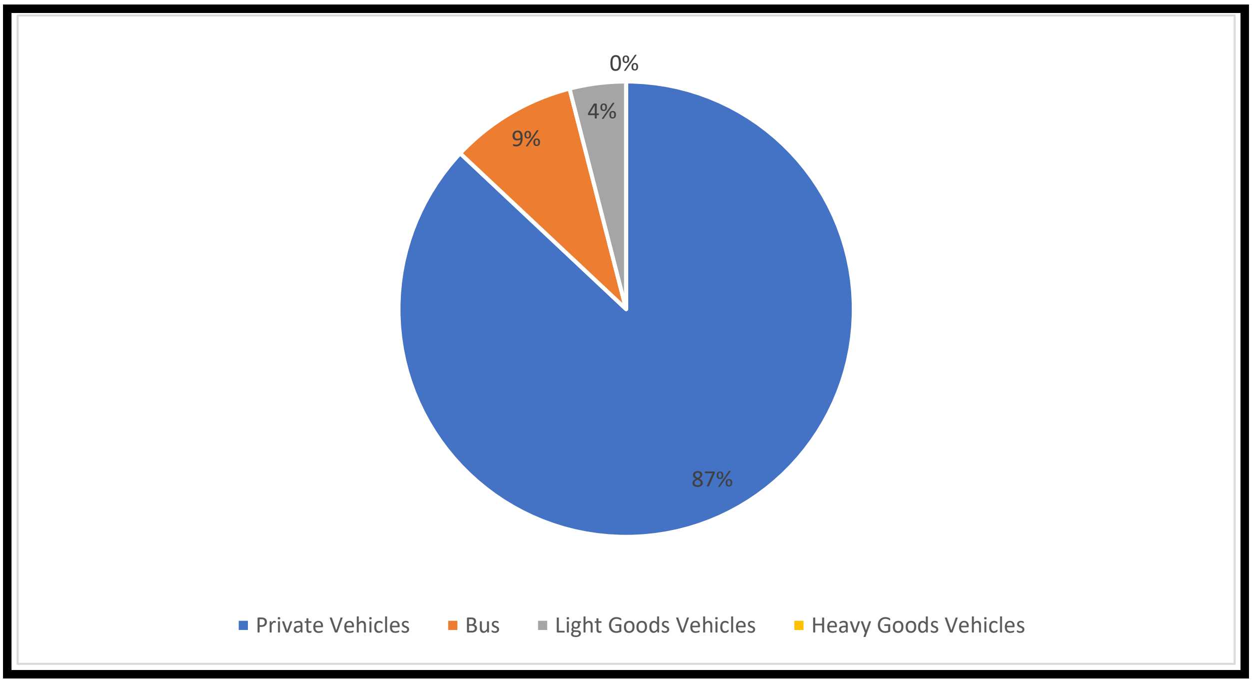


Figure 6-26. Distribution of Vehicle Types in Traffic During the Day

According to Figure 6-26, on 24.12.2022 private vehicles make up 87% of the overall vehicle distribution. Buses and light goods vehicles are following with 9% and 4%.

The close vicinity of the Sub-project is mostly covered by houses. Besides, Faculty of Pharmacy is the sensitive receptor of the Sub-project. The traffic density is at the highest number on weekdays at 15.00-16.00 due to students, academics and employees' leaving hours.

6.12 Biosafety and Biosecurity

Serbian laboratories have the capability to identify and 75% of EU-notifiable communicable diseases according to EU case definitions. National reference laboratories for illnesses such as tuberculosis, HIV, measles, influenza, polio, and AMR actively engage in laboratory surveillance networks and projects guided by either the World Health Organization or the European Centre for Disease Prevention and Control.

According to the Health Statistical Yearbook of Republic of Serbia (2021), the most common causes of death in 2021 were diseases of the circulatory system, accounting for 41.4% of deaths, followed by COVID-19 at 20.3%, neoplasms at 15.1%, diseases of the respiratory system at 5.3%, and endocrine, nutritional, and metabolic diseases at 2.6%. When gender was taken into account, men had a higher percentage of deaths caused by diseases of the circulatory system and neoplasms, while women had a higher percentage of deaths caused by diseases of the respiratory system and endocrine, nutritional, and metabolic diseases. It's important to note that the symptoms, signs, and abnormal clinical and laboratory findings group was excluded from the data analysis.

In 2021, there were 353 outbreaks of communicable diseases recorded in the Republic of Serbia, which resulted in a total of 6417 cases. The most common type of outbreak was a combination of airborne and contact transmission, accounting for 57.2% (202) of all outbreaks, followed by airborne transmission (13.6%, 48), contact transmission (23.2%, 82), foodborne transmission (2.6%, 9), and outbreaks with an unknown mode of transmission (3.4%, 12). Out of all the outbreaks, COVID-19 was responsible for the majority of them, with 186 outbreaks and 3,620 cases reported.

National reference laboratories for TB, HIV, influenza, measles, poliomyelitis, and AMR actively participate in laboratory surveillance networks and projects led by WHO or the European Centre for Disease Prevention and Control (ECDC) (Serbia: health system review, 2019).

Torlak Institute monitors, studies, examines, identifies, introduces, and implements professional and scientific methods of prevention and diagnosis of infectious diseases, performs scientific research and educational activities with the aim of developing new technologies and improving vaccines production. In Serbia, there is no established and certified BSL-3 laboratory for diagnostics, research and production purposes.

6.12.1 Biosafety

Serbia has national biosafety regulation in place that govern the implementation and enhancement of workplace safety and health for those involved in work processes, as well as persons encountered in the workplace. The legislation applies to all laboratories in the country.

According to the Joint External Evaluation (JEE) of International Health Regulations (IHR) core capacities of the Republic of Serbia, the Rulebook on Preventive Measures for Safe and Healthy Work during Exposure to Biological Hazards is one of the biosafety and biosecurity regulation in force. On biosafety and biosecurity, there is a substantial corpus of legal guidelines and rulebooks covering topics including safety at work, waste management, dangerous goods transport, dual-use goods, and dangerous pathogens.

The Directorate for Safety and Health at Work is responsible agency for the enforcement of biosafety legislation and regulations. Additionally, the Directorate is in charge for monitoring and evaluating the state of occupational health and safety and providing professional assistance in the field of employee health and safety.

The public health emergency response is part of the National Strategy for Emergency Protection and Rescue, and emergency response plan is publicly available, addressing plans for several contagious diseases of pandemic potential, this document is a framework for planning the response of all protective and rescue personnel in the event of a disaster or major accidents, including public health emergencies. Torlak Institute has already developed;

- Protection and rescue plan,
- Disaster risk assessment,
- Accident protection plan in accordance with the Law on Disaster Risk Reduction and Emergency Management, Official Gazette 87/2018.

The documents have been approved by the Ministry of Internal Affairs. Torlak Institute will improve these documents and include specific requirements regarding the BSL-3 laboratory. City of Belgrade takes into consideration the accident protection plan for threat assessment.

World Health Organization (WHO) provides international leadership on biosafety by addressing emerging issues, technologies and challenges, and providing guidance on best practice. WHO published the first edition of laboratory biosafety manual in 1983. It encouraged countries to accept and implement basic concepts in biological safety and to develop national codes of practice for the safe handling of pathogenic biological agents in laboratories within their geographical borders. In the fourth edition of the WHO Laboratory biosafety manual, emphasis is placed on the importance of a “safety culture” that incorporates risk assessment, good microbiological practice and procedure (GMPP) and SOPs, appropriate introductory, refresher and mentoring training of personnel, and prompt reporting of incidents and accidents followed by appropriate investigation and corrective actions.

The Sub-project will be developed in compliance with WHO Laboratory Biosafety Manual (4th edition, 2020) in terms of biosafety along with the World Bank Group's applicable Environment, Health and Safety (EHS) guidelines, Biorisk Management: Laboratory Biosecurity Guidance (2006) and other relevant international guidelines besides the national legislation requirements.

6.12.2 Biosecurity

There is no legislation and/or regulations related to biosecurity that address requirements such as physical containment, operation practices, failure reporting systems, and/or cybersecurity of facilities in which especially dangerous pathogens and toxins are stored or processed in place in Serbia.

According to Global Health Security Index, Country Score Justifications and References, 2021: Biosecurity requirements such as physical containment, operation practices, failure reporting systems, and/or cybersecurity of facilities in which especially dangerous pathogens and toxins are stored or processed are not regulated by the Ordinance on Preventive Measures for Safety and Healthy Work with Biological Damages.

Currently, there is no regulation specify that security and other personnel with access to especially dangerous pathogens, toxins, or biological materials with pandemic potential are subject to background checks. However biosecurity management of BSL3 Laboratory will not allow unauthorized access to dangerous pathogens, toxins, or biological materials with pandemic potential.

The information regarding on the safe and secure transport of infectious substances has publicly available information based on the Law on the Transport of Dangerous Goods to oversee the cross-border transfer and end-user screening of especially dangerous pathogens, toxins, and pathogens with pandemic potential.

The Sub-project will include WHO Biorisk Management: Laboratory Biosecurity Guidance (2006, WHO/CDS/EPR/2006.6), ISO 35001: 2009 Bio-risk Management for Laboratories and concerned GIIP's to cover all biosecurity requirements.

6.13 Social Baseline Conditions

The social baseline conditions provided in this section are based on desk studies and fieldwork. People and organizations that will be indirectly affected by the Sub-project will also be interviewed to gather information on social baseline conditions.

Within the scope of social baseline and impact assessment studies, an online questionnaire survey was conducted among the employees working in Torlak, reaching 32 respondents. In addition, an interview with the representative of Kumodraz-1 neighbourhood; FGD with 10 local people (6 women, 4 men); interview with member of Municipality Council of Vozdovac Municipality; FGD with eight participants representing the academic and professional community. The technical participants represented the following institutions and associations: Faculty of Pharmacy, University of Belgrade; Faculty of Medicine, University of Belgrade; Faculty of Pharmacy, University of Novi Sad; Institute of Molecular Genetics and Genetic Engineering; Association for the improvement of clinical trials of Serbia KLINIS; Association of Pharmacists of Serbia. All of the technical participants have extensive knowledge and experience in the fields of immunology, microbiology, molecular genetics, and genetic engineering, some with specific knowledge on the functioning and design of BSL-3 and BSL-4 diagnostic laboratories. While FGD was held online with professionals, interviews with local people and representative were held face-to-face in Kumodraz-1 settlement. All face to face and online interviews and FGDs were conducted in Serbian by local social experts from May 18-22, 2023.

Site-specific data such as population, demographics, employment, education, services, land ownership, etc. have been collected through desk studies and field surveys. In addition, country-wide baseline information has been provided and demographic characteristics of Serbia and Belgrade are included in this section. The Social baseline was gathered by field surveys (community level questionnaires and interviews with stakeholders already identified in the SEP) and interviews with governmental organizations. The baseline data is used in the next chapters to identify impacts and mitigation measures and recommend communication practices with all stakeholders, including citizens.

6.13.1 Population and Demographics

The Republic of Serbia is located in South-Eastern Europe and covers the area of 88,361 km^2. Serbia shares a border with eight neighbouring countries as; Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Hungary, Montenegro, Romania and the Northern Macedonia (United Nations Economic Commission for Europe, 2007).

According to Statistical Office of the Republic of Serbia, the estimated population is 6,869,504 (2022). The total fertility rate (number of children per woman) equals 1.52. The birth rate equals 9.2‰, and the death rate equals 14.6‰. The population average age is 43.2 years. In 2022 the life expectancy for males equals 69.96 years, and for females 75.64 years. The average age of mother at giving first live birth is 28.6. The leading death causes, both for male and female population, are bloodstream system diseases (Statistical Office of the Republic of Serbia, 2019).

The official language is Serbian written in Cyrillic, although Latin script is also widely used. In the areas inhabited by ethnic minorities, the languages and scripts of the minorities are in official use (United Nations Economic Commission for Europe, 2007).

Basic population data for Voždovac Municipality are given in Table 6-35.

Table 6-35. Basic Population Data of Voždovac

	Voždovac	Year
Surface area (km^2)	148	(2020)
Number of settlements	4	(2020)
Mid-year population (estimation)	169695	(2021)
Population density (people per sq km)	1147	(2021)
Live births rate	11	(2021)
Deaths rate	17	(2021)
Natural increase rate	-6	(2021)
Life expectancy at birth (years)	76	(2021)
Average age (years)	43	(2021)
Ageing index (60+ yrs / 0–19 yrs)	133	(2021)
Average number of household members	2,65	(2011)
Population projections (medium variant with zero net migration)	138096	(2041)
Population projections (medium variant)	203727	(2041)

Source:Devinfo, *Municipalities and regions,* 2022

Table 6-36. Population by age and sex of Voždovac

Sex	Female	Male
Number of young population (15–29 years of age)	12824	12827
Working age population (15–64 years of age)	57792	52724
Total population	90450	79245

Source: Devinfo, Municipalities and regions, 2022

According to the information received during the interview with the official MZ representative, there are about 6,500 inhabitants on the territory of Kumodraž 1, approximately an equal number of men and women. According to the assessment of the respondent, there are around 1,200 households in Kumodraž 1 and these are mostly multi-member and multi-generational households, and the majority of the settlement consists of family houses. There were no significant changes in the population structure. As Roma people are among the Project stakeholders as a vulnerable group (see SEP), the MZ representative was asked about their status in the area. There are only a few Roma households in the settlement. There are no refugees in impact area.

6.13.2 Economy and Employment

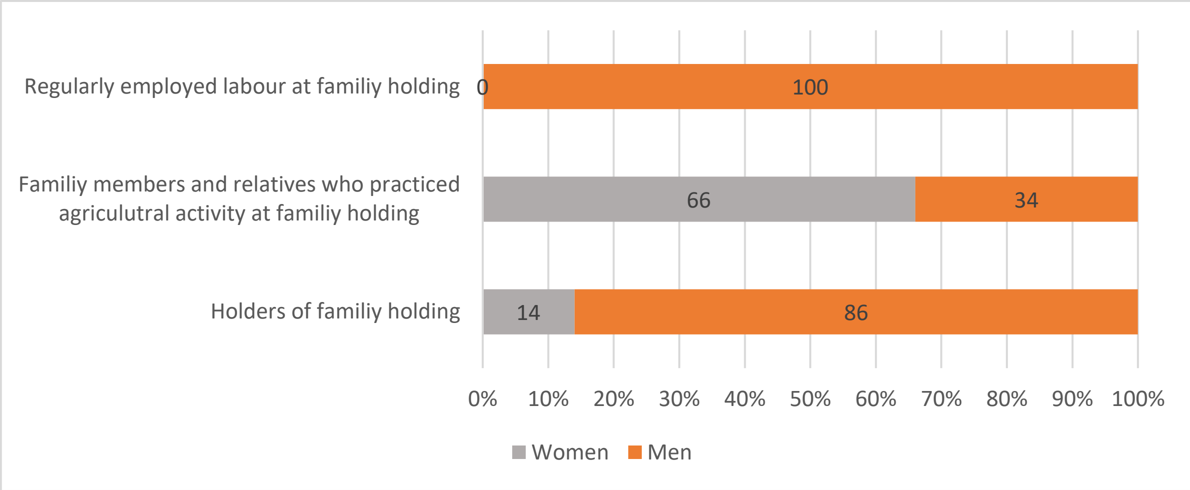
Serbia is one of the top 10 European countries that exports agricultural and food products (Public Policy Research Center, 2019). In 2018, the area of 754,048 ha was sown in the autumn sowing season, which in comparison to the final results of the autumn sowing season 2017 indicates a decrease by 7.3%. Observed by crop cultures, decreased values were noted for wheat (by 10.6%), barley (by 2.0%), ray (by 19.7%), oat (by 26.7%) and oilseed rape (by 17.2%). When related to the ten-year average of autumn sowing values (2008 – 2017), the areas under wheat are larger by 0.5% (Statistical Office of the Republic of Serbia, 2019).

In 2018, the average gross salaries and wages amounted to RSD 68,629, while the average net salaries and wages (tax and contributions excluded) amounted to RSD 49,650. Related to 2017, the average gross salaries and wages increased by 6.0% in nominal terms, and by 3.9% in real terms, while the average net salaries and wages (tax and contributions excluded) increased by 6.5% in nominal terms, and by 4.4% in real terms. In 2018 the total number of registered employed amounted to 2,131,079, presenting increase of 3.3% if related to 2017. In comparison to the year 2017 the number of employed persons increased in all regions. The employment growth rate was most expressive in Region Vojvodine (4.1%), while the lowest growth rate was notable in Region Južne i Istočne Srbije (1.8%).

The largest share in individual consumption of households goes to expenditures for food and non-alcoholic beverages by 34.3% and housing, water, electricity, gas and other fuels by 16.7% (Statistical Office of the Republic of Serbia, 2019).

Registered employees by municipality of Vozdovac of residence are 58,518, while registered employees by municipalities of residence are 67,547. 5,913 people are registered as unemployed. The number of registered unemployed per 1,000 inhabitants is 35. The average net salary is RSD 86,175. There are 5,666 active companies and 8,213 active entrepreneurs in Voždovac.

There are 1675 agricultural enterprises and 5,629 agricultural family enterprises.



Source: Devinfo, *Municipalities and regions,* 2022

Figure 6-27. Labour force in agriculture by sex, in 2012, in %

According to Devinfo (2022), a total area of municipality of Vozdovac 2,572.6 ha is used for agricultural production, of which 1,353.6 ha is cultivable land, 979.6 ha is meadow and pasture and 164.8 ha is fruit plantations.

Registered animals in the Municipality of Voždovac: 584 cattle, 5,103 pigs, 2,132 sheep and 46,193 poultry, totalling 54,012.

According to the information received during the interview with the official MZ representative, a large part of the residents of the Kumodraž 1 works at the Torlak Institute; part of the population works in other public companies (mostly in “Gradska čistoća” and Public transit company), and part of the population works in private companies. The unemployment rate is low in this settlement.

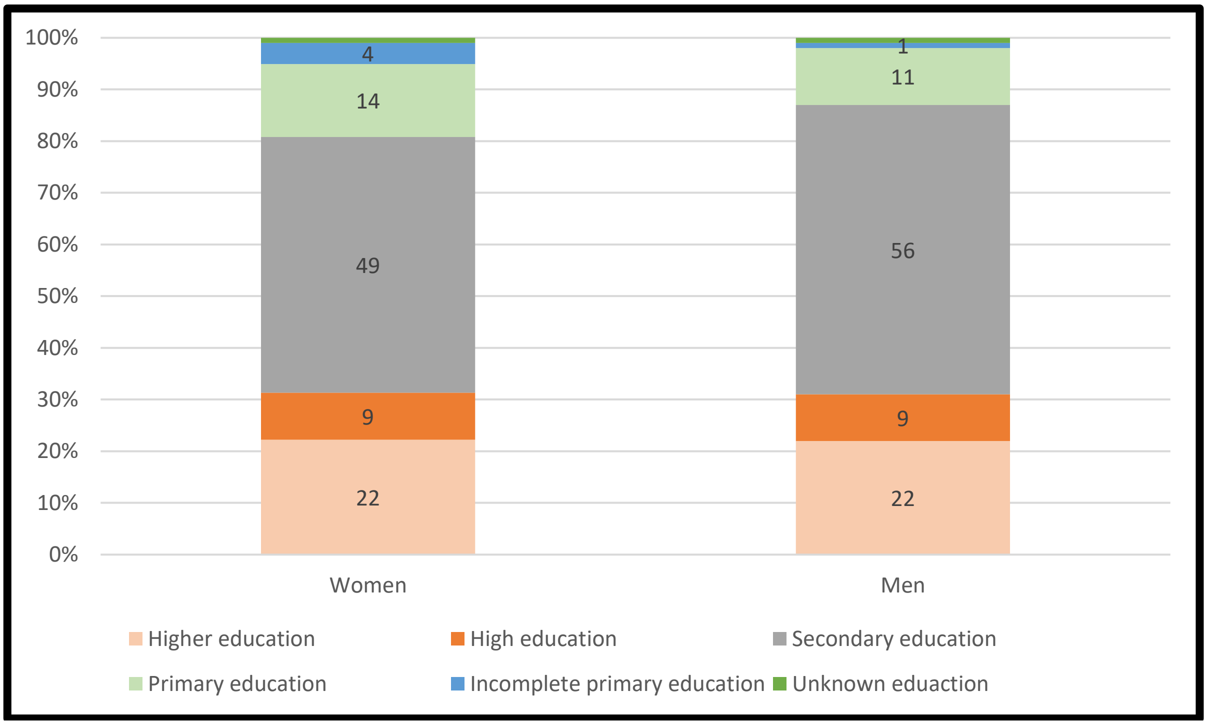
6.13.3 Education and Health

The health care system in Serbia is based on a network of public health institutions funded by the National Health Insurance and from the state budget. Access to public health institutions is subject to health insurance. Preventive and curative services are provided at the local level in primary health care centres. Secondary medical care is offered in paediatric departments of local and regional general hospitals or outpatient clinics, and in specialized hospitals for children or adults. Tertiary medical care is provided by inpatient or outpatient subspecialty services in 5 major university children’s clinics (Bogdanovic, Lozanovic, Milica, & Jovanovic, 2016).

The average life expectancy of Serbian people is 75.9 years, where for males it is 73 years and for females 79 years. The death rate is estimated to be 13.6 death per 1000 people and the birth rate is 8.6 births for every 1000 people. The fertility rate is pretty low being 1.44 children per woman and takes 208th place in the world rating (Central Intelligence Agency, 2018).

According to Devinfo (2022) there are 151 doctors in Voždovac, with 0.9 doctors per 1,000 inhabitants.

Participation in education in the Municipality of Voždovac by age and gender is given in the Figure 6-28.



Source: Devinfo, Municipalities and regions, 2022

Figure 6-28. Population aged 15 and over by educational attainment and sex, 2011

According to the information received during the interview with the official MZ representative, there is one elementary school in Kumodraž 1, which is 500m away from the Torlak Institute. There is one state-owned and one private-owned kindergarten. According to local people who participated in the FGD, the respondents points out that this is not enough for the number of children in their neighbourhood and children from the surrounding neighbourhoods (that also attend kindergarten in their neighbourhood). There is one ambulance in the settlement.

6.13.4 Infrastructure Services

Electricity, water, wastewater, and transportation infrastructure of the Sub-project area already exist, therefore construction of any associated facility is not foreseen.

- Electric Power Distribution Belgrade (Belgrade PE) provides electricity distribution for 2,839 square meters, spreading over the entire territory of Belgrade, excluding the municipality of Lazarevac.

- Regarding natural gas distribution, Srbijagas delivers the services for the residents in Belgrade. Heating and Hot Water Systems is under the control of Belgrade Power Plants.
- Belgrade Waterworks and Sewerage is the organisation responsible for providing infrastructural services for water and sewerage systems in Belgrade province.

The water quality control is performed according to the valid of rules on hygienic accuracy of drinking water[20] that defines requirements for control performance concerning type of analyses, number of samples, place and time of sampling. The rulebook is harmonized with EU directives and recommendations of WHO. The modern equipped laboratories perform physical, chemical, microbiological and biological analyses of parameters as prescribed. Water from production plants is controlled every day, from water tanks once a week, and from consumers' taps on working days, 45 samples a day, according to the sampling schedule. At the Belgrade city area, 190 tapping locations that are controlled twice a month, and on the basis of these analyses we have an insight into water quality. Along with the water quality control performed at Belgrade Waterworks, there is a water control at the Institute for Public Health (the third level). Almost the two-third of consumed water is underground water[21]. The average water consumption per capita in Serbia is approximately 321 l/capita/per day[22].

According to local people who participated in the FGD, the electrical infrastructure is adequate. The electrical infrastructure of Kumodraž 1 is connected to the Torlak Institute;

- Drinking, household and irrigation water – adequate.
- Sewerage network – inadequate, but at this moment the works on the sewerage network are being completed, after that, Kumodraž should have an adequate sewerage network.
- Internet – adequate.
- Road quality – adequate. In previous years, the streets were renovated.
- Since 2010, a gas network has been built in the settlement and part of the households are heated with gas.

6.13.5 Cultural Heritage

Cultural heritage can be considered as site, structure, and remains of archaeological, historical, religious, cultural, and aesthetic value. It is important to assess the site to understand the significance of a site and to provide due protection according to its aesthetic, historic, scientific, and social value.

20 The Rulebook on Hygiene Safety of Drinking Water ("Official Journal of the FRY" No. 42/98)
21 Belgrade Waterworks and Sewerage
22 SDG 6 Clean Water and Sanitation Report, December 2020-March 2021

There is no cultural property registration record that needs to be protected in the area where the Sub-project will be built. However, as in any excavation work, it is possible to come across a cultural heritage item by chance. "Chance Find Procedure" added to the Sub-project's ESIA, and project staff will receive training on this procedure.

Chance find procedure has been prepared according to the following guidelines:

- Law on Cultural Property, dated 1994;
- ESS8: Cultural Heritage;
- European Convention on the Protection of the Archaeological Heritage (Valletta Agreement, 1992) (Ratification date: 05 August 1999);
- Convention concerning the Protection of the World Cultural and Natural Heritage (Paris, 1972) (Ratification date: 14 February 1983).

6.13.6 Land Ownership

The Sub-project Area belongs to the Project Owner and there are already Torlak Institute buildings in the area according to Cadastral Plan. The Sub-project Area is completely surrounded by fence. During the interviews with the representatives of the Project Owner, it was stated that the land is in public ownership. There are no informal or formal users on the land. No land acquisition will be required under the Sub-project. Similarly, there will be no physical and/or economic displacement under the Sub-project.

6.13.7 Vulnerable Groups

Vulnerable/disadvantaged individuals or groups refers to individuals and groups that are likely to be more vulnerable to Project-related impacts. Persons to which adverse project impacts may disproportionately fall on or those likely to be excluded/unable to access Project benefits. Such groups may often do not have a voice to express their concerns or understand the impacts of a project. The vulnerability may stem from person’s origin, gender, age, health condition, economic deficiency and financial insecurity, disadvantaged status in the community (e.g. minorities or fringe groups), dependence on other individuals or natural resources, etc. Engagement with the vulnerable groups and individuals often requires the application of specific measures and assistance aimed at the facilitation of their participation in the project-related decision-making so that their awareness of and input to the overall process are commensurate to those of the other stakeholders. The vulnerable groups identified for the Sub-project are as follows:

- **Front line health staff:** They may be exposed to direct exposure during the operation phase of the project. They are more likely to be affected by OHS risks than other employees.

- **Women staff:** They may be exposed to direct exposure during the operation phase of the project. Women staff may be more likely to be affected by issues such as exposure to SEA/SH and working in the laboratory during pregnancy period.
- **Staff with disabilities:** They may be exposed to direct exposure during the operation phase of the project.
- **Retired elderly and people with disabilities and chronic diseases in home lockdown and disabled people:** Their access to participation activities may be limited due to certain constraints. Their direct participation in decision-making process should be encouraged.
- **Households below poverty line that could not afford medicine, private doctors services, adequate nutrition:** They may be more affected by exposure to any impacts (dust, noise, traffic, unexpected accidents, etc.) during both the construction and operation period of the project / these impacts may take more time to be reversed.
- **Single parent headed households, male and female (with children up to 14 years; without some other relatives in the household):** Single parents are more likely to live in poverty when compared to cohabiting couples, and single mothers are much more likely to be poor when compared to single fathers. Special attention should be paid to the single parent in decision-making processes.
- **Homeless and** Roma population living in unhygienic settlements (enclaves) without water facilities, sewage, improvised houses**;** They are more sensitive to any potential negative impacts from the project.
- **Waste pickers:** It is important that they participate in consultation processes against diseases that can be transmitted from waste.

In the field work, vulnerable group screening will be carried out in community level surveys. The approach to vulnerable/disadvantaged individuals or groups in order to minimise any impacts arising from the Sub-project is included in the Stakeholder Engagement Plan.

According to the information received during the interview with the official MZ representative, it is estimated that there are approximately 100 socially vulnerable people in Kumodraž 1. However, a small number of residents of this local community receive social assistance. There are certain number of people who are also in a poor financial situation and who need help, but because they own property (the house they live in) they do not meet the conditions for receiving social assistance. Also, there are several people with disabilities in the settlement. There is a small number of elderly households in the settlement because the elderly mostly live in extended households (with their children and grandchildren).

6.13.8 Information Disclosure

The Sub-project was disclosed to the public by the Serbian Ministry of Health through its website[23]. In the ESIA phase, a study has been conducted on the level of stakeholders' knowledge about the Sub-project and the ways in which they prefer to access information. For this purpose, interviews were held with 10 local people and local community representative, apart from professionals and municipality official.

Local people and community representative did not have any information about the laboratory during the fieldwork process. Many of the participants were confusing BIO4 Campus with BSL-3 Laboratory. The Sub-project brochure was presented to the participants and a brief explanation was provided during the interviews and FGDs to get their opinions, concerns and questions.

During the fieldwork, the most serious concern of the local community was the traffic and parking problem. They do not think that a construction to be made within the Torlak Institute, which is surrounded by a fence and has been in this area for years, will have another impact.

During the interview the local community representative pointed out that this is the first time he has been able to express their concerns about the construction to be done in their settlement.

The demand from the local community was to share the calendar of the works to be done during the construction period with them. They requested to reach this information through the local community representative through official channels.

A public participation meeting (PPM) was organised after the Scoping Report was finalised. The meeting was originally scheduled for 5 May 2023 in person but due to unusual circumstances in Serbia (the attack on Vladislav Ribnikar primary school in Belgrade and the shooting in the village of Dubona) it was held online.

The information from this meeting has contributed to the ESIA report. After the ESIA report is disclosed, a second PPM was organised and the impacts discussed in the ESIA and the measures to be taken to address them were shared with stakeholders. The consultation during ESIA was also enable the stakeholders to have awareness on the feedback mechanisms proposed by the Sub-project. The PCU social specialist prescribes the procedure for public consultations and ensures that all important requests are fulfilled.

Please see Chapter 10.5 for more detail.

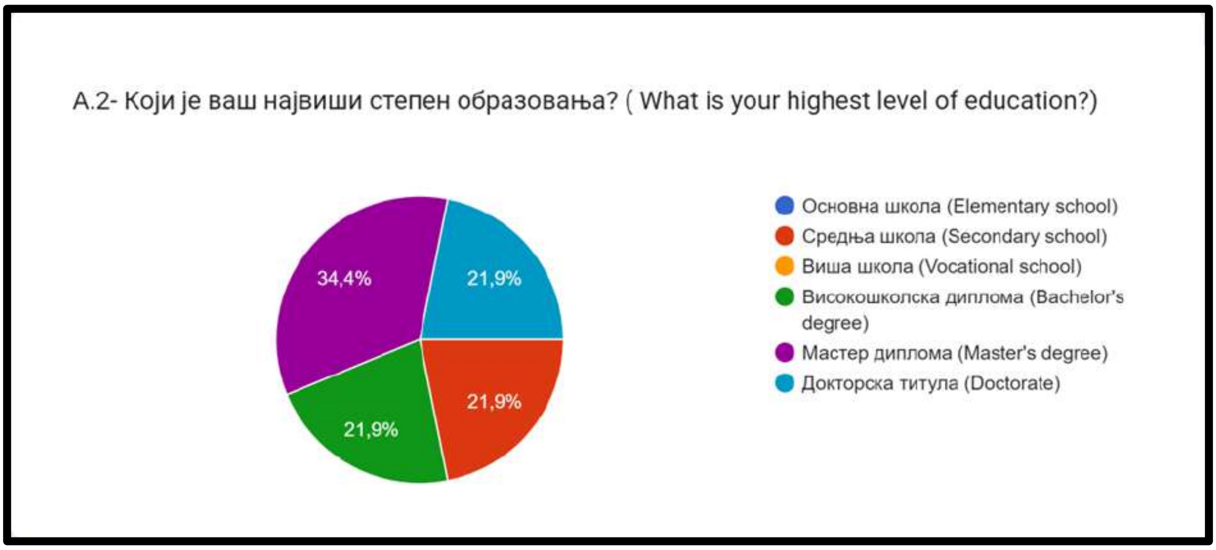
[23] https://www.zdravlje.gov.rs/vest/372445/projekat-izgradnje-dijagnosticko-istrazivackog-objekta-sa-laboratorijom-treceg-nivoa-bioloske-bezbednosti-u-okviru-instituta-za-virusologiju-vakcine-i-serume-torlak.php

All participants in the SEP will invited to stakeholder engagement activities throughout the life of the Sub-project, including but not limited to: project staff, citizens, government agencies, NGOs, nearby communities, vulnerable groups/individuals.

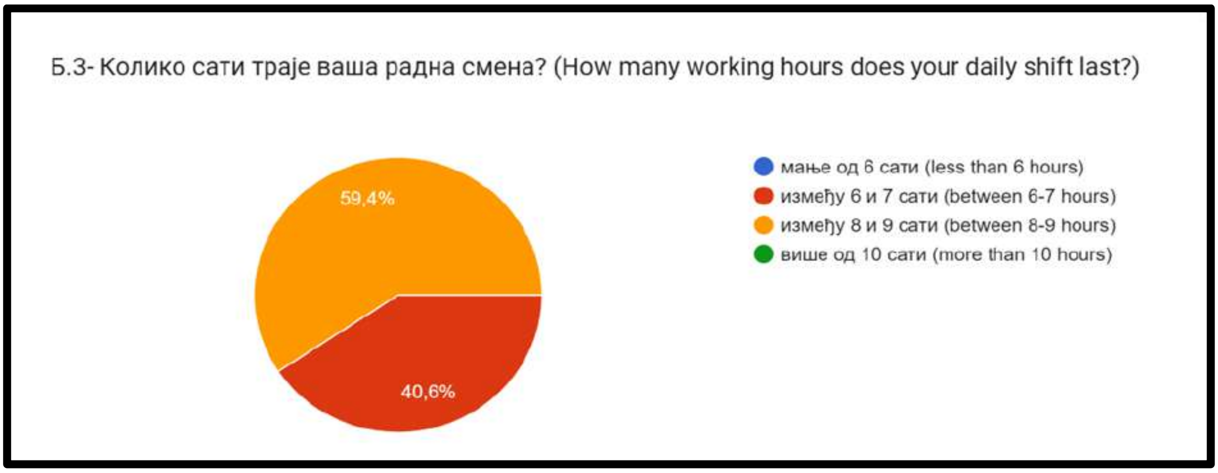
6.13.9 Labour and Working Conditions

In order to gather baseline information on labour and working conditions at Torlak Institute, a questionnaire survey was conducted with 32 current employees. In this research, none of'the employees' identity information was requested and they approved the consent form. The findings obtained according to this study are as follows.

Of the 32 respondents, 8 were male and 24 were female. While 75 per cent of all respondents have 11 years or more of professional experience, 59.4 per cent of the respondents have been working at Torlak Institute for more than 11 years. The graph showing their educational background is given below.

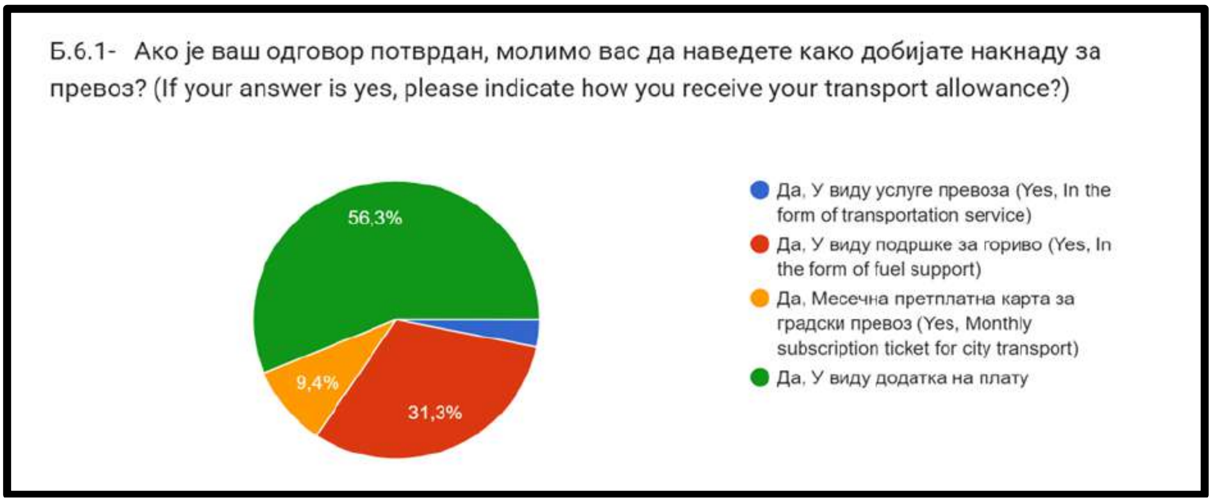


All of the participants stated that they signed a contract with all their rights and responsibilities before they started working and that they were aware of all their rights as workers. Working hours at the Institute are given below.



When asked about their overtime rights, 25 per cent of the participants stated that they did not receive overtime pay even if they worked overtime, 43.8 per cent stated that they received overtime pay, and 31.3 per cent stated that they did not work overtime. At the Institute, overtime hours are determined by scanning personal cards into the system.

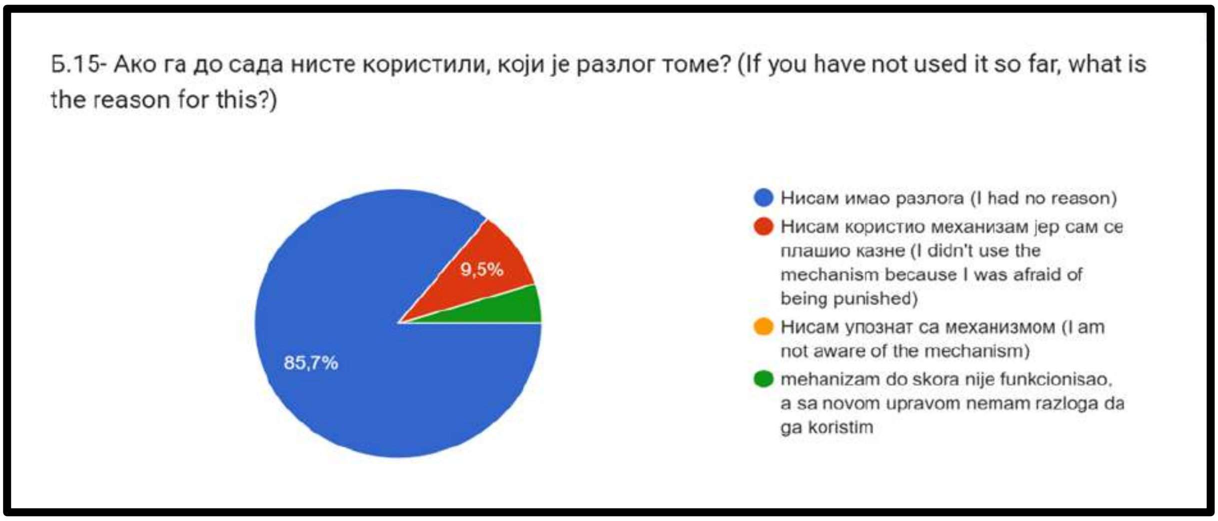
All employees receive support for transport. The distribution of the support received is as follows.



Employees were asked about workers' access to shower and toilet facilities. More than 70 per cent of workers said they had access to these facilities. About 30 per cent said that shower and toilet facilities often malfunctioned. They also stated that the number of showers and toilets is insufficient. Employees also stated that showers and toilets are cleaned adequately and at regular intervals. There are common areas where employees can spend their free time. In this area, there are facilities such as cooker, tableware, refrigerator, table and chairs. All of the participants indicated that they had annual holidays.

84.4 per cent of the participants are not members of any trade union. When asked about the reason for this, almost all of the non-unionised employees stated that they were not members by their own choice.

The number of participants who stated that they know that there is a mechanism for resolving complaints at the workplace is 21. However, none of the 21 respondents has ever used the mechanism. The reasons for not using it are given below.



In the question about sexual abuse, harassment or workplace harassment in the workplace, 31 participants stated that they had not encountered such an incident. 1 participant stated that he/she had encountered such an issue before and nothing was done to resolve it.

In the next section, the participants were asked questions about OHS practises. 31 of the participants stated that they received regular OHS training. 30 participants stated that warning signs and notices were sufficient. In addition, 29 participants stated that personnel protective equipment (PPE) was sufficient. 26 participants stated that their job descriptions included health monitoring. According to the participants, health monitoring is carried out once a year.

Participants were asked whether they had experienced health problems since they started working at the Institute. 3 people stated that they had, one person stated that they had psychophysical problems due to the intense workload during the covid period, one person stated that they had heart problems, and one person stated that they had heart problems and hearing problems.

More than 80 per cent of the participants stated that they had sufficient information about the BSL-3 Laboratory to be established. They think that they will be in a safer laboratory while working with pathogens and that the laboratory will contribute to their professional development. They also stated that such a nationwide laboratory would be an important development. The negative impact on the workplace is stated as a potential increase in workload.

7 ENVIRONMENTAL AND SOCIAL RISKS, IMPACTS AND MITIGATION MEASURES

In this chapter all relevant environmental and social risks and impacts of the Sub-project is taken into account. Environmental and social risks and impacts specified in ESS 1-10, except ESS 5, ESS 7 and ESS 9 which are not relevant to the Sub-project, as well as other environmental and social risks and impacts that may arise as a result of the specific feature and context of the Sub-project are determined together with the risks and impacts specified in paragraph 28 of ESS-1. E&S risks and impacts are elaborated separately for construction and operational phases and given in Table 7-1.

Table 7-1. Environmental and Social Impacts

Relevant ESS	E&S Impacts
ESS2	Occupational health and safety Child labour, forced labour and unregistered employment SEA/SH induced impacts Labour and working conditions (worker rights, emergency situations, health risks) Grievance mechanism
ESS3	Air quality and climate Water and wastewater Resource efficiency Waste Noise Chemicals and hazardous materials Soil pollution
ESS4	Traffic Emergency situations, health risks Life and fire safety Community health and safety Potential impacts on vulnerable/disadvantaged groups/individuals; Potential impacts on community perception, health, safety and security
ESS6	Habitat loss
ESS8	Chance finds
ESS10	Employment opportunities; Local procurement. Potential impacts on community perception Grievances

Mitigation measures and significant negative residual impacts that cannot be mitigated are identified and the acceptability of these negative residual impacts is evaluated to the extent possible.

Differentiated measures are established so that adverse impacts do not disproportionately affect disadvantaged or vulnerable groups.

The applicability of environmental and social mitigation measures, the capital and current expenditures of the proposed mitigation measures, their compliance with local conditions, as well as institutional, training and monitoring requirements for the proposed mitigation measures, are evaluated.

Considerations that do not need further attention are determined and the justifications for this determination are presented.

7.1 Geology and Soil Quality

7.1.1 Introduction

The Sub-project activities related to geology and soil quality have the potential to cause significant impacts on the environment and human health. During the construction and operational phases of the Sub-project, various activities such as excavation, transportation, and disposal of soil may affect soil properties. The purpose of this section is to assess the impacts of the Sub-project activities on geology, soil, and contaminated land and to propose appropriate mitigation measures to minimize adverse effects on the environment and human health.

The impact assessment was conducted based on the best available scientific and technical information and was carried out in compliance with national and international regulations and guidelines. The assessment considers the baseline conditions of geology, soil, and contaminated land, including the presence of hazardous substances and the sensitivity of the receptors. The assessment also evaluates the potential impacts of the Sub-project activities on soil, geology and topography, and land use.

The following sources of information were used during the assessment:

- Existing environmental studies and reports related to geology, soil, and contaminated land;
- Site investigation reports;
- National and international regulations and guidelines related to soil and water quality, geology, and contaminated land;
- Best practices and industry standards related to soil and water management and remediation.

The significance criteria for the impact assessment were based on the magnitude and sensitivity of the impacts. The methodology for the determination of impact intensity, receptor sensitivity, and criteria to identify impact significance was established based on the specific characteristics of the Sub-project and will be described in detail in Section 7.1.3 of this chapter.

Overall, the impact assessment of geology and soil quality provide a comprehensive evaluation of the potential impacts of the Sub-project activities on the environment and human health. The assessment enables the identification of appropriate mitigation measures to minimize adverse effects and to ensure the sustainable management of the geology and soil quality.

7.1.2 Legal Context

7.1.2.1 National Regulations on Geology and Soil Quality

- The Law on Environmental Protection. Published in the Official Gazette of the Republic of Serbia. 135/04, 36/09, 36/09 (other law), 72/09 (other law), 43/11 (US), 14/16, 76/18 and 95/18 (other law):

  In order to protect the natural values and environment, special laws and other regulations are governed such as protection of air, water, soil, forests, geological resources, waste management and so on.

  Protection of land area and its sustainable use shall be achieved through the measures of systematic monitoring of land quality, monitoring of indicators for the assessment of risk of land degradation, as well as through the implementation of remediation programs for removing consequences of land contamination and degradation, regardless if they occur naturally or are caused by human activities.

- Law on soil protection 112/2015:

  This Law regulates soil protection, systematic monitoring of condition and quality, rehabilitation measures, remediation, recultivation, inspection and other issues of importance for protection and conservation of soil as a natural resource of national interest.

- Regulation on systematic monitoring of soil condition and quality 67/2018;

  This Regulation defines Soil Monitoring Program, methodology for systematic monitoring of soil quality and condition, criteria for determining the number and layout of measurement sites, list of parameters for the particular soil type, list of methods and standards used for soil sampling, samples analysis and processing, extent and frequency of measurements, indicators for assessing the risk of soil degradation, deadlines and method of delivery data.

- Regulation on limit values for pollutant, harmful and dangerous substances in soil 30/2018 and 64/2019;

  This regulation prescribes limit values for pollutants, harmful and dangerous substances in soil and groundwater which summarized in Table 7-2.

Table 7-2. Limit Values in Soil and Groundwater

Substance	Limit value in soil (mg/kg)	Limit value in groundwater (µg/L)
Arsenic	20	10
Cadmium	3	5
Chromium	100	50
Copper	100	2000
Lead	100	10
Mercury	0.1	0.1
Nickel	100	20
Zinc	300	5000

- Law on Protection Against Natural Disasters 92/2015

  The law requires the development of seismic hazard maps and the implementation of seismic design standards for new buildings and infrastructure. Additionally, the "Regulation on Technical Norms for Design and Construction in Seismic Areas (73/2018)" provides technical guidance for the design and construction of buildings in areas prone to seismic activity.

7.1.2.2 International Regulations on Geology and Soil Quality

- WB's ESS 1 Assessment and Management of Environmental and Social Risks and Impacts
- WB's ESS 4 Community Health and Safety
- IFC's General EHS Guideline 1.8 Contaminated Land
- IFC's General EHS Guideline 1.5 Hazardous Material Management
- Stockholm Convention on Persistent Organic Pollutants (Ratification date: 14 May 2004)

7.1.3 Impacts

The significance criteria that are used for assessing impacts on geology, soils and sediments are established by identifying the impact magnitudes and the sensitivity/vulnerability/ importance of the resources. The magnitude and sensitivity criteria related to the geology, soil and sediment are summarized in Table 7-7 and Table 7-8.

Table 7-3. Magnitude of Impacts on Geology and Soils

Magnitude	Description
Negligible	- Temporary use of barren land for the storage of excavated materials and construction equipment with no or little impact that is recoverable within a short time scale. - No impacts on the integrity of structures and functionality of the Project from earthquake loads.

Magnitude	Description
Low	- Small-scale oil/chemical spills during construction and during operation (e.g., accidents) activities on soils that lead to contamination below limit values for pollutant, harmful and dangerous substances in soil stated in Regulation 30/2018 and 64/2019. - Small-scale spills during construction and during operation (e.g., accidents) activities on sediments that lead to contamination below limit values for pollutant, harmful and dangerous substances in soil stated in Regulation 30/2018 and 64/2019. - Minor impacts on the integrity of structures and functionality of the Project (e.g., minor cracks in the structures) from earthquake loads. - In case of disturbance of existing contaminated soils: Increase contamination in nearby non-contaminated soils to slightly above the background level but below the limit values for pollutant, harmful and dangerous substances in soil stated in Regulation 30/2018 and 64/2019.
Moderate	- Moderate oil/chemical spills during construction and during operation activities on soils and during operation (e.g., accidents) (concentrations of pollutants in the soil exceed the limit values for pollutant, harmful and dangerous substances in soil stated in Regulation 30/2018 and 64/2019 but below long-term cancer and hazard risk). - Moderate spills during construction and during operation (e.g., accidents) activities on sediments that lead to contamination below limit values for pollutant, harmful and dangerous substances in soil stated in Regulation 30/2018 and 64/2019. - Moderate impacts on the integrity of structures and functionality of the Project (e.g., major cracks on the structures) from earthquake loads. - In case of disturbance of existing contaminated soils: Increase contamination in nearby non-contaminated soils to above the background level and above the limit values for pollutant, harmful and dangerous substances in soil stated in Regulation 30/2018 and 64/2019.
High	- Major oil/chemical spills during construction and during operation activities on soils and during operation (e.g., accidents) (concentrations of pollutants in the soil exceed limit values for pollutant, harmful and dangerous substances in soil stated in Regulation 30/2018 and 64/2019 to cause long-term cancer and hazard risk). - Major spills during construction and during operation (e.g., accidents) activities on sediments that lead to contamination below limit values for pollutant, harmful and dangerous substances in soil stated in Regulation 30/2018 and 64/2019. - Major impacts on the integrity of structures and functionality of the Project (e.g., collapse of the buildings) from earthquake loads. - In case of disturbance of existing contaminated soils: Increase contamination in nearby non-contaminated soils to above the background level and above the limit values for pollutant, harmful and dangerous substances in soil stated in Regulation 30/2018 and 64/2019, and contamination results from hazardous wastes.

There are no applicable national standards regarding the soil classification in Serbian Law or Regulation. Therefore, for the assessment of the soil classification for the Sub-project, IFC soil classification system is used. The IFC Soil Classification System has six classes, which are based on the soil's ability to support different types of land use and management practices. The classes are:

- Class A: Suitable for most land use and management practices, with no limitations.

- Class B: Suitable for most land use and management practices, with moderate limitations.
- Class C: Suitable for some land use and management practices, with significant limitations.
- Class D: Suitable for few lands use and management practices, with severe limitations.
- Class E: Not suitable for most land use and management practices, with very severe limitations.
- Class F: Not suitable for any land use or management practices, with extremely severe limitations.

Table 7-4. Geology and Soils Resource Sensitivity/Vulnerability/Importance According to IFC Soil Classification System

Value	Description	IFC Soil Classification
Negligible	Soils with negligible permeability Areas with no seismic risk Areas with no potential for groundwater recharge	Class E, Class F
Low	Soils with low permeability Areas with low seismic risk Areas with low potential for groundwater recharge	Class C, Class D
Medium	Soils with medium permeability Areas with medium seismic risk Areas with medium potential for groundwater recharge	Class B
High	Soils with high permeability Areas with high seismic risk Areas with high potential for groundwater recharge	Class A

The Sub-project area is located within the karstic aquifer which is susceptible to contamination due to the rapid transport of pollutants through the interconnected network of conduits and fractures. For this reason, the geology and soils resource sensitivity/vulnerability/importance were determined as medium.

7.1.3.1 Impacts during Construction

Construction of the Sub-project will not expose significant volumes of the earthworks in the scope of the Sub-project. Though relevant measures are required to be taken into consideration, in order to avoid significant impacts on the soil environment.

The sedimentary sequence which the Sub-project Area is located is interrupted by several faults that are part of the North-South trending Serbian-Macedonian tectonic zone, which is characterized by a high degree of tectonic activity.

The potential impacts of the land preparation and construction activities on the soil environment are summarized as;

- Disturbance such as loss of fertile top layer;
- Mixing of soil layers and types; and
- Soil contamination due to unexpected leakages or spills.

In case of not implementing the mitigation measures, topsoil itself or its vegetative properties in the Sub-project Area may be lost due to mixing with coarse or contaminated soils. Thus, topsoil management measures will be applied in the scope of the Sub-project.

Besides that, soil quality sampling during excavation works will be conducted in the construction phase of the Sub-project in case any contamination is identified. If any contamination is detected during construction works, soil sampling studies will be conducted, and remediation plan will be prepared according to the sampling study results in line with type of the contaminants.

Table 7-5 shows the summary of the conclusions mentioned above and the impact significances for the monitoring points in the Construction Phase of the Sub-project. Impact significances are determined based on the methodology given in Chapter 5 of this ESIA Report.

Table 7-5. Summary of Impact Significances of the Receptors during the Construction Phase-Geology, Soil Quality

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							Receptor Sensitivity	Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)		
Land Degradation and Soil Loss	Negative Direct	Definition	Potential contamination due to accidental spills of oil, fuel, or chemicals or due to poor material management and handling (e.g., poor storage conditions, deposition of chemicals or wastes on barren land) of chemicals, wastes or construction materials is expected to be limited to the area of the Sub-project	Unless proper mitigation measures are taken contamination and combined impacts may continue depending on the nature of the potential pollutants	Potential contamination of sediment is expected to create contaminant concentrations above the national legislative limit values some impairments might be expected regarding environmental elements	-	In the case of poor management, handling and storage of chemicals, construction material and/or fuel accidental releases are considered	Potential impacts will be evaluated to be reversible in the short- to mid-term with treatment and rehabilitation activities	Medium	**Low**
		Score	Sub-project Area	Short	Low	NA	Likely	Short/Mid-term		
		Value	1	2	2	-	3	2		
	Impact Magnitude (G+D+I+F (or L)) x R		**10**						**3**	**30**
Soil Pollution caused by Construction Activities	Negative Direct	Score	Local	Short	Low	NA	Likely	Short/Mid-term	Medium	**Low**
		Value	2	2	2	-	3	2		
	Impact Magnitude (G+D+I+F (or L)) x R		**11**						**3**	**33**

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)								
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)	Receptor Sensitivity	Impact Significance (Magnitude x Significance)
Impacts related to seismic risk	Negative Direct	Definition	Potential seismic risks and relevant impacts during the Sub-project construction are evaluated to be on a regional scale considering potential adverse impacts on the health and safety of the workers	The duration of potential impact is considered to be less than 1 year period.	In the case of an earthquake of PGA around 0.3g, moderate impacts are expected on the integrity of structures and functionality of the Sub-project works and associated facilities	-	Depending on the relatively short duration of the construction works the probability of a high-intensity earthquake is evaluated as unlikely, i.e., event is unlikely but may occur at some time during implementation	An earthquake disaster with moderate impact during the construction phase is considered to have potential impacts that can be restored within weeks or months after the incident.	Medium	**Low**
		Score	Regional	Short-term	Medium	NA	Unlikely	Short-term		
		Value	3	2	3	-	1	1		
	Impact Magnitude (G+D+I+F (or L)) x R		**9**						**3**	**27**

The table shows the overall rating of the impacts before and after mitigations. Land degradation, soil loss and soil pollution caused by construction activities are considered low since the magnitude and the receptor sensitivity of the impacts are determined as medium. For potential earthquake related impact, the design of the Sub-project to took consideration of national requirement while conducting seismic design and risk assessment of the Sub-project. In addition, construction specific emergency preparedness and response plan will be adopted throughout the construction phase.

7.1.3.2 Impacts during Operation

During the operation phase, soil contamination risks may be caused by the improper handling of the hazardous materials to be generated in operation activities and leakage/spill of fuels, chemicals, etc. during the unexpected accidents. In that case, the associated impacts would be similar to the impacts described for the construction phase and a similar mitigation strategy would be adopted for the mitigation of potential impacts.

Last, seismic risks would be of concern for the entire operational life of the Sub-project thus further evaluation on the potential risks and mitigation approaches is provided below.

Table 7-6. Summary of Impact Significances of the Receptors during the Construction Phase-Geology and Soil Quality

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							Receptor Sensitivity	Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)		
Soil Pollution caused by Operation Activities	Negative Direct	Definition	Potential contamination due to accidental spills of oil, fuel, or chemicals or due to poor material management and handling (e.g., poor storage conditions, deposition of chemicals or wastes on barren land) of chemicals, wastes or construction materials is expected to be limited to the area of the Sub-project	Unless proper mitigation measures are taken contamination and combined impacts may continue depending on the nature of the potential pollutants	Potential contamination of sediment is expected to create contaminant concentrations above the national legislative limit values some impairments might be expected regarding environmental elements	-	In the case of poor management, handling and storage of chemicals, construction material and/or fuel accidental releases are considered	Potential impacts will be evaluated to be reversible in the short- to mid-term with treatment and rehabilitation activities	Medium	**Low**
		Score	Local	Short	Low	NA	Likely	Short/Mid-term		
		Value	2	2	2	-	3	2		
	Impact Magnitude (G+D+I+F (or L)) x R		**11**						**3**	**33**

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							Receptor Sensitivity	Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)		
Impacts related to seismic risk	Negative Direct	Definition	Seismic risks during the Sub-project operation are evaluated to be on a regional scale considering potential combined incidents such as accidents, spills, fire, etc. related to the seismic incident along with the damage to the Sub-project structures.	The duration of potential impacts is expected to be medium.	In the case of an earthquake of PGA over 0.3g, moderate impacts are expected on the integrity of structures and functionality of the Sub-project, unless proper measures are taken.	-	The operation phase is planned to continue for long years. Hence, an earthquake with moderate damage potential is likely to occur during operation.	An earthquake disaster with moderate impact during the operation phase is considered to have potential impacts that can be restored within one year after the incident through restoration.	Medium	**Medium**
		Score	Regional	Medium	High	NA	Likely	Short/Mid-term		
		Value	3	3	4	-	3	2		
	Impact Magnitude (G+D+I+F (or L)) x R		**26**						**3**	**78**

The Sub-project site mainly comprises permeable which is classified as karstic. Hence, the vulnerability of soil matrix can be taken as medium. During operation, soil may be contaminated from spills of hazardous materials, poor management of hazardous wastes generated at the site and leakage from underground pipes used for wastewater discharges. The resulting impact magnitude is determined as low to medium depending on the magnitude and duration of the adverse events.

7.1.4 Mitigation Measures

Mitigation measures to avoid and/or mitigate the potential impacts and risks regarding site stability and earthquake hazard are listed below:

- The Sub-project will be designed, constructed, and operated in accordance with the Law on Protection Against Natural Disasters (92/2015) and The Regulation on Technical Norms for Design and Construction in Seismic Areas (73/2018) for protection against seismic activity. For the design and construction all technically and financially feasible best practices will be followed to minimise relevant risks;
- Construction and decommissioning works shall be conducted in line with the IFC General EHS Guideline regarding the measures on the environmental and health and safety measures;
- In line with the IFC General EHS Guideline hazardous material inventories on site will be reduced through inventory management in order to reduce or eliminate the potential off-site consequences of releases during an earthquake or other emergency incidents;

Specific measures for the protection of soil during the construction and operation phases will include the following:

- In the construction stage, before the start of the excavation and construction activities, soil stripping will be undertaken to remove the surface soil or topsoil (vegetation, fertile soil layer) and subsoil. During soil stripping, necessary precautions will be taken to keep them separately intact. Top and subsoil will be deposited separately, and long-term erosion and sedimentation will be prevented through rehabilitation/planting;
- It is expected that one or joint venture of two or three companies will be designated as contractors after the completion of a bidding process. Nevertheless all contractors will be required to adopt good construction practices at the site for the protection of soils and follow WB’s General EHS Guidelines;
- Proper drainage systems shall be created which will remove the underground-, surface- and wastewater from the site.
- Contaminated soils (if generated any) will be disposed of in an appropriately licensed disposal site;
- Regarding the prevention, impact minimisation and response to contaminated land the requirements by IFC’s General EHS Guideline 1.8 Contaminated Land will be followed;

- In line with the preferred strategy of the reduction of the contamination level (EHS Guideline 1.8 Contaminated Land), the storage of chemicals, hazardous materials, and other potential contaminants will be kept at a minimum as practically feasible for construction and operation works;
- The use of cement and wet concrete in or close to any exposed soil surfaces will be carefully managed;
- Regarding the management of the hazardous material the requirements by IFC's General EHS Guideline 1.5 Hazardous Material Management will be followed;
- Drummed hazardous materials with a total volume equal to or greater than 1,000 L will be stored on areas with an impervious floor. The floor of the storage area should be designed with a slope to enable proper drainage and with a spill, leak collection system capacity to contain a minimum of 25 % of the total storage volume. Drip trays will be used for fuelling areas for mobile equipment;
- Appropriate secondary containment structures consisting of berms, dikes, or walls capable of containing at least 110% of the largest tank or 25% of the combined tank volumes will be provided. Secondary containment will be made of impervious, chemically resistant material;
- Any spillage from handling fuel and liquids will be immediately contained on site and the contaminated soil will be removed from the site for suitable treatment and disposal;
- A Spill Response Plan as a part of Emergency Preparedness and Response Plan should be prepared which include;
  - Risk Assessment: A thorough risk assessment should be conducted to identify potential hazards and risks associated with the operation. This includes natural disasters, equipment failure, hazardous material spills, and other emergencies that may arise;
  - Contingency Planning: A contingency plan should be developed to deal with potential emergencies that cannot be prevented, including the identification of alternative suppliers, production process, and transport options in case of critical equipment failures or shutdowns.
  - The locations of spill response equipment and procedures to be used and ensure that procedures are clear and concise;
  - Step-by-step instructions for the response to spills at a facility;
  - Individuals responsible for implementing the plan;
  - Safety measures to be taken with each kind of waste;
  - How to notify appropriate authorities, such as police and fire departments, hospitals, or municipal sewage treatment facilities for assistance;
  - Procedures for containing, diverting, isolating, and cleaning up the spill;

- Spill response equipment to be used, including safety and clean-up equipment;
- The spill response plan should be announced to all employees.

7.1.5 Residual Impacts

With the implementation of above-mentioned mitigation measures and use of good site practices, the magnitudes and significances of the residual impacts can be estimated to be negligible. The assessment of the magnitudes and significances of the residual impacts after mitigation measures are shown in Table 7-7 and Table 7-8 respectively.

Table 7-7. Construction Phase Residual Impact Significances-Geology and Soil Quality

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							Receptor Sensitivity	Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)		
Land Degradation and Soil Loss	Negative Direct	Score	Sub-Project Area	Short	Negligible	NA	Unlikely	Short/Mid-term	Medium	**Negligible**
		Value	1	2	1	-	1	2		
	Impact Magnitude (G+D+I+F (or L)) x R		7						**3**	**21**
Soil Pollution caused by Construction Activities	Negative Direct	Score	Local	Short	Negligible	NA	Unlikely	Short/Mid-term	Medium	**Negligible**
		Value	2	2	1	-	1	2		
	Impact Magnitude (G+D+I+F (or L)) x R		**7**						**3**	**21**
Impacts related to seismic risk	Negative Direct	Score	Regional	Short	**Low**	NA	Unlikely	Short-term	**Medium**	**Negligible**
		Value	3	2	**2**	-	1	1		
	Impact Magnitude (G+D+I+F (or L)) x R		**9**						**3**	**27**

Table 7-8. Operation Phase Residual Impact Significances-Geology, Soil and Contaminated Land

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							Receptor Sensitivity	Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)		
Soil Pollution caused by Oper Activities	Negative Direct	Score	Local	Short	Low	NA	Unlikely	Short/Mid-term	Medium	**Negligible**
		Value	2	2	2	-	1	2		
	Impact Magnitude (G+D+I+F (or L)) x R		9						**3**	**27**
Impacts related to seismic risk	Negative Direct	Score	Regional	Short	low	NA	Unlikely	Short-term	Medium	**Negligible**
		Value	3	2	2	-	1	1		
	Impact Magnitude (G+D+I+F (or L)) x R		**9**						**3**	**27**

7.2 Water and Wastewater Management

7.2.1 Introduction

In this section, water and wastewater management of the Sub-project's construction and operation phases will be detailed.

In this context, water requirement of the Sub-project both phases will be met from city water network. The average specific water consumption per capita in the Republic of Serbia in towns and cities is approx. 400 litre per day, National Program for Environmental Protection, 2010. In addition to this, it assumed that all water originating from workers/employees will be transformed into domestic wastewater.

7.2.2 Legal Context

7.2.2.1 National Regulations on Water Resources and Wastewater Management

Law on Waters (Official Gazette of RS, No. 30/10, 93/12, 101/16, 95/18, 95/18 - other law) is the general law on water in Serbia. On the other hand, the regulations on water and wastewater during both construction and operation phases of the Sub-project are detailed below.

- Regulation on the method and conditions for measuring the quantity and testing the quality of wastewater and the content of the report on the measurements (Official Gazette of RS, No. 33/16)
- Regulation on the content and form of requests for the issuance of water acts, the content of opinions in the procedure for issuing water conditions and the content of reports in the procedure for issuing a water permit (Official Gazette of RS, No. 72/17, 44/18 – other law, 12/22)
- Regulation on determining the cases in which it is necessary to obtain a water permit (Official Gazette of RS, No. 30/17)
- Regulation on the hygienic suitability of drinking water (Official Gazette of RS, No. 42/98, 44/99, 28/19)

7.2.2.2 International Regulations on Water Resources and Wastewater Management

The concerned international regulations on Water Resources and Wastewater Management are follows.

- Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (Official Journal/Date: L327/22.12.2000; Entry into force: 22.12.2000; last amended on 20.11.2014);

- Council Directive 91/271/EEC of 21 May 1991 concerning urban wastewater treatment (Official Journal/Date: L135/30.05.1991; Entry into force: 19.06.1991; last amended on 01.01.2014);
- World Bank Group EHS Guidelines applicable to Water and Sanitation;

7.2.3 Water Use and Potential Water Supply of the Sub-Project

The existing water network of the existing Torlak Institute will be used as the water source for both phases of the Sub-project.

It is planned that Sub-project's construction works last approximately six (6) months and about 40 workers are expected to be involved in construction works.

$$400 \, {}^{litre}/_{person.day} \times 40 \, person = 16 \, {}^{m^3}/_{day}$$

Thus, it is estimated that approximately 16 m^3 /day water consumption during the construction phase of the Sub-project.

The new diagnostic laboratory building will be constructed in left and right wings and 4 floors with a total area of approximately 4,200 m^2. Assuming the direct water consumption for a building construction (including excavation works, brickwork, cement plastering, curing, flooring, finishing, carpentry, cleaning, etc.) is 0.5 to 0.6 m^3/m^2 (Rajeev Garg, 2022) and the construction activities will be conducted for 25 days a month for 6 months, approximately 14-17 m^3/day water consumption is expected during the construction of the Sub-project.

As for the operation phase, 25 people are planned to be employed throughout the operation phase of the Sub-project.

$$400 \, {}^{litre}/_{person.day} \times 25 \, person = 10 \, {}^{m^3}/_{day}$$

Hence, it is expected to consume about 10 m^3 /day water during the operation phase of the Sub-project.

7.2.4 Wastewater Production

Wastewater is also referred to as sewage, includes water from household or building use (such as toilets, showers, and sinks) that can contain human fecal waste, as well as water from non-household sources.

Assuming that all water originating from workers/employees will be transformed into domestic wastewater, 16 m^3/day for construction phase and 10 m^3/day for operation phase domestic wastewater are expected to be generated during corresponding phases of the Sub-project. On the other hand, Sub-project as BSL-3 laboratory is intended to be constructed as dry-lab.

Liquid waste per day is expected to be about five (5) litres and chemical decontamination of liquid waste is foreseen during the operation phase of the Sub-project.

7.2.5 Impacts

7.2.5.1 Impacts during Construction

Water will be met from drinking and potable water within six (6) months construction period. Hence, characterization of generated wastewater originating from workers is mainly domestic.

Table 7-9 shows the summary of the conclusions mentioned above and the impact significances for water and wastewater management of the Sub-project's construction phase. In this respect, concerned impact significances are determined based on the methodology given in Chapter 5 of this ESIA Report.

Table 7-9. Summary of Impact Significances during the Construction Phase- Water and Wastewater Management

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Reversibility (R)	Receptor Sensitivity (S)	Impact Significance (Impact Magnitude x Sensitivity)
Water and Wastewater Impacts Due to Construction Activities	Negative Direct	Definition	Considering potential impacts during the construction activities the geographical extent of the impact is expected to be local.	Water and wastewater impacts will continue during the six (6) month construction period of the Sub-project.	The main wastewater source is workers.	Water and wastewater impacts will continue throughout the construction phase of the Sub-project.	Due to the water usage, wastewater potential and their intensities, the relevant impacts are expected to be reversible in the short/mid-term.	Due to the potential nature and intensity, the relevant impacts are expected to be medium.	Low
		Score	Local	Short	Medium	Continuous	Short/mid-term	Medium	
		Value	2	2	3	5	2	3	
Impact Significance = [Impact Magnitude (G+D+I+F (or L)) x R] x S			24					3	**72**

Considering potential impacts during the construction activities and the geographical extent of the impact for six (6) month construction period, water usage, wastewater impacts are expected to be reversible in the short/mid-term and impact significance is expected to be low.

7.2.5.2 Impacts during Operation

The Sub-project as BSL-3 laboratory is intended to be constructed as dry-lab. However, it has been stated by the project representatives that approximately five (5) litres of liquid waste are expected per day, the liquid waste will be autoclaved and disposed as non-hazardous waste. Hence, other than domestic wastewater originating from employee, wastewater will be generated during the life of the Sub-project due to laboratory operation activities.

Table 7-10 shows the summary of the conclusions mentioned above and the impact significances for water and wastewater management of the Sub-project's operation phase. In this context, concerned impact significances are determined based on the methodology given in Chapter 5 of this ESIA Report.

Table 7-10. Summary of Impact Significances during the Operation Phase- Water and Wastewater Management

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Reversibility (R)	Receptor Sensitivity (S)	Impact Significance (Impact Magnitude x Sensitivity)
Water and Wastewater Impacts Due to Operation Activities	Negative Direct	Definition	Considering potential impacts during the operation activities the geographical extent of the impact is expected to be local.	Water and wastewater impacts will continue for more than five (5) years throughout the life of the Sub-project.	The main wastewater sources are employees and laboratory activities throughout the operation phase of the Sub-project.	Water and wastewater impacts will continue throughout the operation phase of the Sub-project.	Due to water usage, wastewater potential and their intensities, the relevant impacts are expected to be reversible in the short/mid-term.	Due to the potential nature and intensity, the relevant impacts are expected to be medium.	Medium
		Score	Local	Very Long	High	Continuous	Short/mid-term	Medium	
		Value	2	5	4	5	2	3	
Impact Significance = [Impact Magnitude (G+D+I+F (or L)) x R] x S			32					3	**96**

Considering potential impacts during the operation phase and the geographical extent of the impact for lifetime of the Sub-project, water usage, wastewater impacts and wastewater related risks, impact significance is expected to be medium.

7.2.6 Mitigation Measures

During the construction phase of the Sub-project, domestic wastewater will be generated only from drinking and potable water. Thus, with an assumption that all used water will be converted to domestic wastewater, daily approximately 16 m^3/day domestic water from workers will be directed to the current sewage network or stored in impermeable septic tank as wastewater to be transferred with authorized septic trucks and sent to be disposed of at nearest WWTP deemed appropriate by the authority. Thus, considering the wastewater quantity in the construction phase of the Sub-project, the wastewater impact significance is determined as low. Also, a stormwater and wastewater drainage and collection system will be established on site to collect and manage uncontaminated and contaminated drainages separately.

As for the operation phase of the Sub-project as BSL-3 laboratory, it is intended to be constructed as dry-lab. However, liquid waste per day is expected to be about five (5) litres and the liquid waste will be autoclaved and disposed as non-hazardous waste. In this respect, the design criteria of the Sub-project will be adhered to the mitigation measures detailed below, despite the small amount of liquid waste generation.

<u>Laboratory Design in Wastewater Management</u>

Due to the varying risk of biological agents, the facilities that handle these agents need to be designed and classified according to specific special wastewater treatment specifications. There are common elements to the design and operation of wastewater treatment systems for BSL3 facilities. These fixtures include restroom lavatories, sinks located in the laboratories and the anterooms, and the floor drains located.

The number of taps and sinks should be reduced to the minimum needed, as they are error prone and might cause accidental flooding of the laboratory. All individual floors must be equipped with water barriers to avoid any flooding of adjoining parts of the building in case the sprinkler system or water-based extinguishers are used. Thus, sensors to detect water on the floors must be installed at the appropriate place and height. All sinks must drain their effluent into containers or into a validated on-site waste effluent treatment plant, which then must be autoclaved before draining it into the public sewage system. A double-door autoclave is best for handling individual sewage containers. To avoid overflow of the sewage containers, they also should be sensor controlled. The amount of wastewater to be autoclaved increases dramatically when air conditioning systems are installed inside the laboratory. Thus, it is more convenient and practical to chill down air outside the laboratory before it passes the first filter of the laboratory ventilation system. The energy input for precooling may even be lower than the energy input for air conditioners and additional autoclaving of condensate. Furthermore, any wastewater also needs to be autoclaved or otherwise treated for disinfection before leaving the laboratory. All technical systems must be controlled electronically by sensors and technical faults must be recorded and reported immediately to well-trained technical staff. Discharge of sanitary wastewater and wastewater from utility operations treatment systems should:

- Meet the pre-treatment and monitoring requirements of the sewer treatment system into which it discharges.
- Not interfere, directly or indirectly, with the operation and maintenance of the collection and treatment systems, or pose a risk to worker health and safety, or adversely impact characteristics of residuals from wastewater treatment operations.
- Be discharged into municipal or centralized wastewater treatment systems that have adequate capacity to meet local regulatory requirements for treatment of wastewater generated from the Sub-project.
- Pre-treatment of wastewater to meet regulatory requirements before discharge from the Sub-project site is required if the municipal or centralized wastewater treatment system receiving wastewater from the Sub-project does not have adequate capacity to maintain regulatory compliance.

Practices in Wastewater Management for the Torlak Institute

Belgrade is served by a public sewer line for effluent management. Wastewater and effluent are a potential source of heavy metals and other inorganic and organic wastes. The presence of these wastes in an aquatic ecosystem adversely affects it’s biological, physical and chemical characteristics and thus the capacity to support aquatic life. For this reason, such wastes should be treated as required prior to release into the sewage system. Torlak Institute will discharge its treated effluents into existing sewage network. It is expected that the laboratory discharges effluents of approximately 5 litres per day. Also, it is planned that there is shower in exit personal air lock for only in case of accident, it is special shower with tank for collecting wastewater from showering and it will be chemical decontamination inside of that collecting tank. The emergency eye and body-wash should meet the criteria of ANSI/ISEA Z358.1-2014 for Emergency Eyewash and Shower Equipment. As the standard requires approximately requires 88 litres for per wash (eye and body), the capacity of collecting tank for liquid waste should be around 120 litres capacity.

The full capacity of the existing collecting tank system in Torlak Institute serving the entire laboratory complex has sufficient capacity to accommodate additional effluent from the proposed facilities. The effluent system should ensure the liquid waste and wastewater is uniformly mixed using pumping or gravity. The pump-fed Effluent Decontamination Systems (EDS) can be used if the tanks are not located underground or in a cellar. To regulate the passage of effluent into the collection tanks, pumps are utilized.

The collecting tank decontamination process will be designed to be completely automated. When wastewater reaches to a predetermined level (75% of the tank's usable volume), it should be disposed. A radar closes the wastewater valve on top of the collecting tank. The same radar controls the inlet of disinfectant concentrate until the validated concentration is reached. Disinfectant is sprayed into the spaces at the top of the collecting tank using a spray nozzle connected to the in-house disinfection system. Continuous stirring with a magnetic agitator ensures that the disinfectant is distributed evenly throughout the tank. Samples for evaluating the effectiveness of the inactivation can be collected at various times via a sampling outlet. The final liquid waste is discharged into the municipal sewage system if it complies with national and international regulations.

In summary, in Torlak Institute, the complex will have two separate wastewater networks for management of BSL3 activity related waste effluent (from emergency shower, sink) and domestic waste effluent. The BSL3 activity related waste will be collected into a leak proof storage tank whose filling capacity will be auto monitored so as not to exceed ¾ full. The wastewater will then be chemically decontaminated.

<u>Monitoring wastewater</u>

A wastewater and water quality monitoring program with adequate resources and management oversight should be developed and implemented to meet the objective(s) of the monitoring program. The monitoring program should consider the following elements:

- The monitoring parameters should indicate the pollutants of concern from the process, and should include parameters that are regulated under compliance requirements;
- The monitoring locations should be determined according to the bio risk assessment for the work carried out.
- The monitoring programs should apply internationally approved methods for sample collection, preservation, and analysis.

Monitoring of all critical physical and chemical parameters guarantees compliance with legal requirements at any time. For biosafety reasons, the room containing the wastewater and HEPA-filter stations is part of the BSL3 containment. Within the laboratory, lab staff have to wear full personal protective equipment (PPE). As a preventive measure against the potential release of aerosols, the wastewater inactivation department will be integrated into the pressure cascade of the containment shell. Under standard operation conditions, this room can only be entered through the safety laboratory and the appropriate safety rules must be followed. As note, wastewater surveillance will be performed, and data collected first at the Institute level and analysed appropriately by the EHS (Environmental Health and Safety) and biosafety committee. The Center for Disease Control (CDC for USA) produced a policy and method for screening SARS-CoV-2 in wastewater. CDC recommends conducting these processes with a precautions, including respiratory protection and a designated area to don and doff personal protective equipment. Laboratory waste from wastewater samples that may contain SARS-CoV-2 will be autoclaved and managed in accordance with BSL guidelines. Additionally, the monitoring of wastewater will be conducted against waterborne infective agents such as;

Legionella spp., gram-negative bacteria present in potable water as P.aeruginosa, Pseudomonas spp., Burkholderia cepacia, Ralstonia pickettii, Stenotrophomonas maltophilia, Nontuberculous Mycobacteria and finally for Cryptosporidium parvum.

Domestic wastewater from diagnostics building with BSL3 will be connected to Torlak wastewater infrastructure and then discharged to municipal sewerage system in line with Decree on the limit values of pollutants in water and deadlines for their reach (Official Gazette of RS, No. 67/11, 48/12, 1/16).

As policy, Torlak Institute will have trained EHS personnel to conduct routine monitoring and surveillance of the wastewater management system (as a part of waste management system) working together with biosafety committee at the complex. For wastewater, the officers will be responsible for collecting wastewater samples, for isolation of indicator organisms which ideally are not naturally found in the environment, at several sampling points including medical wastewater storage tank, after the wastewater autoclaving and solid particle filtration systems. Analyses integrated into existing Torlak Institute will be carried out in-house. Currently, the existing Torlak Institute monitors the wastewater quality by conducting an analysis every 3 months. Sampling and Analysis Quality Assurance/Quality Control (QA/QC) plans will be prepared and implemented. QA/QC documentation will be included in monitoring reports. In addition, Torlak will have a dedicated maintenance unit that will be responsible for routine maintenance of the wastewater management system.

7.2.7 Residual Impacts

The extent of impact on water and wastewater is local with medium intensity during the construction phase. The duration is also expected to be short as there is continuous source of water usage and contamination. Intensity can be higher if good management or housekeeping is not fully implemented (i.e. wastewater tank overflow etc.). The residual impact of water and wastewater will be negligible with the necessary mitigation measures to be taken and good water and wastewater management practices during the construction phase.

The potential impact for water and wastewater will be local for very long term and with high intensity throughout the operation phase of the Sub-project. Intensity can be higher if good waste management is not fully implemented (i.e. poor water and wastewater management etc.). In this respect, the residual impact of waste is expected to be low with the necessary mitigation measures to be taken during the operation phase of the Sub-project.

In this context, Water and Wastewater Management Residual Impact Significances for the construction and operation phases of the Sub-project are presented in Table 7-11 and Table 7-12.

Table 7-11. Construction Phase Residual Impact Significances- Water and Wastewater Management

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Reversibility (R)	Receptor Sensitivity (S)	Impact Significance (Impact Magnitude x Sensitivity)
Water and Wastewater Residual Impacts Due to Construction Activities	Negative Direct	Definition	Considering potential impacts during the construction activities the geographical extent of the impact is expected to be local.	Water and wastewater impacts will continue during the nine (9) month construction period of the Sub-project.	Water and wastewater impact intensity will be lowered with taking aforementioned mitigation measures during the construction phase of the Sub-project.	Water and wastewater impact frequency will be lowered with taking aforementioned mitigation measures during the construction phase of the Sub-project.	Due to the water usage, wastewater potential and their intensities, the relevant impacts are expected to be reversible in the short term.	Due to the potential nature and intensity, the relevant impacts are expected to be medium.	Negligible
		Score	Local	Short	Low	Single event	Short-term	Medium	
		Value	2	2	2	1	1	3	
Impact Significance = [Impact Magnitude (G+D+I+F (or L)) x R] x S			7					3	**21**

Table 7-12. Operation Phase Residual Impact Significances- Water and Wastewater Management

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Reversibility (R)	Receptor Sensitivity (S)	Impact Significance (Impact Magnitude x Sensitivity)
Water and Wastewater Residual Impacts Due to Operation Activities	Negative Direct	Definition	Considering potential impacts during the operation activities the geographical extent of the impact is expected to be local.	Water and wastewater impacts will continue for more than five (5) years throughout the life of the Sub-project.	Water and wastewater impact intensity will be lowered with taking aforementioned mitigation measures throughout the operation phase of the Sub-project.	Water and wastewater impact frequency will be lowered with taking aforementioned mitigation measures throughout the operation phase of the Sub-project.	Due to water usage, wastewater potential and their intensities, the relevant impacts are expected to be reversible in the short term.	Due to the potential nature and intensity, the relevant impacts are expected to be medium.	Low
		Score	Local	Very Long	Low	Single event	Short-term	Medium	
		Value	2	5	2	1	1	3	
Impact Significance = [Impact Magnitude (G+D+I+F (or L)) x R] x S			10					3	**30**

7.3 Waste Management

7.3.1 Introduction

As a result of the use of resources, construction, and operation/maintenance activities as well as domestic requirements of the personnel, different types of waste will be generated throughout the life of the Sub-project.

In this section, all waste impacts that may occur during the construction works of the Sub-project, including the land preparation period, and during the operation phase of Torlak Institute are discussed. Following subsections determine magnitude of waste related impacts to the environment and how to manage, reduce or prevent them with recommended mitigation measures.

All the waste to be generated during the land preparation and construction and operation phases of the Sub-project are required to be properly managed in line with the requirements of Serbian waste management legislation and international good practice in order to avoid impacts on soils, nearby water resources and flora and fauna elements. This Chapter identifies the waste to be generated in this context and assesses the impacts associated with waste generation. Waste management measures to be applied in accordance with relevant Serbian regulations and international standards (i.e. WBG EHS Guidelines) are also described in this Chapter. The potential impacts on the physical, biological, and socio-economic environment in the construction and operation phases of the Sub-project, as well as measures to prevent/minimize these effects have been elaborated in detail.

The possible sources that will generate various type of waste are listed below:

- Municipal solid waste,
- Packaging waste such as wood, paper, cardboard, and plastic etc.
- Hazardous and special wastes that may be generated within the scope of the land preparation and construction and operation phases of the Sub-project can be listed as contaminated vessels, cloths and overheads, waste batteries and accumulators, waste oils etc.
- Excavation and construction waste,
- Laboratory related waste.

Waste to be generated in the scope of Sub-project activities will be managed in accordance with the waste management hierarchy as given in Figure 7-1. In this respect, waste generation will be avoided/prevented at the source. In cases where prevention is not possible at the source, respectively; minimization of waste generation, selection of materials that will not cause generation of hazardous waste as much as possible, separate collection of waste according to their type (hazardous, non-hazardous, recyclable, etc.), reuse of generated wastes at site as much as possible, assessment of alternatives such as recycling and energy recovery for waste (where reuse is not possible) will be considered. The final step in the hierarchy of waste management involves the final disposal of wastes in accordance with relevant regulations, where reuse, recycling and energy recovery options are not possible.

Figure 7-1. Waste Management Hierarchy

Belgrade is the largest city in Serbia and its capital, with a population of about 1.7 million people. According to 2022 census data, the population in the inner-city area has increased by about 10 %, which doesn't have significant influence on daily amount of generated waste per capita.

The Public Utility Company "Gradska čistoća" is the only provider of municipal solid waste services, e.g., collection, transportation, and disposal. The waste collection service of the company is organized in ten functional units located on correspondent municipality (Popović, Filipović, & Božanić, 2012).

In the Republic of Serbia, there is no systematically organized separate collection, sorting, and recycling of municipal waste. Although the source separation in the Republic of Serbia is determined by law and envisages the separation of plastic, paper, glass and metal in specially marked containers, separate collection does not work in practice, except sporadically in some local governments *(Waste Management Program of the Republic of Serbia for the Period 2022-2031).*

The existing facility as Torlak institute has an in-house developed "Waste Materials and Waste Management Policy" for the waste management in line with Serbian legislation. The concerned policy is defined including waste management plan for wastes with or without special treatment (waste material handling, storage and finally care), who is responsible for waste management and her/his duties.

The operation of the BSL3 facility will generate different types of wastes (liquid and solid) in nature and general and hazardous in categorization. The wastes will emanate from the different activities in the BSL3 facility. The wastes will be infectious waste and non-infectious in nature and will include, but is not limited to, cultures and stocks of infectious agents, pathological wastes, waste human blood and blood products, sharps used in patient, biological laboratory wastes among others. In general, the hazardous waste will be generated primarily from the BSL3 laboratory facility including its onsite support laboratories. All wastes generated in the laboratories of the facility would leave the laboratories only after being autoclaved. The office functions and occupation will generate mainly domestic waste. Decontamination can be done by autoclaving, but the method and the protocol must be based on a risk assessment and be properly validated. Decontamination and final disposal are closely interrelated. Decontamination procedures and waste management are part of the risk assessment. Solid waste landfills may accept autoclaved wastes for disposal depending on their individual waste acceptance criteria and operating permit requirements. The space to be decontaminated would be sealed, personnel would be excluded, and the gas would remain in the space for several hours before release to the environment. This procedure would be conducted by an authorised technician using a standard protocol which would also specify the frequency of treatment. The quantities of chemicals used would be well below the reportable/acceptable amount (if available and determined by the Institute biosafety committee). Only small quantities of these chemicals (sufficient for daily activities) would be present in the facility at any time due to an absence of storage space in BSL3 laboratories. These small quantities of chemicals would be used up during the research activities. Therefore, the proposed action would require very limited waste management at the existing facilities. Waste storage, treatment, discharge, and disposal would be the responsibility of BSL3 facility staff and would be in accordance with approved waste management procedures in place for operations at laboratories accessed under the proposed action.

7.3.2 Legal Context

7.3.2.1 National Regulations on Waste Management

- Law on Waste Management (Official Gazette of RS, No. 36/09 and 88/10, 14/16 and 95/18- other law) is the general law on waste in Serbia. On the other hand, the regulations on waste during both phases of the Sub-project are given below.Rulebook on Medical Waste Management ("Official Gazette of RS", No. 48/19)
- Regulation on storage, packaging, and labelling of hazardous waste (Official Gazette of RS, No. 92/10, 77/21)
- Rulebook on Conditions and Manner of the Collection, Transport, Storage and Treatment of Waste Used as Secondary Raw Material or To Generate Energy (“Official Gazette of the RS” No 98/10)

- Regulation on the form of the document on the movement of waste and instructions for its completion (Official Gazette of RS, No. 114/13)
- Regulation on the form of the document on the movement of hazardous waste, the form of the prior notification, the method of its delivery and the instructions for filling them in (Official Gazette of RS, No. 17/17)
- Regulation on the form of daily records and annual report on waste with instructions for its completion (Official Gazette of RS, No. 7/20, 79/21)
- Waste Management Program in the Republic of Serbia for the period 2022-2031 (Official Gazette of RS, No. 12/22)
- Regulation on the conditions, method, and procedure of waste oil management (Official Gazette of RS. No. 71/10)
- Regulation on the list of electrical and electronic products, measures prohibiting and limiting the use of electrical and electronic equipment containing hazardous substances, methods, and procedures for waste management of electrical and electronic products (Official Gazette of RS, No. 99/10)
- Regulation on the method and procedure for managing waste fluorescent tubes containing mercury (Official Gazette of RS, No. 97/10)
- Decree on products that become special waste streams after use, form of daily records on the quantity and type of manufactured and imported products and annual report, method and deadlines for submitting the annual report, obliges to pay the fee, criteria for calculation, amount and method of calculation and payment of the fee (Official Gazette of RS, No. 54 /10, 86/11, 15/12, 3/14, 95/18 - other law, 77/21)
- Law on packaging and packaging waste (Official Gazette of RS, No. 36/09 and 95/18)
- Rulebook on the management of waste containing asbestos ("Official Gazette of RS", No. 75/10)
- Rulebook on the content of documentation submitted in support of the application for the permit for import, export, and transit of waste ("Official Gazette of the RS" Nos 60/09 and 101/10)

7.3.2.2 International Regulations on Waste Management

Relevant Legislation in European Union about waste are Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (Official Journal/Date: L312/22.11.2008; Entry into force: 12.12.2008; last amended on 05.07.2018). Also, World Bank Group (WBG)'s Environmental, Health and Safety Guidelines (EHS) and EHS Guideline for Health Care Facilities include requirements regarding to the Sub-project on waste.

7.3.3 Waste Generation and Management

7.3.3.1 Waste Generation and Management during Construction

It is planned that construction works last approximately six (6) months. Approximately 40 workers should be involved in construction works. It is not planned to establish temporary worker accommodation area on Sub-project Area during construction phase.

Following waste materials are expected to be generated during the land preparation and construction phase of the Sub-project.

Excavation Materials: Wherever possible, materials excavated from excavation sites will be reused as fillers on the construction site or for reinstatement purposes. This will maximize the rate of use of materials on-site and reduce the need for off-site disposal. On the other hand, unsuitable soil from excavations is not expected to be generated in large quantities during the construction of the Sub-project.

If there is excess unsuitable excavation material, proper storage and evacuation of the material will be carried out in order to not carry the pollution to another location considering the high heavy metal values found in the soil during the baseline studies. When it needs to be moved to another location, it should be proved that it will not create pollution in that area by conducting soil and field analyses.

Domestic Waste: It is foreseen that there will be approximately 40 workers for the land preparation and construction phase of the Sub-project.

The domestic waste to be produced in the Sub-project Area will be collected and stored in containers placed at suitable points and the recyclable waste will be collected separately. These wastes will be collected periodically by licensed companies and sent to the nearest waste disposal facility.

In Serbia, municipal waste generated per person per day averages 1.17 kg *(Waste Management in the Republic of Serbia in the period 2011-2020; Environmental Protection Agency, 2021)*.

$$1.17\ {}^{kg}/_{person.day} \times 40\ person = 46.8\ {}^{kg}/_{day}$$

Thus, it is estimated that a total of 46.8 kg of domestic waste will be produced during the land preparation and construction phase of the Sub-project.

In summary, it is foreseen that the importance of the impact of domestic wastes to be produced during construction phase will be small as the generated wastes will be collected at certain intervals.

Waste Oil: During the land preparation and construction phase, waste oil originating from the maintenance of construction machinery, equipment and vehicles will be generated. Maintenance activities such as oil change of construction machinery and equipment will be carried out. Therefore, drip trays will be used to avoid soil pollution.

The waste oil produced required to be collected in safe sealed containers. It will be stored in an area with a concrete surface and in a suitable secondary container to prevent spills and leaks from reaching the soil and groundwater. Containers will be appropriately labelled. These labels will also indicate the amount of waste stored and the time of storage. If containers are damaged, waste will be transferred to other containers with the same characteristics.

It is recommended that the waste oil containers are kept in bounded areas; such that there will be a permeable wall around the oil storage areas to contain any spillage. Ideally, its volume required to contain 110 % of the oil stored there.

The transportation of wastes required to be carried out by persons and institutions licensed for this work and by means of the vehicles appropriate to the characteristics of the waste transported. These hazardous wastes will be sent to an arranged licensed facility. All health and safety precautions related to personnel responsible for activities such as transportation and temporary waste storage at the facility will be taken.

Other typical construction wastes will be stored temporarily onsite in appropriate containers and then transferred to and disposed of (or treated) via licensed waste facilities located in vicinity of the Sub-project. The waste facilities used during construction will be selected by the EPC contractor. The wastes that will be generated during the construction process include:

- Recyclable wastes: waste metals, plastics, cables, glass, paper (packaging material, clean air filters, clean containers, drums bins, crushed stone)
- Non-hazardous waste from construction operations (scrap metal)
- Hazardous waste (chemicals, additives, paints) generated from use of hazardous materials for construction,
- Machinery operation and maintenance related wastes (machinery parts replacement, used filters, etc),
- Waste batteries and accumulators,
- Medical waste (first aid operations).

7.3.3.2 Waste Generation and Management during Operation

25 people are planned to be employed throughout the operation phase. In Serbia, municipal waste generated per person per day averages 1.17 kg *(Waste Management in the Republic of Serbia in the period 2011-2020; Environmental Protection Agency, 2021)*.

$$1.17\ {}^{kg}/_{person.\,day} \times 25\ person = 29.25\ {}^{kg}/_{day}$$

Thus, it is estimated that a total of 29.25 kg of domestic waste will be produced during the operation phase of the Sub-project.

Other waste types expected to be generated throughout the operation phase of the Sub-project are detailed as follows.

Laboratory Cultures and Microorganism Stocks: This type of waste is expected to be generated predominantly from the BSL3/ABSL3 facilities, cell culture labs, microbiology and biotechnology laboratories, biobank, etc. The waste will include cultures and stocks of biological materials as infectious agents or microorganisms; cultures of medical and clinical specimens from pathology units; and receptacles and other potentially contaminated materials used in processing of microbial cultures and stocks.

Sharps: includes any sharp objects such as used blades, broken glass, syringes, needles (hollow or solid), pipettes, scalpel blades, vials, test tubes, lancets, microscope slides, covers slips, microtome blades and other such objects that would have been in contact with infectious or potentially infectious material.

Chemical Waste: includes, but not limited to most laboratory reagents, drugs, pharmaceutical products, organic and inorganic solvents, disinfectants such as hypochlorite, phenol, chloroform, formaldehyde, alcohols (ethyl alcohol, isopropyl alcohol, amyl alcohol, etc) and others.

Liquid Waste: Several laboratory procedures and functions require the use of water which is eventually discharged as potentially infectious / hazardous waste. This includes discharges from the sluice rooms and re-usable equipment wash units.

Domestic Liquid Waste: This will include wastewater and sewerage from the kitchens, rest rooms / lavatories, showers, and other areas outside the laboratories. The volume of waste is based on maximum occupancy of the facility, expected to be at around ¾ when fully operational.

Non-Hazardous Waste: Common waste in this category includes paper, newsprint, cardboard, plastic wrapping, and other non-infectious / non-contaminated materials. These materials will predominantly be generated from office functions and packaging materials for supplies.

In this context, the Sub-project as BSL-3 laboratory is intended to be constructed as dry-lab. All the laboratory consumables are planned to be for single use. Solid waste per day is expected be 20 kg and decontamination of solid waste is planned to be on site by autoclaving during the operation phase of the Sub-project. Expected Quantities of Waste and Methods of Treatment are detailed in Table 7-13.

Table 7-13. Expected Quantities of Waste and Methods of Treatment

Type of waste	Source facility/laboratory	Quantity of waste generated per day	Treatment Method
Infectious waste	Microbiology, biotechnology and biobank laboratories, vaccine production and experimental organism laboratories	20 kg / day	Infectious wastes are disinfected/sterilized as described in Standard operating procedures (SOPs) using appropriate method and equipment (ex. autoclave) according to risk assessment
Samples of Blood, Blood Products	Microbiology (ex. virus, bacteria, parasitology) biotechnology and diagnostic laboratory		Chemical disinfection, autoclaving (within the lab)
Sharps	Throughout all the laboratory activities		Sharps to be collected in puncture-proof sharps containers with nearby first-aid kit. When three-quarters full, the sharps containers will be disinfected/ sterilized or disposed as described in SOPs using appropriate method and equipment (ex. autoclave) according to risk assessment
Chemical Waste	Throughout all the laboratory activities		Chemicals will be collected and disposed as described in its Safety Data Sheet (SDS) document and Chemical Safety Group. The expired pharmaceutical products to be returned to supplier or disposed of at the facility.
Liquid Waste:	Throughout all the laboratory activities	5 litres / day	The waste is directed to a wastewater collecting tank for both storage and treatment in the complex. Infectious wastes are disinfected / sterilized as described in SOPs using appropriate method and equipment (ex. autoclave) according to risk assessment. The treated wastewater will be discharged into the existing sewage network.
Domestic Liquid Waste	Rest rooms, lavatories, showers, kitchens	10,000 litres/day	The domestic wastewater will be discharged into the existing sewage network.
Municipal waste as Non-Hazardous Waste:	Office areas, BSL3 facility, support laboratories	29.25 kg / day	Non-hazardous wastes would be sent to disposal after segregating

7.3.4 Impacts

7.3.4.1 Impacts during Construction

Construction activities are expected to be completed in six (6) months. In this context, waste will be generated in that period throughout the construction phase of the Sub-project.

Table 7-14 shows the summary of the conclusions mentioned above and the impact significances for waste management of the Sub-project's construction phase. In this respect, concerned impact significances are determined based on the methodology given in Chapter 5 of this ESIA Report.

Table 7-14. Summary of Impact Significances during the Construction Phase-Waste Management

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)						Receptor Sensitivity (S)	Impact Significance (Impact Magnitude x Sensitivity)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Reversibility (R)		
Waste Impacts Due to Construction Activities	Negative Direct	Definition	Considering potential impacts during the construction activities the geographical extent of the impact is expected to be local.	Waste impacts will continue during the nine (9) month construction period of the Sub-project.	The most significant waste sources are expected to be machinery, equipment, and human activities.	Waste impacts will continue throughout the construction phase of the Sub-project.	Due to the waste potential and intensity, the relevant impacts are expected to be reversible in the short/mid-term.	Due to the potential nature and intensity, the relevant impacts are expected to be medium.	Medium
		Score	Local	Short	Medium	Continuous	Short/mid-term	Medium	
		Value	2	2	3	5	2	3	
Impact Significance = [Impact Magnitude (G+D+I+F (or L)) x R] x S			24					3	**72**

7.3.4.2 Impacts during Operation

Laboratories operational activities are expected throughout the life of the Sub-project. In this context, waste will be generated during this period.

Table 7-15 shows the summary of the conclusions mentioned above and the impact significances for waste management of the Sub-project's operation phase. In this context, concerned impact significances are determined based on the methodology given in Chapter 5 of this ESIA Report.

Table 7-15. Summary of Impact Significances during the Operation Phase-Waste Management

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Reversibility (R)	Receptor Sensitivity (S)	Impact Significance (Impact Magnitude x Sensitivity)
Waste Impacts Due to Operation Activities	Negative Direct	Definition	Considering potential impacts during the operation activities the geographical extent of the impact is expected to be local.	Waste impacts will continue for more than five (5) years throughout the life of the Sub-project.	The most significant waste source is expected to be laboratory activities throughout the operation phase Sub-project.	Waste impacts will continue throughout the operation phase of the Sub-project.	Due to the waste potential and intensity, the relevant impacts are expected to be reversible in the short/mid-term.	Due to the potential nature and intensity, the relevant impacts are expected to be medium.	Medium
		Score	Local	Very Long	High	Continuous	Short/mid-term	Medium	
		Value	2	5	4	5	2	3	
Impact Significance = [Impact Magnitude (G+D+I+F (or L)) x R] x S			32					3	**96**

7.3.5 Mitigation Measures

During the land preparation and construction phase, the Waste Management Plan will be carried in accordance with the IFC General EHS Guidelines (2007).

All excavated material will be disposed in accordance with local regulations. Excavated soil, concrete or other construction material will be disposed to the legal landfill outside of the Torlak complex as per contractor preparation works elaborate. Another material i.e. iron, plastic, glass will be disposed to the other companies for secondary raw materials handling.

Mitigation measures during the land preparation and construction phase of the Sub-project are follows.

a) Identify waste collection and disposal pathways for all major waste types expected from demolition and construction activities,
b) Separate mineral construction and demolition wastes from general refuse, organic, liquid, and chemical wastes by on-site sorting and stored in appropriate containers,
c) Collect construction waste and dispose properly to the designated locations,
d) Whenever feasible, reuse and recycle appropriate and viable materials (except asbestos).
e) Temporarily store all hazardous or toxic substances on site in safe containers labelled with details of composition, properties, and handling information,
f) Place containers of hazardous substances in leak-proof containers to prevent spillage and leaching,
g) Transport waste to official landfills and dispose excess excavated material at sites agreed with the local authorities,
h) Do not use paints with toxic ingredients or solvents, or lead-based paints.

The presence of contaminated lands or asbestos containing material was not established. If any asbestos is identified, asbestos management of the Sub-project is follows.

a) If asbestos is located on Sub-project Area, mark it clearly as hazardous material,
b) When possible, appropriately contain and seal asbestos to minimize exposure,
c) Treat asbestos prior to removal (if removal is necessary) with a wetting agent to minimize asbestos dust,
d) Handle and disposed asbestos using skilled & experienced professionals,
e) If asbestos material is being stored temporarily, securely enclosed it inside closed containments and mark appropriately. Take security measures against unauthorized removal from the area,

f) Do not reuse the removed asbestos.

As for the operation phase of the Sub-project, two BSL 3 pass-through autoclaves with a bio seal, interlocking doors to prevent opening the clean side prior to cycle completion, sterilization of air discharge, cycle recording mechanisms and alarms are foreseen. Autoclaves will have the required technical qualifications for BSL3 laboratory for the decontamination. Decontamination process will be validated.

During the operation phase of the Sub-project, it is foreseen that the domestic waste will be limited to the small volumes related to the maintenance works and the maintenance of the landscape areas.

Sterilization

Autoclaving protocols will be used as sterilization method in the BSL3 Laboratory.

Table 7-16. The Common Autoclaving Protocols for Different Type of Wastes

Material	Temperature (^{0}C)	Time (hour)
Infectious waste	121(^{0}C)	1 hr
Liquid waste	121(^{0}C)	1 hr

Autoclave bags must be resistant to puncture, tear, high temperature such as polypropylene ones are resistant to 141°C, polyethylene ones are resistant to 121ºC. In the proposed laboratory, in the sterilization of equipment, wet sterilization with steam is applied at 121°C-134°C for 15-45 minutes or 10 minutes at 134°C. The validation and commissioning stages of autoclaving procedures are vital part of design, construct, and operation in BSL3 facilities.

Dry heat will be used for materials (some glassware, instruments, and anhydrous materials) that are sensitive to moisture or the corrosion it may cause. Dry heat requires higher temperatures and a longer exposure time than autoclaving. Dry heat for 2-4 hours at 160°C is needed to sterilize a load requiring 30 minutes at 121°C in an autoclave. Another dry heat protocol is at 300°C for 3 minutes.

Monitoring the sterilization procedure will be monitored routinely by using a combination of mechanical, chemical, and biological indicators to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items. The mechanical monitors for steam sterilization will include the daily assessment of cycle time and temperature by examining the temperature record chart (or computer printout) and an assessment of pressure via the pressure gauge.

Decontamination

No waste materials would be removed from the laboratories unless those materials are first autoclaved or decontaminated by a method approved and managed by the Laboratory Environmental Health and Safety (EHS) and Biosafety Committee.

In the proposed laboratory General Decontamination Handling Practices:

- Waste from BSL3 facilities will be autoclaved in the lab..
- Liquids will be inactivated by autoclaving or by inactivating with household bleach. Final concentration of 10% bleach against the volume of waste to be inactivated. A minimum contact time of 30 minutes is required. The liquid is then disposed of down the sink using large amounts of water followed by a disinfectant.
- Solid wastes will be inactivated by autoclaving. Autoclaves will be operated as described in autoclave sterilisation section. The biohazard autoclave bags will be not be taped closed. After autoclaving, all waste leaving the facility must be doubled bagged before placing in a box-bag unit.

The decontamination in BSC:

- Interior surfaces (work surface, grilles, sides, back and inside front view screen) will be decontaminated with an appropriate disinfectant after removal of all materials, cultures and apparatus.
- If using 10% bleach solution on work surfaces, it will be allowed to air dry then follow up with 70% ethanol wipe to prevent rusting of stainless-steel surface.
- Liquid waste will be decontaminated with household bleach diluted 10% against the volume of the waste and allowed at least a 30-minute contact time for full decontamination.
- Waste will be transported waste to autoclave in a leakproof container.

Decontamination of Spore Forming Microorganisms

Bacterial spores, by nature, are resistant to extreme physical, chemical, and thermal conditions, and are second only to prions in their resistance to different types of decontamination. A particular care and diligence should be used to decontaminate equipment and apparatus used for work with spore-forming agents. Adequate sterilization requires direct exposure to 121°C for at least 90 minutes. Chlorine (0.01-5%) is less positive and glutaraldehyde (2%) is positive against spores.

Decontamination Procedures for Prions

Prions are characterized by resistance to conventional inactivation procedures including irradiation, boiling, dry heat, and chemicals (formalin, beta propiolactone, alcohols). Current methods for inactivation of prions are based on the use of sodium hypochlorite, sodium hydroxide, and the moist heat of autoclaving in combination.

The decontamination of Hazardous Biological Toxins

- Decontaminate work surfaces with 5-10% household bleach or 0.1N sodium hydroxide.
- Treat liquid waste with 50% household bleach (soak overnight). For T-2 mycotoxin use a combination of 50% household bleach and 0.25N sodium hydroxide
- Collect and autoclave waste at the end of the day.
- Autoclave or chemically disinfect contaminated protective clothing before reuse

Others:

Room decontamination will be performed with gas phase of H_2O_2 in accordance with the relevant protocols. Vapor phase hydrogen peroxide is effective at a 30% concentration (less than 10 mg/litre) to disinfect surfaces. The higher the temperature, the less contact time is needed. The end products of disinfection are nontoxic (water and oxygen) which makes vapor phase hydrogen peroxide safer to use than other gas disinfectants. However, hydrogen peroxide vapours are corrosive to some materials and degrade natural rubber and nylon.

Room disinfection is also performed using UV-C at 254nm. The UV-C impact distance is limited to 1-2 meters and is affected by ambient temperature. The lamps require to wipe to prevent dust accumulation with ex. 91% isopropyl alcohol or 70% ethyl alcohol for every 2-4 weeks. The number of UV lamps to be placed in a room varies according to the dimensions of the laboratory room.

Table 7-17. The number of UV-C lamps according to the room dimension

	Ceiling height: 2.7–3m	
	Room length:3–4 m Width: 3-4m	**Room length:3–4 m Width: 5.5–7 m**
90% air disinfection	1 at 15 Watt (W)	3 at 15 W or 1 at 30 W or 1 at 40W
99% air disinfection	2 at 15W or 1 at 30W	6 at 15 W or 2 at 30 W or 2 at 40W

The equipment to be used will come from the sterilization area as clean material. All the contaminated materials will exit after autoclaving.

Decontamination of Biological Waste

The proposed BSL3 laboratory complex would include a multi-sterilization system for BSL3 and a dedicated liquid effluent decontamination system. The multi-sterilization system would include at a sufficient number and volume of autoclaves. Once waste material has been autoclaved in biodegradable bags and removed from the BSL3 facility contained space. A dedicated liquid effluent decontamination system would treat all liquid wastewater from the BSL3 facilities, including both autoclave drains and chemical disinfectant wash waste. The liquid waste would be plumbed through a dedicated drainage system directly into the cook tanks for processing prior to discharge to the municipality sanitary system.

In all cases, BSL3 research waste would be autoclaved onsite prior to shipping. The laboratories would be responsible for autoclaving the waste material prior to shipment. Following completion of laboratory work in the BSL3 facilities, workspace areas would be disinfected using a newly prepared 1:10 bleach solution or other EHS approved disinfectant.

Validation

Autoclaves, effluent decontamination systems, and other decontamination technologies and processes are validated prior to implementation of the procedure. Validation demonstrates that the equipment and method are effective at decontaminating, inactivating, or removing the specific pathogen(s) or toxin(s) to be handled and stored. It is inferred that a validated method is suitable for its intended purpose. Biological indicators or parametric monitoring devices (e.g., thermocouples, for heat-based technologies and processes only) can be used to confirm that treatment parameters have been achieved throughout a representative load. The selection of an appropriate biological indicator is critical so that the resistance of the test organism adequately represents the resistance of the pathogens handled in the containment zone. In general, Geobacillus stearothermophilus spores are adequate for heat-based technologies and processes, whereas Bacillus subtilis spores can be used to validate chemical-based technologies and processes. In cases where biological or chemical indicators are not appropriate (e.g., prions), parametric monitoring devices, such as thermocouples or gauges that capture cycle time, temperature, and pressure, can be used to accurately monitor the performance of the decontamination equipment. Validation of all decontamination technologies and processes is required prior to initial use and whenever significant changes are implemented or new pathogens are introduced so that decontamination procedures and standard operating procedures (SOPs) can be established, amended, or updated as necessary. Validation through the use of representative loads is required annually. Performing validation tests on non-contaminated representative loads that simulate a batch of materials of similar type (e.g., gloves, plastics, liquids, reusable personal protective equipment [PPE]) and quantity (i.e., number of items or size) that will be regularly processed allows an operator to place indicators safely to demonstrate that appropriate decontamination parameters are achieved throughout the load (e.g., in the bottom, middle, and top of the batch of materials).

Verification

After effective and proper decontamination parameters have been established through validation, it is important that decontamination processes and procedures be monitored by verifying. Verification is the routine monitoring of equipment and processes to ensure they are functioning properly and continue to meet the parameters established during validation. This can be accomplished using parametric monitoring devices, biological indicators, chemical indicators, or chemical integrators. The information captured during verification should include the similar data provided during validation and/or simulation studies. During each run performed, the parameters captured may include time and temperature charts and biological indicator results. The Institutional risk assessment policy will help determine the procedures for routine monitoring (e.g., daily, weekly, monthly), taking into consideration the frequency of use.

Indicators, Integrators, and Parametric Monitoring Devices

Achieving the target level of reduction in viable spores indicates that the decontamination process was effective by using biological indicator which is a standardized population of bacterial spores used to demonstrate effectiveness sterilization conditions in a loaded waste. An appropriate attention must be paid for the selection of indicators, as their design and construction vary depending on the intended use (e.g., liquid versus dry load, self-contained system, enzyme-based rapid method); the indicator should be representative of the pathogen or toxin being decontaminated. Chemical indicators are meant to be used in conjunction with biological indicators and physical monitors (i.e., pressure and temperature gauge readings). Chemical indicators include autoclave tape, labels, and pouches embedded with a thermochromic ink (e.g., Bowie-Dick test packs). They provide instant results for day-to-day monitoring indicating that a certain parameter (e.g., temperature, steam, gas exposure) has been reached, but they are not an indicator of decontamination efficacy. Where biological or chemical indicators are not appropriate, parametric monitoring devices such as thermocouple can be used to capture cycle parameter (e.g., time, temperature, and pressure) to confirm that the conditions have been met for effective in heat-based decontamination.

Waste Management within the Complex

All biological wastes from BSL3 are marked as“treated biohazard waste” prior to disposal in designated containers for treated infectious waste. Decontamination and disposal are the responsibility of the person/laboratory generating the waste. The proposed BSL3 laboratory will have procedures for compliance with all applicable regulations for collecting, storing, processing, and disposing of sanitary liquid wastes, solid wastes and hazardous wastes generated during the activities in the complex. All biological waste from the BSL3 laboratory would undergo either autoclaving or chemical disinfection. During operation of the BSL3 laboratories, waste products would be generated by the disinfection of the interior working surfaces of the BSCs after each use. These wastes would be discharged from laboratory sinks, floor drains, or the tissue digesters and would be held and disinfected in retention tanks before being discharged into the sanitary sewer system. Tap water entering the BSL3 laboratories through spigots in the sinks or shower heads would have backflow preventers to protect the potable water distribution system from contamination. Biological cultures could be disposed of in the sinks after undergoing treatment with chemical disinfectants for an appropriate amount of time. The autoclaving process involves placing waste to be autoclaved in a special container. When autoclaving occurs, an indicator strip on the container changes its colour. This allows facility workers and waste management workers to be able to tell at a glance whether waste has undergone autoclaving. To apply the appropriate method for waste management, the laboratory should perform a risk assessment and take into consideration the points below:

- facilities & decontamination methods available,
- type and volume of waste,
- method of decontamination,
- segregation categories (uncontaminated, contaminated, sharps, glass),
- packaging, labelling and transport,
- presence of chemicals, and
- recycling and reuse requirements.

All personnel handling contaminated materials need to be specially trained and must use appropriate PPEs.

In the proposed BSL3 laboratory complex, appropriate plans, strategies, and actions would be established to ensure minimization of wastes. The proposed BSL3 laboratory should implement the following waste minimization strategies:

- Using less wasteful materials;
- Recycle materials and products when applicable
- Ensure risk management and control practices during collecting, storing, processing, and disposing stages for all kinds of wastes
- Enforcing a rigorous and careful segregation of the wastes at source.

In this context, the Sub-project as BSL-3 laboratory workflow on on-site waste management is presented in Figure 7-2.

Figure 7-2. The Sub-Project Workflow on Waste Management

Waste Segregation

Proper segregation of waste at source generation is essential, efficient, and effective in managing Biosafety laboratory wastes. It helps in reducing the quantity of waste requiring treatment prior to final disposal and ultimately reduces the cost of waste treatment/management. Contaminated waste is treated onsite in BSL3/ facilities. The following elements need to be considered for segregation and storage:

- Nature of the waste, for example, liquids, solids, general waste, infectious waste, chemical waste, sharps (contaminated or not) and perishables;
- Volume of the waste to process;
- Where waste decontamination takes places (ex. in the laboratory itself, onsite, off-site)
- Need to store waste before decontamination
- Kind and type of packaging for storing the waste
- Use of a uniform and consistent identification system (colour codes and proper hazardous symbols
- Limitations for transferring material internally and for transporting it off-site
- Access to a restricted storage area before off-site transport
- Duration and conditions of storage (ex. short- or long-term storage, temperature/humidity/ ventilation control & requirements)
- Regular cleaning and disinfection of the storage area.

Biohazard bags leaving the laboratory should be transported and stored in a safe way, by using a secondary container or a trolley or any other means that prevents contamination of the floor and walls of the storage site.

After decontamination process, it must be clearly visible and known to all personnel handling the waste that the items (ex. bins, bags, containers) that underwent a decontamination process do not represent an infectious risk anymore.

In exceptional cases, off-site treatment may also be needed when a major technical breakdown in the onsite decontamination systems or a disease outbreak). In those situations, the waste should be packed in United Nations (UN) certified containers and transported by a licensed contractor. All the processes should be described and performed according to the written SOPs designed with risk assessment.

Waste Collection

The prompt and routine collection of waste as described in SOPs are extremely important particularly to avoid over spilling of collection containers. The laboratory staff will be actively involved in collection of waste as would the waste handlers. The following points would also be adhered to when collecting waste:

- Performed by approved and trained personnel fully equipped with appropriate PPEs to the level of risk. The PPEs would be removed prior to leaving the work area and to place it in a designated area or container.
- All the facility wastes would be sorted on site before collection and transportation.
- Separate schedules and collection times for different colour coded containers.
- Separate trolleys for different types of waste.
- A fixed schedule for the collection of waste bags and containers from each unit in the facility.
- No bags would be removed without labelling indicating the point of generation and content.
- Immediate replacement of the bags or containers with new ones of the same type.
- Disinfect and clean the vehicles daily or at the end of haulage with an appropriate disinfectant at an appropriate site where wastewater will be properly disposed of.
- The vehicles used to transport the waste will be carefully designed so that they are stable, quiet in operation, and so that transportation can be achieved with the minimum of effort and inconvenience.
- The vehicles of trolleys or carts would be large enough so that waste is not piled up on them in an unsafe way and the trolleys and carts would be designed to prevent and accommodate any form of spillages.
- Immunization according to risk management in dealing with different types of facility wastes will be undertaken for the facility waste handlers.
- Appropriate hand-wash and disinfection materials would be readily available for the facility waste handlers.
- If there is a possibility of splashing or infectious material contacting of the waste workers' body parts, the following medical protective clothing and PPE is provided in addition to gloves;
    - Appropriate protective clothing to prevent biological waste from penetrating and reaching workers clothes or skin.
    - Eye protection, surgical face masks and face shields when possible facial exposure to biological waste.

- In Dealing with Sharps,
  - Make sure before that a fully and properly assembled safety boxes before lab activities,
  - Properly labelled the safety boxes,
  - Sharps containers will be placed in close proximity within arms reach,
  - Needles will not be recapped or bent when handling,
  - Syringe will be placed in a safety box immediately,
  - Seal and collect safety boxes when they are ¾ full and will never be emptied or opened,
  - Safety box will not be shaken to settle their contents,
  - Safety boxes will not be placed in high traffic areas (corridors outside laboratory rooms or sample preparation rooms) to prevent possible laboratory accidents,
  - Containers will not be placed on the floor or anywhere they could be knocked over.

Waste Temporary Storage in Institute

Storage is classified into internal and external. Consideration for storage will be based on the classification or type of waste being dealt with and the potential risk of infection to the laboratory personnel and waste disposal staff. As good microbiological practices in working BSL3 laboratories, the laboratory personnel work in heightened control measures with goes in and comes out in a clean manner. That means, the laboratory personnel apply before and after decontamination procedures with minimising waste. A validated and certified autoclave in the BSL3 unit is the main sterilising component to good microbiological practices. Together with these principles, the following rules are required for proper storage of facility wastes:

- Initial packaging and storage would take place where the waste is generated,
- Storage of waste will then be moved to a temporary on-site storage location,
- Non-risk wastes would always be stored in a separate location from the infectious/ hazardous wastes to avoid cross-contamination.

Internal storage is the temporary placement of waste at the point of generation before transfer to external storage points. A storage location for the laboratory wastes would be designated inside the BSL3 laboratory. The waste in the bin-liners or containers would be stored in a separate area, room or building appropriate to the quantity of waste produced bearing in mind the frequency of collection. There would be planned periodic cleaning and disinfection of temporary storage areas and the containers. The storage time for the laboratory wastes before it is transferred to external storage facilities would on daily basis. External storage refers to the transit point where waste is stored after removal from primary storage to the time it is collected and transported for treatment and final disposal. The external waste storage will be located in a secure area and the requirements for external storage should meet below:

- Ensure that waste is kept separated according to colour coded bags/containers
- There will be externally one or more geographically separate section at BSL 3 laboratory for storage of hazardous and non-hazardous waste depending on the layout of BSL3 facility
- The walls and floors would be smooth, without cracks, impervious, easy to clean and disinfect
- The site will be spacious, well ventilated and lit
- The site will be monitored for temperature and humidity
- All loading and unloading of waste would take place within the designated collection area
- Larger volume waste bins would be available at the external storage facility to receive waste containers from the internal storage points

The BSL3 laboratory facility will designate an area within its premises where waste may be temporarily stored until final collection for disposal and onward treatment. Such a general storage location will be located away from the view of the public and it will be included in design of the proposed BSL3 building. The storage area will be totally enclosed and secured from unauthorized access, be inaccessible to animals, insects, and birds, and easy to clean and disinfect with an impermeable hard-standing base, good water supply, drainage, and ventilation.

The proposed laboratory aimed to establish in line with the national regulation. Before the liquid wastes are discharged into sewage system, the waste will be decontaminated in BSL3 laboratories according to the relevant procedures. The samples will be taken from each control points determined according to risk analysis for decontamination sampling. In case of any risk, additional measures are planned in accordance with the national regulation. However, apart from the liquid and solid waste decontamination in BSL3 areas, the laboratory management claims to not to work on an agent that pose a risk of biological contamination will be used in any part or unit of the facility. All the wastes in the facility will be segregated and stored in categories such as medical waste, pathological waste, chemical waste, and domestic waste. Facility specific biosafety policies which describe decontamination and disposal methods of solid waste will be developed. Torlak Institute has already developed and been implementing waste management procedures and will include required specifications and adapt these documents for the BSL-3 laboratory. Solid wastes after appropriately decontaminated will be disposed from the facility using authorized contractor in accordance with the national regulation. In the facility environmental management plan, necessary trainings will be given to all the relevant personnel dealing with waste management and environmental risks in the entire facility will be kept under control.

Waste Transportation

Consideration for transportation must be based on the classification or type of waste being dealt with and the potential risk of infection to laboratory workers and waste disposal staff. Transportation is classified into on-site transport and off-site transport, since the waste generated from the BSL3 complex is treated at the facility as on-site. Although not preferable, off-site transport may be done for, autoclave disinfected solid waste, sludge from the onsite wastewater treatment and wastewater).

On site transportation

The on-site transport involves conveying of wastes from the various points of generation within a laboratory to a temporary storage location also within the same area. The following points would be adhered to when carrying out on-site transportation and every effort would be made to avoid unnecessary handling of the laboratory wastes;

- All waste bags would in-place and intact at the end of transportation,
- The vehicles to carry as trolley, or containers used for the transportation of the laboratory waste would not be used for other purposes,
- Waste that has the potential to leak will be double bagged,
- Waste bags would be placed in appropriate containers before being placed directly into the transportation vehicle,
- The collected waste will not be left unattended and even temporarily anywhere other than at the designated storage room,
- Containers would be covered with lids during storage and transport.

Off-site Transportation

During the transportation of waste outside the complex by licenced operators following safety precautions would be included:

- Staff would be properly trained in the handling, loading and unloading, transportation, emergency issues and disposal of waste,
- Single-bagged waste and containers of sharps and liquids would be placed within a rigid/semi-rigid container,
- Containers would be covered with lids during transportation,
- Outside the complex, infectious waste would be transported in closed, leak-proof, rigid containers using trucks,

- When transporting plastic bags of infectious waste, care would be taken to prevent tearing of the bags,
- Infectious waste would not be compacted before treatment,
- The vehicles are solely used for the transportation of the laboratory wastes and would not be used for other purposes,
    - The vehicles would be free of sharp edges, easy to load and unload by hand, easy to clean and disinfect and fully enclosed to prevent any spillage in the facility premises or on the road during transportation,
    - The vehicles would carry adequate supplies of plastic bags, all kinds of PPEs, disinfecting and emergency kits in case of any spillage/incident,
    - Staff would be fully aware of emergency procedures for dealing with accidents and spillage.

Waste Management Documentation

The following documentation as waste records should be gathered:

- List of the personnel authorized to handle the waste including their training records,
- SOP for waste handling (including internal transport, short-term storage, and decontamination),
- Validation records for decontamination,
- Off-site transport records and final disposal records,
- Database (paper or electronic) of the relevant material safety data sheets, and,
- Contingency plan, including for spill management emergency procedures.

In case of an emergency, the information below must be made readily available:

- What is disposed of (for example, pipette tips, bottles, chemicals)?
- What special needs have to be considered?
- Where/How is different waste stored (ex. the location, room temperature/humidity)?
- Who is authorised to dispose the waste?
- Who is the trainer of those personnel? And when is training carried out (ex. frequency)?
- Who is responsible in case of an emergency?

Disposal of BSL3 related Waste

In Serbia health care and other institutions are responsible for medical waste management. Medical and pharmaceutical waste is subject to a separate system of separate collection. This system has been established in all healthcare institutions in the Republic of Serbia. Producers are obliged to either treat the waste themselves in accordance with the applicable legal provisions, or to conclude a contract with the operator of the plant for the treatment of this waste. Torlak Institute has in place and implements a policy and a standard operating procedure regarding waste management. The waste management policy is valid after the approval of the Ministry of Health. The policy defines the types of wastes as wastes without special treatment and wastes with special treatment. The procedure defines the activities of sorting, packaging, labeling, storage, transportation of waste for treatment and final disposal of waste at Torlak Institute. All employees who handle infectious waste are trained in handling infectious waste. Torlak Institute has also established Waste Treatment Department with 2 certified employees according to the current national regulations. The procedure defines;

- Materials and equipment to be used (bins, containers and labels are defined)
- Separation, packaging and labeling of different types of waste (hazardous waste, infectious waste, chemical waste, pharmaceutical waste, paper waste, packaging waste, electrical and electronic waste, metal waste, etc. are separately labeled and stored)
- Storage of waste (storage conditions of different types of waste until handed over to authorized operators for final disposal are described)
- Waste treatment (Decontamination of the medical infectious waste is performed within the Torlak Institute until the properties of non hazardous medical waste are obtained)
- Delivery of waste to an authorized operator (hazardous and non-hazardous waste is handled over to an authorized operator for final disposal). Torlak Institute conducts public procurement procedure annually to make a contract with licensed operators for the waste disposal and treatment.

The medical waste generated at the Sub-project will be autoclaved and sent to a licenced landfill by an authorized operator after sterilization according to the national legislation. There is an operational regional sanitary landfill “Vinca” Belgrade with a capacity of 200,000 ton/tear. There are 11 sanitary and 138 unsanitary landfill areas in Serbia. Also in 2021, a sanitary landfill named "Beocista Energija” in Belgrad which is an Energy-to-Waste PPM Project started operating according to EU Directives.

In summary, no significant impact is anticipated given that appropriate waste treatment, storage and disposal procedures will be adopted and detailed information on waste disposal sites to be potentially used, to be provided in the Sub-project’s waste management plan within the scope of the Sub-project’s ESIA.

BSL 3 laboratory is intended to be constructed as dry lab. All the laboratory consumables will be for single use. Maximum solid waste per day is expected to be 20 kg. Decontamination of solid waste is planned to be on site by autoclaving, and chemical decontamination of liquid waste is foreseen. Regarding all other types of waste, Institute has established procedures for handling and treatment. In the light of this information, the impact of waste management is expected to be minimum if aforementioned national and international requirements are complied with.

7.3.6 Residual Impacts

The extent of impact on waste is local with medium intensity during the construction phase. The duration is also expected to be short as there is continuous source of contamination. Intensity can be higher if good housekeeping or housekeeping is not fully implemented (i.e. poor waste management etc.). The waste residual impact will be negligible with the necessary mitigation measures to be taken and good waste management practices during the construction phase.

The potential impact for waste will be local for very long term and with high intensity throughout the operation phase. Intensity can be higher if good waste management is not fully implemented (i.e. poor waste management etc.). Also, small quantity of solid waste generation is expected during laboratory activities. In this respect, the residual impact of waste is expected to be low with the necessary mitigation measures to be taken during the operation phase of the Sub-project. Grievances raised by community are the main indicator of the waste-related impact as well as effectiveness of the measure that implemented to decrease the level of the impact.

In this respect, Waste Management Residual Impact Significances for the construction and operation phases of the Sub-project are presented in Table 7-18 and Table 7-19.

Table 7-18. Construction Phase Residual Impact Significances-Waste Management

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Reversibility (R)	Receptor Sensitivity (S)	Impact Significance (Impact Magnitude x Sensitivity)
Waste Residual Impacts Due to Construction Activities	Negative Direct	Definition	Considering potential impacts during the construction activities the geographical extent of the impact is expected to be local.	Waste impacts will continue during the nine (9) month construction period of the Sub-project.	Waste impact intensity will be lowered with taking aforementioned mitigation measures during the construction phase of the Sub-project.	Waste impact frequency will be lowered with taking aforementioned mitigation measures during the construction phase of the Sub-project.	Due to the waste potential and intensity, the relevant impacts are expected to be reversible in the short term.	Due to the potential nature and intensity, the relevant impacts are expected to be medium.	Negligible
		Score	Local	Short	Low	Single event	Short-term	Medium	
		Value	2	2	2	1	1	3	
Impact Significance = [Impact Magnitude (G+D+I+F (or L)) x R] x S			7					3	**21**

Table 7-19. Operation Phase Residual Impact Significances-Waste Management

<table>
<tr><th rowspan="2">Potential Impact</th><th rowspan="2">Impact Type</th><th colspan="8">Nature of Impacts (Magnitude designations)</th></tr>
<tr><th></th><th>Geographical Extent (G)</th><th>Duration (D)</th><th>Intensity (I)</th><th>Frequency (F)</th><th>Reversibility (R)</th><th>Receptor Sensitivity (S)</th><th>Impact Significance (Impact Magnitude x Sensitivity)</th></tr>
<tr><td rowspan="3">Waste Residual Impacts Due to Operation Activities</td><td rowspan="3">Negative Direct</td><td>Definition</td><td>Considering potential impacts during the operation activities the geographical extent of the impact is expected to be local.</td><td>Waste impacts will continue for more than five (5) years throughout the life of the Sub-project.</td><td>Waste impact intensity will be lowered with taking aforementioned mitigation measures throughout the operation phase of the Sub-project.</td><td>Waste impact frequency will be lowered with taking aforementioned mitigation measures throughout the operation phase of the Sub-project.</td><td>Due to the waste potential and intensity, the relevant impacts are expected to be reversible in the short term.</td><td>Due to the potential nature and intensity, the relevant impacts are expected to be medium.</td><td rowspan="3">Low</td></tr>
<tr><td>Score</td><td>Local</td><td>Very Long</td><td>Low</td><td>Single event</td><td>Short-term</td><td>Medium</td></tr>
<tr><td>Value</td><td>2</td><td>5</td><td>2</td><td>1</td><td>1</td><td>3</td></tr>
<tr><td colspan="3">Impact Significance =
[Impact Magnitude (G+D+I+F (or L)) x R] x S</td><td colspan="5">10</td><td>3</td><td>30</td></tr>
</table>

7.4 Air Quality

7.4.1 Introduction

Emissions during the construction and operation phases of the Sub-project will contribute to regional air pollutant levels and thereby may impact the health of nearby communities, workers and other sensitive receptors. This chapter presents the assessment of the impacts of emissions related to the Sub-project on air quality and sets out the mitigation measures to avoid or minimize the risks together with the residual impacts that are foreseen to remain.

The most significant direct or indirect sources of air pollutants from the Sub-project will include short-term effects from construction activities such as dust emissions as well as emissions from increased road traffic. Adverse effects can be caused by emissions from construction machinery and vehicles and also from activities generating particulate matter (such as earthworks and storage of dusty materials). In addition to affecting health, dust can lead to unsightly and potentially harmful deposits on property and vegetation if not managed properly.

The following sources of information have been used during the assessment:

- Baseline air quality measurement report, December 2022;
- National Network of Automatic Stations for Air Quality Monitoring website (http://www.amskv.sepa.gov.rs/index.php);

The significance criteria that were used related to impacts on air quality were established by identifying the impact magnitudes and receptor sensitivity. The magnitude and sensitivity criteria for impact assessment methodology are detailed in *Chapter 5: Scope and Methodology*. For determining the magnitudes of the impacts, impact intensity should also be assessed according to changes in baseline air quality. The details on the methodology for the determination of impact intensity, Sub-project specific receptor sensitivity, and criteria to identify impact significance are given in Section 7.5.5 of this chapter.

7.4.2 Legal Context

7.4.2.1 National and International Ambient Air Quality Standards

This section provides an overview of Serbian and international ambient air quality standards. In Serbia, ambient air quality is regulated under the Law on Air Protection ("Official Gazette of RS" No. 36/2009 and 10/2013) and Regulation on the Conditions for Monitoring and Air Quality Requirements (Official Gazette of RS, No. 11/10 and 75/10, Amend 63/13), which identify ambient air quality limits for pollutants.

Annexes of these regulations specify air quality limits as summarized in Table 7-20. World Health Organisation (WHO) Global Air Quality Guidelines sets out the limits for PM10 and PM2.5 are also considered to be relevant and included in Table 7-20.

Table 7-20. Ambient Air Quality Standards and World Health Organisation (WHO) Global Air Quality Guidelines

Parameter	National Limit Value ($\mu g/m^3$)	WHO Global Air Quality Guidelines 2021 ($\mu g/m^3$)
PM_{10}	50[24]	45
$PM_{2.5}$	25[25]	15

7.4.2.2 Air Quality Index

In accordance with Article 21 of the Law on Air Protection, and according to the level of pollution, starting from the prescribed limit and tolerance values, based on the measurement results, the following categories of air quality are determined:

1) first category – clean or slightly polluted air where the limit values of the levels for any polluting substance have not been exceeded;
2) second category - moderately polluted air where the limit values of the levels for one or more polluting substances are exceeded, but the tolerance values of none of the polluting substances are exceeded;
3) third category – excessively polluted air where the tolerance values are exceeded by one or more pollutants.

According to the Annual report on the state of air quality in the Republic of Serbia in 2021, in 2017-2021 period, Belgrade had excessively polluted air, mainly due to increased concentrations of PM10 and RM2.5, but also due to increased concentrations of NO_2, which was the case in 2017 and 2021.

Air Quality Categories in 2021 by Zone are given in Figure 7-3.

[24] Limit value referring to the 1 - day averaging period
[25] Limit value referring to the calendar year averaging period

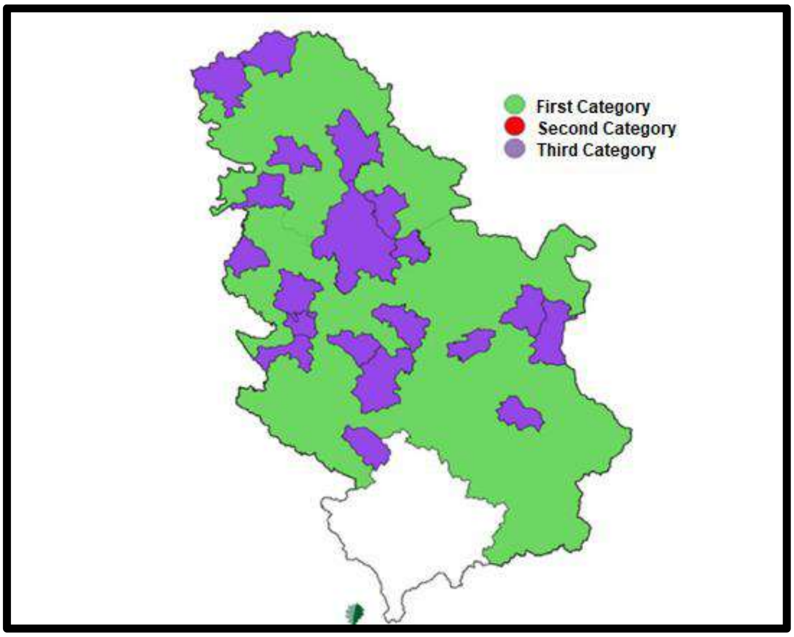


Figure 7-3. Air Quality Categories in 2021 by Zone

In 2021, air quality was excessively polluted in Belgrade due to the presence of nitrogen dioxide and suspended particles PM_{10} and $PM_{2.5}$.

According to the European criteria for air quality (European Air Quality Index), quality categories can be distinguished based on the presence of suspended particles of 2.5 µm ($PM_{2.5}$). The European criteria classify the quality for PM2.5 in the range according to visualization framework given in Figure 7-4.

Annual PM2.5 breakpoints based on WHO guideline and interim targets	PM2.5	Color code	WHO levels
Meets WHO PM2.5 guideline	0-5 (µg/m³)	Blue	Air quality guideline
Exceeds WHO PM2.5 guideline by 1 to 2 times	5.1-10 (µg/m³)	Green	Interim target 4
Exceeds WHO PM2.5 guideline by 2 to 3 times	10.1-15 (µg/m³)	Yellow	Interim target 3
Exceeds WHO PM2.5 guideline by 3 to 5 times	15.1-25 (µg/m³)	Orange	Interim target 2
Exceeds WHO PM2.5 guideline by 5 to 7 times	25.1-35 (µg/m³)	Red	Interim target 1
Exceeds WHO PM2.5 guideline by 7 to 10 times	35.1-50 (µg/m³)	Purple	Exceeds target levels
Exceeds WHO PM2.5 guideline by over 10 times	>50 (µg/m³)	Maroon	Exceeds target levels

Figure 7-4. 2022 World Air Quality Report Visualization Framework

According to the World Air Quality Report (Region & City PM2.5 Ranking, IQAir, 2022), 2022 average PM2.5 concentration for Serbia was measured as 24.7 µg/m³ and for Belgrade as 22.1 µg/m³.

7.4.3 Emissions

Air quality impacts of the Sub-project were assessed for both construction and operation phases of the Sub-project. Relevant assessment is detailed in the following subsections.

7.4.3.1 Construction Phase

The site preparation activities at the early stage of the construction phase will mainly cover earthworks. Significant air pollutants of this step will be dust generated from excavation, construction vehicle movements, and the release of engine emissions from construction equipment and vehicles at the construction site.

During construction phase, all activities including pre-construction land arrangement, construction activities and construction equipment and vehicle movement such as cement mixers, trucks, etc. are sources of air emission.

Significant pollutant will be dust generated from construction activities mentioned above, and the release of engine emissions (such as NO_X, SO_X, particles, CO, VOC etc.) from construction equipment and vehicles.

Earthwork activities including excavation, loading, unloading, and transportation activities for the construction of the Sub-project earthworks (approximately 5,000 m^3 soil) will be completed in 2 weeks as part of overall construction phase. It is assumed that the activities will be conducted for 25 days a month, and for 10 hours a day. The excavated material will be disposed to city landfill and filling material (approximately 2,000 m^3) will be supplied from quarries around Belgrade.

Total fugitive PM emissions are estimated with the following equation according to EMEP/EEA Air Pollutant Emission Inventory Guidebook (EMEP/EEA Air Pollutant Emission Inventory Guidebook, 2019):

$$EM_{PM10} = EF_{PM10}\ x\ A_{Affected}\ x\ d\ x\ (1 - CE)\ x\ \left(\frac{24}{PE}\right) x\ (\frac{s}{9\%})$$

Where:

EM_{PM10}= PM10 emission (kg PM_{10})
EF_{PM10}= the emission factor for this pollutant emission (kg PM_{10}/[m^2.year])
$A_{affected}$= area affected by construction activity (~1000 m^2)
d = duration of construction (year)
CE = efficiency of emission control measures (0.5 for non-residential construction)
PE = Thornthwaite precipitation-evaporation index (54.3, calculated using average values of climate parameters from 1981 to 2010)

s = soil silt content (12% for loamy sand (Soil Map Serbia, -) (World Reference Base, 2022))

In order to calculate particle emissions, emission factors were used. Particulate matter emission factors derived from the EMEP/EEA Air Pollutant Emission Inventory Guidebook 2019- 2.A.5.b Construction and demolition- Table 3-3 Tier 1 emission factors for uncontrolled fugitive emissions for source category 2.A.5.b Construction and demolition – Non-residential construction document. These emission factors are shown in Table 7-21.

Table 7-21. Tier-1 Default Emission Factors for Construction Activities

Pollutant	Value	Unit
PM_{10}	1.0	kg/[m^2.year]
$PM_{2.5}$	0.1	kg/[m^2.year]

According to the equation and emissions factors given, total fugitive PM emissions due to construction activities are calculated as follow;

Table 7-22. Total Fugitive PM for Construction Activities

Pollutant	kg/year	kg/h
PM_{10}	147.3297	0.08185
$PM_{2.5}$	14.73297	0.008185

The total PM_{10} emission calculated for the Sub-project site construction activities is 0.08 kg/h.

Emissions due to construction machinery are estimated with the following equation according to EMEP/EEA Air Pollutant Emission Inventory Guidebook 2019-Non-Road mobile sources and machinery (EMEP/EEA Air Pollutant Emission Inventory Guidebook, 2019):

$$E_{pollutant} = \sum_{fuel\ type} FC_{fuel\ type}\ x\ EF_{pollutant,fuel\ type}$$

Where:

$E_{pollutant}$= the emission of the specified pollutant,
$FC_{fuel\ type}$= the fuel consumption for each fuel (diesel, LPG, four-stroke gasoline and two-stroke gasoline) for the source category
$EF_{pollutant}$= the emission factor for this pollutant for each fuel type.

Tier-1 Emission Factors for Off-Road Machinery are shown in Table 7-23.

Table 7-23. Tier-1 Emission Factors for Off-Road Machinery for Construction Activities

Pollutant	Emission Factor Non-Road (g/tonnes fuel)
NO_x	32 629
SO_2	67[26]
VOC	3 377
CO	10 774
PM_{10}	2 104
$PM_{2.5}$	2 104

With the worst-case assumption that these vehicles will operate at the same time, it is predicted that the maximum amount of diesel fuel a vehicle will consume will be 5 L/hr-vehicle.

Density of Diesel = 0.830 kg/L

5 L/hr-vehicle x 0.830 kg/L x 9 vehicles = 37.35 kg/hour = 0.03735 tons/hr

Total fuel consumption for 6 months construction period is 67.23 tonnes[27].

According to the equation and emissions factors given, emissions due to construction activities are calculated as follow;

Table 7-24. Emission Calculations for Construction Activities

Pollutant	Emission Factor Non-Road (g/tonnes fuel)	Fuel Consumption (tonnes/hour)	Emission (g/hour)	Emission (kg/hour)
NOx	32629	0.03735	1218.6932	1.2186932
SO2	67	0.03735	2.50245	0.0025025
VOC	3377	0.03735	126.13095	0.126131
CO	10774	0.03735	402.4089	0.4024089
PM10	2104	0.03735	78.5844	0.0785844
PM2.5	2104	0.03735	78.5844	0.0785844

7.4.3.2 Operation Phase

The Sub-project will encourage the latest and most effective methods for managing healthcare waste, such as autoclave, to reduce the emission of persistent organic pollutants (POPs) and meet the requirements of the Stockholm Convention, which Serbia is a party. Consequently, a centralized autoclaving system for sterilizing medical waste will be established. As per the

[26] Calculated by 0.05% sulphur content of fuel in accordance with EMEP/EEA 1.a.4

[27] Assuming that construction works continue for 10 hours/day for 6 months

biosafety standards provided by the WHO Laboratory Biosafety Manual, the BSL-3 laboratory waste will first be autoclaved within the facility.

In the operational stage, emissions may occur from the lab ventilations. Release of airborne pathogens processed in the laboratory into the ambient air may cause air pollution. To prevent this, the laboratories will be constructed to be airtight and negatively pressurized. Every section of the laboratories will be equipped with High-Efficiency Particulate Air (HEPA) systems. The fumes from the laboratories will be gathered and directed through the HEPA systems for processing before being released into the air.

7.4.4 Greenhouse Gas Emissions

7.4.4.1 Background

Greenhouse gases can be described as gases that trap heat in the atmosphere. These gases allow sunlight to reach the Earth's surface unimpeded. The visible part of sunlight, which is short-wave energy, heats the surface and invisible long-wave energy radiates back into the atmosphere. Greenhouse gases (GHGs) absorb long-wave energy, thereby allowing less heat to escape back to space, trapping it in the lower atmosphere. Greenhouse gases are responsible for the greenhouse effect, which ultimately leads to climate change. The main anthropogenic source of greenhouse gases is the burning of fossil fuels.

Greenhouse gas emissions assessment is based on the review of the available data on the proposed Sub-project has been undertaken. Information on the Construction Phase of the Sub-project is based on the most up-to-date information available at the time of writing and supplemented with assumptions where necessary.

The Intergovernmental Panel on Climate Change (IPCC) published literature values for CO in AR5 (Fifth Assessment Report) WG1 (Working Group 1) – Chapter 8, and this will help calculate the total emissions from the Sub-project. Table 7-25 gives the Global Warming Potential for CO, CH_4, and N_2O.[28]

Table 7-25. Global Warming Potentials (GWPs) of GHGs as reported by IPCC AR5 (IPCC, 2014)

Greenhouse Gases	Formula	GWP	Greenhouse Gases
Carbon dioxide	CO_2	1	Carbon dioxide
Methane	CH_4	28	Methane
Nitrous oxide	N_2O	265	Nitrous oxide
Carbon monoxide	CO	2 – 3,3	Carbon monoxide

[28] As there is not much detail about global warming potential (GWP) values relative to CO_2 for NMVOCs, NO_x, and SO_2, only the greenhouse gases given in Table 9-28 were calculated.

7.4.4.2 Methodology

In order to calculate emissions from the Sub-project, the IPCC Guidelines for National Greenhouse Gas Inventories published in 2006, The European Bank for Reconstruction and Development (EBRD), The European Investment Bank (EIB), and UK GHG emission conversion factor by Department for Business, Energy & Industrial Strategy were used (IPCC, 2006; EBRD, 2017; BEIS, 2020; EIB, 2020).

7.4.4.3 Construction Phase GHG Emissions

There are two main phases in the construction works, earthworks and main construction (including engineering, procurement and commissioning activities). According to information supplied by the project owners, various types of machinery will be used during construction activities (see. Table 7-26). In calculating Construction phase GHG emissions, UK Government GHG Conversion Factors for Company Reporting 2020 Version 1.0 were used. It is estimated that the load factor is 0.5.

Table 7-26. Machinery List for the Construction Phase

Machinery	QTY
Excavator/Trenching Machine	2
Generator	1
Concrete mixing and placing plant	1
Cranes and lifting equipment	1
Tippers	3
Truck mounted telescopic crane of 25 tons minimum	1

It is planned to use (9) construction machines during the construction phase of the Sub-project including one (1) generator and there will be no use of construction equipment during the operation phase. With the worst-case assumption that these vehicles will operate at the same time, it is predicted that the maximum amount of diesel fuel a vehicle will consume will be 5 L/hr-vehicle. Total fuel consumption for 6 months construction period is 67.23 tonnes[29]. Scope 1 emissions from construction phase are calculated as 366 TCO_2e (tonnes CO_2 equivalent).

Under the construction phase of the Sub-project, Scope 3 emissions from category 3 (Fuel- and Energy-Related Activities, Not Included in Scope 1 or Scope 2) defined in EPA (2021) were calculated as 56 (tonnes) TCO_2e annually (GHG Protocol, 2021).

Total GHG emissions (Scope 1 and Scope 3) from the construction of the Sub-project were calculated as 423 tCO_2e. In addition, as the construction phase activities will not be more than 6 months duration, and there will be limited emission sources.

[29] Assuming that construction works continue for 10 hours/day

7.4.4.4 Operation Phase GHG Emissions

Scope 1 emissions are direct greenhouse (GHG) emissions that occur from sources that are controlled or owned by an organization (e.g., emissions associated with fuel combustion in boilers, furnaces, vehicles). Since electricity will be used instead of fuel combustion in the heating system of the Sub-project, there will not be any Scope 1 emissions.

Scope 2 emissions are indirect GHG emissions associated with the purchase of electricity, steam, heat, or cooling generated from a fossil fuel source. It is planned that electricity consumption in the Sub-project will be approximately 3420 MWh[30] yearly. Scope 2 emissions from operation phase are calculated as 2680 TCO_2e (tonnes CO_2 equivalent).

Under the operation phase of the Sub-project, Scope 3 emissions from category 3 (Fuel- and Energy-Related Activities, Not Included in Scope 1 or Scope 2) defined in EPA (2021) were calculated as 194 (tonnes) TCO_2e annually (GHG Protocol, 2021).

Total GHG emissions (Scope 2 and Scope 3) from the construction of the Sub-project were calculated as 2874 tCO_2e.

7.4.5 Impacts

7.4.5.1 Impacts during Construction

During the construction of the Sub-project, dust emissions will arise from earth movements, loading, unloading and transport of excavation materials both inside and outside the Sub-project site.

Excavation activities are considered to be completed in 2 weeks as part of the total construction phase and it is assumed that the activities will last for 25 days a month for 10 hours a day.

The use of heavy equipment during site preparation and construction could result in air pollution due to the emissions from the combustion engines. However, as there will only be a few pieces of equipment and their usage will be limited, the impact on air quality will be temporary and restricted to the construction area. The operation of construction vehicles such as dump trucks, cranes, and those involved in waste disposal actions may also produce localized emissions of other air pollutants, but their effect will be minimal.

Transporting building materials to the Sub-project site generates emissions of various air pollutants, including SO_2, CO_2, CO, NO_x, and particulates. The proximity of the Sub-project to the road may result in gaseous emissions and dust, but it is not expected to significantly contribute to air pollution.

[30] Asssuming that the transformer operates at 95% efficiency for 12 hours/day and 300 days/year

Table 7-27 shows the summary of the conclusions mentioned above and the impact significances for the monitoring points. Impact significances are determined based on the methodology given in Chapter 5 of this ESIA Report.

Table 7-27. Summary of Impact Significances of the Receptors during the Construction Phase-Air Quality

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)								
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)	Receptor Sensitivity	Impact Significance (Magnitude x Significance)
PM_{10} ($\mu g/m^3$) at Measuring Point 1 (PM10, PM2.5-1)	Negative Direct	Definition	Considering potential impacts during the Site Preparation Activities (excavation, filling, disposal, construction of temporary facilities) the geographical extent of the impact is expected to be local.	Site preparation activities at the Sub-project site will continue for 2 weeks	Emissions in the region is not estimated to exceed low intensity since the potential impact is expected to be mostly limited to machinery and equipment in the case that no measures are taken during construction.	-	Due to the nature of construction activities, emissions are expected.	Emissions from the construction works will be effective for a short time and will not cause permanent effects.	PM10-1	**Low**
	Score	Local	Short	Low		-	Probable	Short-term	Medium	
		Value	2	2	2	-	5	1	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**11**						**3**	**33**
PM_{10} ($\mu g/m^3$) at Measuring Point 2 (PM10, PM2.5-2)	Negative Direct	Score	Local	Short	Low	-	Probable	Short-term	PM10-2 Medium	**Low**
		Value	2	2	2	-	5	1		
	Impact Magnitude (G+D+I+F (or L)) x R		**11**						**3**	**33**

It should be noted that the significances of impacts described above are for the baseline monitoring points that are mostly located at the boundaries of the Sub-project site. The emissions are expected to decrease with increased distance from the emission source and receptors that are away from the source of emissions have the potential to experience impacts less than described above and impact significance is expected not to be as significant considering PM_{10} concentrations values and to vary between minor to moderate.

Transport of construction materials will also cause emissions related to construction traffic which may potentially impact the ambient air quality. This type of transportation will be temporary, and the significance of impacts might range from minor to major, depending on the amount of transportation and the location of receptors. It is expected that these impacts will be reduced to impacts of less significance with the implementation of measures mentioned in Section 7.5.5 below.

7.4.5.2 Impacts during Operation

Laboratories will be constructed to be airtight and negatively pressurized and equipped with HEPA systems to gather and direct the fumes from the laboratories before being released into the air. Since electricity will be used instead of fossil fuels in the heating system of the Sub-project, no emissions are expected due to heating.

The only pollution source during the operation phase is exhaust emissions (NO_x, SO_2, PM_{10}, $PM_{2.5}$ and CO) of the vehicles due to increased traffic.

Table 7-28 shows the summary of the conclusions mentioned above and the impact significances for the measurement points. Impact significances are determined based on the methodology given in Chapter 5 of this ESIA Report.

Table 7-28. Summary of Impact Significances of the Receptors during the Operation Phase-Air Quality

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							Receptor Sensitivity	Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)		
PM_{10} (µg/m^3) at Measuring Point 1 (PM10, PM2.5-1)	Negative Direct	Definition	Considering potential impacts during operation, the geographical extent of the impact is expected to be local.	The Sub-project will be operational for more than 5 years	Emissions from the operation will not cause permanent effects.	-	No emissions expected	Emissions from the operation works will be effective for a short time and will not cause permanent effects.	PM10-1 Medium	**Negligible**
		Score	Local	Very long	Negligible	-	Improbable	Short-term		
		Value	2	5	1	-	0	1		
	Impact Magnitude (G+D+I+F (or L)) x R		**8**						**3**	**24**
PM_{10} (µg/m^3) at Measuring Point 2 (PM10, PM2.5-2)	Negative Direct	Score	Local	Very long	Negligible	-	Improbable	Short-term	PM10-2 Medium	**Negligible**
		Value	2	5	1	-	0	1		
	Impact Magnitude (G+D+I+F (or L)) x R		**8**						**3**	**24**

As in the construction phase, impact of the emissions is expected to decrease with increased distance from the source of emissions. Therefore, receptors that are further from the source of emissions are likely to experience impacts less than described above.

7.4.6 Mitigation Measures

7.4.6.1 Mitigation of Air Quality Impacts during Construction

An Air Quality and Noise Management Plan will be prepared, which will include mitigation measures that will be implemented to reduce dust emissions. Additionally, air pollutants will be monitored at nearby sensitive locations to ensure minimal impacts in accordance with the Air Quality and Noise Management Plan. During earthworks, monthly PM_{10} measurements shall be conducted.

The following mitigation measures will be implemented to address dust emissions during construction:

- Good management and housekeeping practices and dust suppression methods will be applied. Water spraying will be performed at dust generating areas inside the Sub-project site, especially during dry weather conditions;
- Excavated soils will be stockpiled (as necessary) at designated areas and will be placed as far as possible from the settlements. Dusty and loose materials will be properly covered, and top layers will be kept moist;
- Where high dust emission can not be prevented particularly due to wind effect and at locations close to the residential areas in addition to the water spraying polymer emulsions (approved chemical dust suppressants) will be used for dust suppression, particularly at the temporary excavated material storage areas, on stockpiles, slopes, on the temporary unpaved, or earth roads within the Sub-project site;

The following mitigation measures will be implemented to minimize dust emissions related to the transport of materials during construction:

- Vehicle speed limits will be applied inside and outside the Sub-project site for paved and unpaved roads (e.g., unpaved roads around 10km/h, paved roads around 20 km/h within the site). Truck operators will be trained to comply with speed limits and good construction site practices;
- Necessary applications will be made to the relevant authority to upgrade the offsite road conditions. On-site roads will be well-maintained against dust emissions;
- Transfer roads will be sprayed with water as necessary (for example using mobile watering bowsers) to prevent significant dust emissions, especially in dry weather conditions;
- Trucks carrying excavated soils will be covered before leaving the construction area;

- The material drop distance will be limited between the offloading point and stockpile to no more than 1 m and the flow of material will be restricted using dead boxes, socks, drop down spouts/sleeves;
- Frequently used and long-term haulage roads will be paved (e.g., asphalt, concrete, etc.);
- Daily visual inspections will be done at the stockpiles, haulage roads and during the heavy vehicle movements in order to detect dust emission sources.
- Vehicles will be kept clean, so that no dirt is carried on the vehicles into and out of the area.

Exhaust Emissions

- Construction equipment and trucks will be maintained regularly to keep them in good working condition to minimize exhaust emissions caused by poor performance;
- Low sulphur contained fuel will be used;
- Engines of the equipment/trucks will be prevented from idling;
- Unnecessary Sub-project traffic will be avoided inside and outside of the Sub-project side by adequate planning of material transport;
- A Construction Site Traffic Management Plan will be prepared and implemented which will decrease the impacts of traffic resulting from the construction activities.

7.4.6.2 Mitigation of Air Quality Impacts during Operation

The only pollution source during the operation phase is exhaust emissions. Laboratories will be equipped with HEPA systems to gather and direct the fumes from the laboratories before being released into the air. Since electricity will be used instead of fossil fuels in the heating system of the Sub-project, no emissions are expected due to heating.

It is predicted that there will be an increase in the number of vehicles as the number of people receiving service from the Torlak Institute will increase with the Sub-project, and impact of the emissions are expected to decrease with increased distance from the source of emissions. Therefore, no mitigation is determined for the operation phase.

7.4.7 Residual Impacts

For the construction phase, impacts from air emissions can be effectively mitigated through good management practices and the implementation of mitigation measures such as dust suppression, mentioned above. Hence, mitigation measures are expected to minimise such impacts to short and intermittent events that will be reversible in a short-term by the effect of the natural processes. The Residual Impact Significances for the construction phase are given in Table 7-29.

For the operation phase, no emissions are expected due to operation of the proposed Sub-project and no mitigation measure is determined. Therefore, residual impacts are expected to remain same as given in Section 7.5.4.2. The Residual Impact Significances for the operation phase are given in Table 7-30.

Table 7-29. Construction Phase Residual Impact Significances-Air Quality

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							Receptor Sensitivity	Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)			
PM10 (µg/m³) at Measuring Point 1	Negative Direct	Score	Local	Short (During earthworks)	Low	-	Unlikely	Short-term after the cessation of the emission source.	PM10-1 Medium	**Negligible**
		Value	2	2	2	-	1	1		
	Impact Magnitude (G+D+I+F (or L)) x R		**7**						**3**	**21**
PM10 (µg/m³) at Measuring Point 2	Negative Direct	Score	Local	Short	Low	-	Unlikely	Short-term	PM10-2 Medium	**Negligible**
		Value	2	2	2	-	1	1		
	Impact Magnitude (G+D+I+F (or L)) x R		**7**						**3**	**21**

Table 7-30. Operation Phase Residual Impact Significances-Air Quality

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							Receptor Sensitivity	Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)		
PM10 (µg/m³) at Measuring Point 1	Negative Direct	Score	Local	Very long	Negligible	-	Improbable	Short-term	PM10-1 Medium	**Negligible**
		Value	2	5	1	-	0	1		
	Impact Magnitude (G+D+I+F (or L)) x R		**8**						**3**	**24**
PM10 (µg/m³) at Measuring Point 2	Negative Direct	Score	Local	Very long	Negligible	-	Improbable	Short-term	PM10-2 Medium	**Negligible**
		Value	2	5	1	-	0	1		
	Impact Magnitude (G+D+I+F (or L)) x R		**8**						**3**	**24**

7.5 Noise

7.5.1 Introduction

This section presents the assessment of the noise impacts that will be generated during the construction and operation phases of the Sub-project. Noise levels around the AoI will increase during the construction temporarily and operation phase of the Sub-project. The difference between the baseline noise levels and the noise levels during Sub-project implementation will determine the impact and its significance.

The background noise monitoring was carried out at the nearest receptors by Anarhem Laboratory in order to determine background noise levels. The background noise measurements report is presented in Appendix-F.

The significance criteria that were used related to impacts on noise were established by identifying the impact magnitudes and receptor sensitivity. The magnitude and sensitivity criteria for impact assessment methodology are detailed in *Chapter 5: Scope and Methodology*. For determining the magnitudes of the impacts, impact intensity should also be assessed according to changes in baseline air quality. The details on the methodology for the determination of impact intensity, Sub-project specific receptor sensitivity, and criteria to identify impact significance are given in Section 7.6.5 of this chapter.

7.5.2 Legal Context

7.5.2.1 National Regulations on Environmental Noise

Environmental noise is regulated by the Degree on noise indicators, limit values, methods for evaluating of noise indicators, disturbance and harmful effects of environmental noise (Official Gazette of RS, no. 75/10) in Serbia.

The noise indicators for overall annoyance defined by Degree are L_{day}, $L_{evening}$ and L_{night}. The indicators are for A-weighted long-term average sound level determined over all the day periods of a year. The indicators are intented for certain periods of a day. L_{day} day-noise indicator is for between 06:00-18:00 hrs, $L_{evening}$ evening-noise indicator is for between 18:00 – 22:00 hrs, and L_{night} night-time noise indicator is for between 22:00 – 06:00 hrs. The regulation sets noise limits for these indicators applicable to various areas (e.g. industrial areas, residential areas or combination of both). Noise limit values for noise emission sources are presented in Table 6-31 which gives maximum allowable environmental noise levels that shall be met at the nearest off-site receptor.

Table 7-31. Environmental noise limits for industrial facilities (Leq-dBA)

Areas	L_{day}–& L_{eve} (dBA) (06:00 - 18:00 & 18:00-22:00)	L_{night} (dBA) (22:00 - 06:00)
Rest and recreation areas, hospital zones and convalescent centers, cultural and historical sites, large parks	50	40
Tourist areas, camps and school zones	50	45
Purely residential areas	**55**	**45**
Business-residential areas, commercial-residential areas and children's playgrounds	60	50
City center, craft, trade, administrative zone with apartments, zone along highways, highways and city roads	65	55
Industrial, storage and service areas and transport terminals without residential buildings	At the border of this zone, the noise must not exceed the limit value in the bordering zone	

The Sub-project site falls within the category of "Purely residential areas where residential buildings dominate" and the associated noise limits shown in Table 7-31 are applicable during the construction and operation phases of the Sub-project.

7.5.2.2 International Regulations on Environmental Noise

IFC General Environmental, Health and Safety (EHS) Guidelines and World Health Organization (WHO) Noise Guidelines set limits for noise for two types of receptors and two time periods, as shown in Table 7-32.

Table 7-32. IFC and WHO noise level guidelines (one hour Leq-dBA)

Receptor	Daytime (07:00 - 22:00)	Nighttime 22:00 - 07:00
Residential areas	**55**	**45**
Commercial/industrial areas	70	70

WHO and IFC standards state that cumulative noise level limits depend on the background noise levels. As such, in determination of the limits, background noise levels are taken into consideration. In order to evaluate cumulative noise levels, energetic summation of background noise and project noise exposure are assessed. When the cumulative noise levels are less than the limit values of Lday = 55 dBA and Lnight = 45 dBA, the limits are set to these values. If the cumulative noise values are higher than these limit values, the cumulative noise levels should not exceed background noise by more than 3 dBA.

7.5.3 Noise Sources

7.5.3.1 Construction Noise and Vibration

Although the construction noise is temporary, the noise levels will increase significantly during the construction phase of the Sub-project compared to the baseline condition.

Potential source of noise and vibration impacts may be caused by but not limited to:

- noise and vibrations emitted by machinery, equipment and vehicles used during construction,
- production of gravel and concrete,
- construction works (i.e. earthworks, construction, on-site and off-site transport of materials, etc.)

During construction phase, all activities including pre-construction land arrangement, construction activities and construction equipment and vehicle movement such as cement mixers, trucks, etc. are sources of noise.

The Sub-project noise sources list of machinery-equipment to be used in the land preparation and construction phase within the scope of the activities of the Sub-project that will cause environmental noise are presented in the Table 7-33.

Table 7-33. The Sub-Project Noise Sources List of Machinery-Equipment to be used in Land Preparation and Construction Phase

Machineries and Equipment	Total Number of Machineries and Equipment in Project Area
Excavator/Trenching Machine	2
Generator	1
Concrete mixing and placing plant	1
Cranes and lifting equipment	1
Tippers	3
Truck mounted telescopic crane of 25 tons minimum	1

For the calculation of the total sound power levels in the four octave bands of 500-4,000 Hz of the machinery-equipment to be used at the same time within the scope of the Sub-project were used. The calculations made in this context are given in the Table 7-34.

Table 7-34. Sound Power Levels[31]

Type of Equipment	Net installed power P (kW), Electric power Pel (kW), Application mass m (kg), Cutting width L (cm)	Permissible sound power level dB/1 pW	
		Stage I as from 3 January 2002	Stage II as from 3 January 2006
Compaction machines (vibrating rollers, vibratory plates, vibratory hammers))	P ≤ 8	108	105
	8 < P ≤ 70	109	106
	P > 70	89 + 11 log P	86 + 11 log P
Tracked dozers, tracked loaders, tracked backhoe loaders	P ≤ 55	106	103
	P > 55	87 + 11 log P	84 + 11 log P
Wheel dozers, wheel loaders, wheel backhoe-loaders, dump trucks, graders, loader-type	P ≤ 55	104	101
	P > 55	85 + 11 log P	82 + 11 log P

[31] Directive 2005/88/EC of the European Parliament and of the Council of 14 December 2005 amending Directive 2000/14/EC on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors

Type of Equipment	Net installed power P (kW), Electric power Pel (kW), Application mass m (kg), Cutting width L (cm)	Permissible sound power level dB/1 pW	
		Stage I as from 3 January 2002	Stage II as from 3 January 2006
earth-fill compactors, internal combustion engine driven counterweight hydraulic lift trucks, mobile cranes, compaction machines (non-vibration rollers), pavement trowels, hydraulic power generation machines			
Excavators, hoists for hauling goods, construction cranes, motorized cultivators	P ≤ 15	96	93
	P > 15	83 + 11 log P	80 + 11 log P
Hand-held concrete breakers and drills	m ≤ 15	107	105
	15< m < 30	94 + 11 log m	92 + 11 log m
	m ≥ 30	96 + 11 log m	94 + 11 log m
Tower cranes		98 + log P	96 + log P
Welding and power generators	Pel ≤ 2	97 + log Pel	95 + log Pel
	2 < Pel ≤ 10	98 + log Pel	96 + log Pel
	Pel > 10	97 + log Pel	95 + log Pel
Compressors	P ≤ 15	99	97
	P > 15	97 + 2 log P	95 + 2 log P
Lawn mowers, lawn trimmers/lawn edging machines	L ≤ 50	96	94
	50< L ≤ 70	100	98
	70< L ≤ 120	100	98
	L > 120	105	103

Sound power levels are calculated separately for each machinery and equipment by means of the formulas in the table above, based on the engine power or application masses of the machinery and equipment to be used. The engine power levels of the machinery and equipment to be used are given in the Table 7-35.

Table 7-35. Engine Powers of Machinery and Equipment to be used in the Land Preparation and Construction Phase of the Sub-Project

Machinery/Equipment to be used	Motor Power	
	hP	kW (*)
Truck	87	65
Excavator	130	97
Concrete Mixer	120	90
Mobile Crane	87	65
Generator	-	105

(*) Shigley, Design in Mechanical Engineering 8. Metric Edition Translation-Annex-1 Conversion Coefficients Table

Note: All considerations are for 1 hP = 0.746 kW.

Truck

Since the engine power of 87 hp (65 kW) accepted for the truck to be used is P>55 kW given for the dump trucks in the table above, the formula “Lw = 82 + 11log P” has been used in the calculation of the sound power level.

Lw = 82 + 11 log 87
Lw = 103.3 dB

Excavator

Since the engine power of 130 hp (97 kW) accepted for the excavator to be used is P>55 kW given for the excavator in the table above, the formula “Lw = 82 + 11log P” has been used in the calculation of the sound power level.

Lw = 82+ 11 log 130
Lw = 105.3 dB

Concrete mixer

Since the engine power of 120 hp (97 kW) accepted for the concrete mixer to be used is P>55 kW given for the excavator in the table above, the formula “Lw = 82 + 11log P” has been used in the calculation of the sound power level.

Lw = 82+ 11 log 120
Lw = 105dB

Mobile Crane

Since the motor power of 87 hp (65 kW) accepted for the mobil crane to be used is P>15 kW given for the tower crane in the table above, the formula “Lw=80+11 log P” has been used in the calculation of the sound power level.

Lw = 80 + 11 log 87
Lw = 101.3 dB

Generator

Since the motor power of 105 kW accepted for the generator to be used is P_{el}>10 given for the generator in the table above, the formula “Lw=95+ log P_{el}” has been used in the calculation of the sound power level.

Lw = 95+ log 105
Lw = 97 dB

In this context, the sound power levels calculated above are summarized in the Table 7-36.

Table 7-36. Sound Power Levels of Noise Sources

Machinery/Equipment to be used	Sound Power Level (dB)
Truck	103.3
Excavator	105.3
Concrete Mixer	105
Mobile Crane	101.3
Generator	97

Noise calculations were made using the formulas below (Börje Nilsson, 2008). The worst case scenario where all vehicles would operate at the same point, at the same time was taken into account when calculating noise values.

The total equivalent noise level generated by noise sources is calculated using the formula (1) given below. In this formula, noise sources are considered to be in the same plane.

$$L_{eq} = 10 \times \log \sum_{i=1}^{n} 10^{L_i/10} \quad \text{..(1)}$$

Where;

n = number of noise sources,

L_i = Sound power level of each source (dB(A))

= Total equivalent noise level

L_{eq} = 113.08 dBA

The power level (L_p) of the sound which is caused by machinery/equipment and which reaches a given distance was calculated using the formula (2) given below ;

$$L_P = L_{eq} + 10 \times \log\left(\frac{Q}{4.\pi.r^2}\right) \quad \text{.....................................(2)}$$

L_p : Sound power (noise) level (dBA)

Q : Coefficient of Direction (Accepted as 1 in Free Space)

r : Distance (m)

The distance-dependent change in sound level is presented in Table 7-37 and Figure 7-1.

Table 7-37. Levels of Noise from Equipment by Distance

Distance (m)	Leq (dBA)	Sound Pressure Level (dB)			
		500 Hz	1,000 Hz	2,000 Hz	4,000 Hz
10	88.92	78.89	82.08	83.25	82.92
25	80.74	70.93	74.11	75.22	74.70
50	74.41	64.90	68.06	69.09	68.24
100	67.90	58.86	61.98	62.86	61.35
250	59.01	50.86	53.86	54.24	50.78
500	52.05	44.78	47.57	47.14	40.41
1000	44.87	38.62	41.00	38.94	25.68

Distance (m)	Leq (dBA)	Sound Pressure Level (dB)			
		500 Hz	1,000 Hz	2,000 Hz	4,000 Hz
2000	37.43	32.33	33.89	28.57	0.00
5000	27.15	23.55	22.67	7.55	0.00
7500	22.46	19.35	16.43	0.00	0.00
10000	19.11	16.17	11.21	0.00	0.00

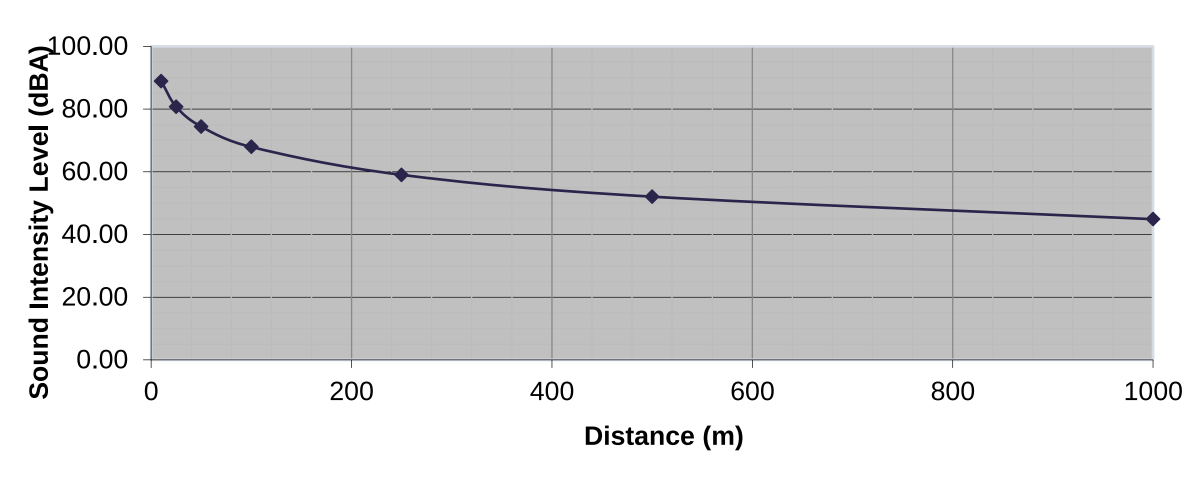


Figure 7-1. Levels of Noise from Equipment by Distance

The limit values in Degree on noise indicators, limit values, methods for evaluating of noise indicators, disturbance and harmful effects of environmental noise (Official Gazette of RS, no. 75/10) and WHO Noise Guidelines, which should not be exceeded by the noise from construction operations at the nearest receptor, are given in Table 7-37, and the limit values determined by WHO in Table 7-32.

The closest settlement to the construction site is the lodging facilities located 170 meters away. The expected noise level at this distance is 63 dBA. The calculated noise level is above the limit values presented in Table 7-37. Considering that the construction works will continue for a certain period of time, it is apparent that the expected effect will be temporary. Similarly, it is obvious that the actual noise level will be far below the calculated value, considering the calculated values were calculated estimated based on the worst-case scenario where each equipment would operate at the same point, at the same time. For this reason, the noise from the construction works under the Sub-project is not expected to have a long-term negative impact on the nearest sensitive receptors to the work site.

Blasting, which is an important source of vibration for construction, will not be performed as part of the Sub-project. Potential vibration effects within the scope of the Sub-project will be caused by truck movements and use of construction machinery. The increase in vibration may disturb the occupants of residential buildings and other noise-sensitive buildings close to the Sub-project area boundaries. Truck movements caused by excavated materials removed from the site will not be frequent, and there is no sensitive receptor that is close enough to the Sub-project area to feel the vibration. A road runs between the sensitive receptors and the Sub-project area. The route that will be used by the equipment and vehicles used to transport excavation and construction materials as part of the Sub-project features vehicle traffic according to the traffic counting study conducted on December 2022. For this reason, the resulting vibration is not expected to lead to an adverse impact.

7.5.3.2 Operation Noise and Vibration

During operation period, laboratory equipment, heating and cooling system fans will be the main noise sources. Due to isolated closed units and building, there is no noise source that will generate noise. No activity other than existing road traffic that may cause noise is expected during the operation phase since the Sub-project does not involve open machinery operation.

No vibration is foreseen during operation period of the Sub-project.

7.5.4 Impacts

The significance criteria that were used for assessing noise impacts are established by evaluating the magnitude of the impacts together with the sensitivity/vulnerability/importance of the receptors. Impact significances are determined based on the methodology given in Chapter 5 of this ESIA Report with more detailed descriptions of the impact intensity types that are used for the determination of the impact magnitudes and receptor sensitivities given in the Table 7-38 to Table 7-39 below.

Table 7-38. Intensity of Noise Impact on Receptors

Magnitude	Description
Negligible	Increase in average sound pressure levels between 0 and 3 dB from the expected construction activity induced ambient sound level (proposed rating level). No change in ambient sound levels discernible. Noise impact can be heard, but does not cause any change in behaviour or attitude.
Low	Increase in average sound pressure levels between 3 and 5 dB from the (expected) ambient sound level (proposed rating level). The change is barely discernible, but the noise source might become audible.
Moderate	Increase in average sound pressure levels between 5 and 10 dB from the (expected) ambient sound level (proposed rating level). Sporadic complaints expected. Causes a material change in behaviour and/or attitude, e.g. avoiding certain activities during periods of intrusion. Potential for sleep disturbance resulting in difficulty in getting to sleep, premature awakening and difficulty in getting back to sleep. Quality of life diminished due to change in character of the area.
High	Increase in average sound pressure levels higher than 10 dBA from the (expected) ambient sound level (proposed rating level). Change of 10 dBA is perceived as ‘twice as loud’, leading to widespread complaints and even threats of community or group action. Significant changes in behaviour and/or an inability to mitigate effect of noise leading to psychological stress or physiological effects Any point where noise levels exceed 65 dBA at any receptor.

Table 7-39. Receptor Sensitivity to Noise Impact

Value	Description
Low	Commercial and residential areas where workplaces dominate. Users of the agricultural lands to the west of the Project Site .
Medium	Commercial and residential areas where residential buildings dominate.
High	Areas where sensitive receptors are located including education, culture, health, summer houses and camping areas.

7.5.4.1 Impacts during Construction

The main noise sources during construction activities include use of construction machinery and equipment during earthworks and other construction activities, construction traffic related to the transportation of excavated soils and construction materials. Increased noise levels during construction activities have the potential to create negative impacts on the background noise levels which may lead to further impacts on sensitive receptors such as, health risks at nearest sensitive receptors. The actual impact level due to construction activities will also depend on other parameters such as the type of equipment to be used, time period and duration, and the perception of specific noise patterns (e.g., continuous, regular intervals, irregular).

The frequent truck movements due to haulage of construction and fill materials at the site, potential off-site transfer of excavated materials for disposal may cause disturbance particularly to the residents of nearby neighbourhoods.

As described in detail in the sections above, in order to predict the impacts of the Sub-project on the existing background noise levels, noise level calculation study was conducted.

Insitu background noise monitoring at two receptor points identified in the vicinity of the Sub-project site revealed the following:

- Baseline background noise levels are below the IFC / WHO standards and national limits at Measurement Point 1.
- Baseline background noise levels are exceeding the IFC / WHO standards and national limits at Measurement Point 2.

The results of the noise calculation revealed that predicted noise levels exceed the IFC / WHO and national noise limits at the nearest sensitive receptor.

Impact significances are determined based on the methodology given in Chapter 5 and magnitude and sensitivity criteria summarized in Table 7-40 .

Table 7-40. Construction Phase Noise Impact Magnitudes

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)								
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)	Receptor Sensitivity	Impact Significance (Magnitude x Significance)
Noise Impacts due to Earthworks	Negative Direct	Definition	Considering potential impacts during the Site Preparation Activities (excavation, filling, disposal, construction of temporary facilities) the geographical extent of the impact is expected to be local.	Site preparation activities at the Sub-project site will continue for 2 weeks	Based on the results of the calculation study, it can be concluded that the IFC / WHO noise limit values will be exceeded during construction phase at the nearest sensitive receptors.	Machinery and equipment causing noise emissions will be used during site preparation activities in the day-time.	-	Due to the potential nature and intensity, the relevant impacts are expected to be reversible in the short term when the earthwork activities are completed.	Residential area and residential buildings in the close vicinity of the Sub-project area	Low
		Score	Local	Very short	Very High	Frequent	-	Short-term	High	
		Value	2	1	5	4	-	1	5	
	Impact Magnitude (G+D+I+F (or L)) x R		**12**						**5**	**60**
Noise Impacts due to Construction Activities	Negative Direct	Definition	Considering potential impacts during the Construction Activities (civil works, structural works, building works, mechanical, electrical and instrumentation works etc.) the geographical extent of the impact is expected to be local.	Construction activities at the Sub-project site will continue for 6 months.	Noise from the construction works will be effective for a short time and will not cause permanent effects. Noise impacts in the region is not estimated to exceed medium intensity since the potential impact is expected to be mostly limited to machinery and equipment in the case that no measures are taken during construction.	Machinery and equipment will be used during construction activities generally in the day-time.	-	Due to the potential nature and intensity, the relevant impacts are expected to be reversible in the short term when the construction is completed.	The Sub-project is within a residential area including sensitive receptors such as education and health facilities. Baseline background noise levels are exceeding the IFC / WHO standards and national limits at Measurement Point 2.	Low
		Score	Local	Short	High	Recurrent	-	Short-term	High	
		Value	2	2	4	3	-	1	5	
	Impact Magnitude (G+D+I+F (or L)) x R		**11**				**5**	**55**		

The intermittent character and short duration of the impact are expected to keep the impact significance low. Additionally, the impact will directly cease with the stopping of the activities.

Based on the results of the background measurements and calculation study, it can be concluded that the IFC / WHO noise limit values will be exceeded during the construction phase at the nearest sensitive receptors. However, this impact will be temporary and observed only during the construction period. As discussed, the noise calculation study considered operation of all types of equipment and machinery at the same time to assess the worst-case conditions. Considering this approach, the exceedance of background noise levels is expected to be lower than the calculated values.

It is important to note that there may be other noise sources that were not foreseen at this stage and may have an additional impact on noise levels. For this reason, it is important that regular monitoring is conducted, particularly at sensitive receptor points during high noise generating activities such as excavation activities.

7.5.4.2 Impacts during Operation

The main noise sources during the operational phase include operation of laboratory equipment and heating and cooling system fans and the increase in road traffic from the operation of the Sub-project.

For the operational phase, IFC / WHO noise limit values will not be exceeded at the nearest sensitive receptors due to operation of the Sub-project. There may be other sources that were not foreseen at this stage that may have an additional impact on noise levels.

Impact significances are determined based on the methodology given in Chapter 5 and magnitude and sensitivity criteria summarised in Table 7-41 and Table 7-42.

Table 7-41. Operation Phase Noise Impact Magnitudes

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)						
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)
Noise Impacts Due to Operation Activities	Negative Direct	Definition	Considering potential impacts and measurement results during the Operation Activities the geographical extent of the impact is expected to be local.	Noise impacts will continue throughout the life of the Sub-project.	The most significant noise sources are expected to be indoor machinery and equipment activities.	Noise impacts will continue throughout the life of the Sub-project.	-	Due to the potential nature and intensity, the relevant impacts are expected to be reversible in the short term.
		Score	Local	Very-Long	Negligible	Continuous	-	Short-term
		Value	2	5	1	5	-	1
	Impact Magnitude (G+D+I+F (or L)) x R		**13**					

Table 7-42. Impact Significances for Operation Phase-Noise

Potential Impact	Potential Receptor	Impact Magnitude	Sensitivity	Impact Significance		
				Value	Score	Description
Noise Impacts Due to Operation Activities	Residential area and residential buildings in the close vicinity of the Sub-project area	13	5	**65**	**Low**	The cumulative noise impact (sum of the background and operation-originated noise) will exceed the IFC and WHO guideline values since the background noise levels are already above the limits.. The noise impact due to Sub-project operations is expected to be below 5 dBA. Hence, low significance of impact is expected at the sensitive receptors including the closest residential areas.

7.5.5 Mitigation Measures

7.5.5.1 Mitigation of Noise Impacts during Construction

The following mitigation measures will be implemented during the construction phase in order to ensure that noise limit values set in the standards are met and the noise impacts are minimised as much as possible:

- 'Low-noise' equipment will be used during the construction phase as far as possible. Where construction equipment is provided with sealed acoustic covers or enclosures, the covers will be kept closed whenever the machines are in use.
- Machines will be shut down or throttled down to a minimum when not in operation.
- Maintenance procedures will be implemented in order to keep equipment in good working condition to minimise extraneous noise caused by poor performance.
- Noisy activities taking place within construction sites will be located away from the residential areas and kept short as much as possible. The activities should be conducted only during daytime.
- Noise related to traffic during construction will be properly managed through implementation of a Construction Site Traffic Management Plan.
- Awareness will be increased among construction workers regarding noise mitigation.
- Noise monitoring measurements will be conducted monthly to identify the need for noise barriers. It is important to note that noise monitoring may be undertaken more frequently if there is significant number of complaints from stakeholders.

OperationIn general, equipment's generating noise during the operation of the Sub-project will be located in isolated closed buildings. Therefore, no significant noise impact, except OHS, is expected at nearest receptor. The following mitigation measures will be taken during the operation phase in order to ensure that noise limit values set in the standards are met:

- 'Low-noise' equipment will be used during operation phase as far as possible. Depending on technical suitability, noise generating equipment will be kept in confined spaces to the extent possible.
- Equivalent sound pressure level for 8 hours, superimposed on the existing background noise level, in the work area within the new facilities will not exceed 85 dB(A) at any point 1 meter away from any equipment surface in accordance with the Serbian Law on Safety and Health at Work. If it is unavoidable that the work area limit will be exceeded around particular equipment, action will be taken to reduce the area involved as much as feasible; this may include the installation of an acoustical enclosure.
- During the procurement of equipment and machinery, sound levels given in the technical specifications/data sheet will be taken into consideration.
- Regular maintenance of noisy equipment and replacement of aged parts, which cause undesired noise, will be conducted to avoid or reduce noise impacts.

7.5.6 Residual Impacts

Construction phase noise impacts will be temporary and can be mitigated with the implementation of measures mentioned above. It is expected that the residual impact would be minimised to low and negligible through the mitigation measures. However this will be confirmed based on the results of noise monitoring during construction. Table 7-44 shows the residual impact significances for construction period.

Residual impact is expected as "Low" and "Negligible" at nearest receptors by the operation of the Sub-project after implementation of the mitigation measures. Table 7-46 shows the residual impact significances for operation period.

Table 7-43. Construction Phase Residual Impact Magnitude-Noise

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)						
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)
Noise Impacts due to Earthworks	Negative Direct	Definition	Considering potential impacts during the Site Preparation Activities (excavation, filling, disposal, construction of temporary facilities) the geographical extent of the impact is expected to be local.	Site preparation activities at the Sub-project site will continue for 2 weeks	By ensuring the high noise generating activities are performed and heavy machinery are operated during the day-time and by application of the mitigation measures exceedance of the guideline values and national legislative limit values will be prevented and the intensity of impacts will be minimised as much as possible.	Machinery and equipment will be used during site preparation activities generally in the day-time.	NA	Due to the potential nature and intensity, the relevant impacts are expected to be reversible in the short term when the land preparation is completed.
		Score	Local	Very short	Low	Frequent	-	Short-term
		Value	2	1	2	4	-	1
	Impact Magnitude (G+D+I+F (or L)) x R		**9**					
Noise Impacts due to Construction Activities	Negative Direct	Definition	Considering potential impacts during the Construction Activities (civil works, structural works, building works, mechanical, electrical and instrumentation works etc.) the geographical extent of the impact is expected to be local.	Construction activities at the Sub-project site will continue for 6 months.	By ensuring the high noise generating activities are performed and heavy machinery are operated during the day-time and by application of the mitigation measures exceedance of the guideline values and national legislative limit values will be prevented and the intensity of impacts will be minimised as much as possible.	Machinery and equipment will be used during construction activities generally in the day-time.	NA	Due to the potential nature and intensity, the relevant impacts are expected to be reversible in the short term when the construction is completed.
		Score	Local	Short	Low	Recurrent	-	Short-term
		Value	2	2	2	3	-	1
	Impact Magnitude (G+D+I+F (or L)) x R		**9**					

Table 7-44. Construction Phase Residual Impact Significance-Noise

Potentail Impact	Potential Receptor	Impact Magnitude	Sensitivity	Impact Significance	
				Value	Score
Noise Impacts Due to Earthworks Activities	Residential area and residential buildings in the close vicinity of the Sub-project area	9	5	**45**	**Low**
Noise Impacts Due to Construction	Residential area and residential buildings in the close vicinity of the Sub-project area	9	5	**45**	**Low**

Table 7-45. Operation Phase Residual Impact Magnitude-Noise

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)						
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)
Noise Impacts Due to Operation Activities	Negative Direct	Definition	Considering potential impacts and measurement results during the Operation Activities the geographical extent of the impact is expected to be local.	Noise impacts will continue throughout the life of the Sub-project.	The most significant noise sources are expected to be indoor machinery and equipment activities.	Noise impacts will continue throughout the life of the Sub-project.	NA	Due to the potential nature and intensity, the relevant impacts are expected to be reversible in the short term.
		Score	Local	Very-Long	Negligible	Continuous	-	Short-term
		Value	2	5	1	5	-	1
	Impact Magnitude (G+D+I+F (or L)) x R		**13**					

Table 7-46. Operation Phase Residual Impact Significance-Noise

Potentail Impact	Potential Receptor	Impact Magnitude	Sensitivity	Impact Significance	
				Value	Score
Noise Impacts Due to Operation Activities	Residential area and residential buildings in the close vicinity of the Sub-project area	13	5	**65**	**Low**

7.6 Traffic

7.6.1 Introduction

This chapter describes the potential traffic impact during the construction and operation phases of the Sub-project.

Vojvode Stepe Street with two lanes is located in the north-east of the Sub-project area, which is nearest main road being round-trip. There is also a single lane alleyway in the north-west of the Sub-project area. There are 3 intersections around the Sub-project area. There will be an entrance and exit to the Sub-project facility through a separate door. In order to determine the effects of the Sub-project on traffic, a special study, traffic counting carried out.

The Torlak Institute is close to sensitive receptors of MZ Jajinci. The closest place to Torlak Institute is the Faculty of Pharmacy, which belongs to University of Belgrad.

The following chapter will discuss traffic conditions and transportation infrastructure during the construction and operation phases.

7.6.2 Legal Context

The Sub-project will comply with the following national regulations to mitigate the potential traffic impacts of the Sub-project:

- Constitution of Serbia (Official Gazette of RS, No. 98/06, 115/21, 16/22),
- Law on Public Health (Official Gazette of RS, No. 15/16),
- Law on Planning and Construction (Official Gazette of RS, No. 72/09, 81/09 - amendment, 64/10 - US, 24/11, 121/12, 42/13 - US, 50/13 - US, 98/13 - US, 132/14, 145/14, 83/18, 31/19, 37/19 - other law, 9/20, 52/21).

In addition to the national regulations, the Project Owner will also follow the guidelines of "The Community Health and Safety" in terms of World Bank's Environmental and Social Standards (ESS).

According to World Bank's ESS 4: Community Health and Safety, the Project Owner is responsible to monitor the potential traffic density and provide road safety. Measurements determined by the World Bank are:

- Projects may involve construction of new roads or rehabilitation or structural changes/improvements to existing roads, which can create traffic and road safety risks. Besides, due to the changes in the Project Area, traffic speed can be increased. Both direct and indirect changes can be controlled by mitigations which are determined before the construction phase (G11.1);

- Projects that affect traffic flow or volume on existing roads, the environmental and social assessment considers the risks arising from the proposed changes, paying attention to vehicle mix, volume, speed, and condition (including vehicle weight, height, length, and any hazardous materials likely to be carried) (G11.2.);
- The identification of risks begins at project identification, so that measures to address potential risks can be incorporated into the project design (G11.3);
- To be sure about the community's health and safety, road safety assessment must be conducted (G11.4);
- The road safety assessment includes details of the road safety measures. (G11.5)
- Information gathering about traffic incident and accidents are useful to manage future traffic risks and impacts which are originated from the Project;
- For vehicles or fleets of vehicles (construction vehicles, logging vehicles, cars, trucks, school buses, ambulances, and in certain circumstances, boats and aircraft) for the purposes of the project (owned or leased), the Project Owner have to implement monitoring system and enforcement (G12);
- The Project Owner is responsible for drivers' proficiency and vehicles' examinations (G12.1);
- In the construction phase of projects, the Project Owner have to provide community health and safety. Determining speed limits, seatbelt use, GPS usage and drivers' qualifications are fundamental measurements to provide safety standards (G12.2);
- The Project Owner will take appropriate safety measures to avoid the occurrence of incidents and injuries to members of the public associated with the operation of construction equipment (G13).

7.6.3 Traffic Management

7.6.3.1 Traffic Management during Construction

A Construction Traffic Management Plan will be prepared prior to the construction phase of the Sub-project. The Construction Traffic Management Plan will include detailed safety measures for (i) internal traffic management and personnel working on site, (ii) traffic management and use of access roads outside the Sub-project Area, (iii) entry and exit gates, (iv) regular training and health and safety induction, (v) regular maintenance of vehicles and roads, and (vi) interactions with local communities and activities related to their safety.

The Faculty of Pharmacy and residential areas are located in the immediate vicinity of the Sub-project site. The Construction Traffic Management Plan will identify measures to manage off-site traffic to minimise impacts on the identified sensitive receptors in the vicinity. Construction material required for the Sub-project will be transported to the site from selected suppliers via existing roads. If fill material is brought to the Sub-project Area, additional traffic will be generated due to the transport of excavated material.

The Project Owner shall ensure that detailed layouts showing entrance/exit gates and traffic movements within and around the Sub-project Area will be integrated into Traffic Management Plans to be developed for construction and operation phases of the Sub-project.

7.6.3.2 Traffic Management during Operation

It is planned that 25 employees will work in the laboratory during the operation period. However, not all 25 employees will be new employees. According to the information provided by Torlak Institute management, approximately 5 new employees will be hired. Therefore, no traffic impact due to employees is expected. Apart from the employees, it is expected that there will be citizens who will use the laboratory services. However, this number is not expected to bring an additional burden to the traffic in the region.

7.6.4 Impacts

7.6.4.1 Impacts during Construction

Construction activities may lead to an increase in the number of vehicles during the transport of construction materials and may increase the risk of traffic-related accidents. In the field study, local people mostly mentioned their concerns about traffic and transport. The BIO4 Campus and BSL-3 laboratory will be built on a busy street in terms of public transport.

Table 7-47. Construction Phase Impact Significances

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)						
			Geographical Extent (G)	**Duration (D)**	**Intensity (I)**	**Frequency (F)**	**Likelihood (L)**	**Reversibility (R)**
Impacts related to Traffic*	Negative Direct	Definition	During the construction of the BSL-3 Laboratory, traffic density will be experienced only around the Torlak Institute. Therefore, the impact will be local.	The construction phase will be last six (6) months.	The traffic resulting from the construction will be regulated according to legal standards. Besides, major changes that will affect community are not expected.	Construction vehicles will cause tidal traffic. Even though it is a natural affect due to the building process, residents can be slightly affected from the traffic density. However, it will not cause major impacts.	-	After the construction phase, there will be no permanent impacts.
		Score	Local	Short	Low	Infrequent	N/A	Short Term
		Value	2	2	2	2	-	1
	Impact Magnitude (G+D+I+F (or L)) x R		**8**					

**In this section, traffic density is considered as the impact which will be signified under traffic related impacts. Traffic accidents which may occur during the construction phase is processed in Community Health, Safety and Security Section.*

7.6.4.2 Impacts during Operation

The existing road network is not expected to experience a significant traffic load with the commencement of the operational phase of the Sub-project.

Table 7-48. Operation Phase Impact Magnitude

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)						
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)
Impacts related to Traffic	Negative Direct	Definition	During the operation phase, due to the waste transportation, traffic density is expected in Vodice and Zavodska streets. Therefore, the impact will be local.	The operational period of the Sub-project will last a long period of time. Therefore, the impact is very long.	The traffic resulting from operation phase will be regulated according to legal standards. Besides, major changes that will affect community are not expected.	Due to the waste transportation, there will be tidal traffic during the operation phase. However, it will not cause major impacts.	-	During the operation phase, there will be no permanent impacts of traffic density.
		Score	Local	Very Long	Low	Infrequent	N/A	Short Term
		Value	2	5	2	2	-	1
	Impact Magnitude (G+D+I+F (or L)) x R		**11**					

Table 7-49. Vulnerabilities and Receptor Sensitivity

Potential Receptor	Sensitivity		
	Sensitivity Score	Description of the Sensitivity	Sensitivity Value
Social Infrastructure facilities (Faculty of Pharmacy)	**Low**	During the construction period, traffic density will be rised in the crossroad which is linked to Vodice and Zavodska streets. There is the Faculty of Pharmacy nearby the crossroad. Therefore, students, academics and employees of the faculty can be affected due to the construction. A traffic plan which prioritizes the non-working hours to maintain the construction would prevent adversities.	**1**
Communities around the Route	**Medium**	During the construction period, households which live by Vodice and Zavodska streets can be affected by the increase of traffic density. Since residents actively use the road, adversities can be expected in their daily lives for six (6) months.	**3**

Table 7-50. Impact Significances

Potentail Impact		Impact Magnitude	Sensitivity	Impact Significance		
				Value	Score	Description
Construction Phase	Impacts related to Traffic	8	4	**32**	**Low**	During the construction phase, traffic density will rise due to vehicles carrying workforce and load on Vodice and Zavodska streets. The magnitude of the effect is low.
Operation Phase	Impacts related to Traffic	11	4	**44**	**Low**	During the life time of the BSL-3 Laboratory, there will be traffic density due to the transportation of waste and materials on Vodice and Zavodska streets. The magnitude of the effect is low.

7.6.5 Mitigation Measures

In the scope of the Sub-project, a Construction Traffic Management Plan will be prepared. The aim of the traffic plan is to avoid risks and minimize impacts which will be caused by rising traffic density due to the construction. It will be implemented by authorities and stakeholders.

In the current situation, Vodice and Zavodska streets will be used during the construction phase. Therefore, the primary recommendation is to ensure higher safety on this road regarding traffic flow conditions. Following mitigation measures should be considered for securing pedestrians and drivers:

- Entrances and exits of the Sub-project Area will be managed with visibility displays;
- There will be 1.5 m x 3 m signs located at every 300 m around the Sub-project Area to give contact address in case of any potential grievances which can be caused by the Sub-project;
- All operators of construction vehicles will be given educational seminars on traffic safety;
- Information flyers will be distributed to all the residential buildings and to authorities of the surrounding neighborhoods;
- Necessary precautions will be taken and the residents will be informed as necessary in MZ Jajinci in order to ensure their safety. These precautions will be implemented especially at working-hours traffic. These precautions will be planned in coordination with relevant public authorities;
- Shuttle services will be provided for employees to reduce the traffic density which is caused by construction;
- Roads which are out of the scope of Traffic Management Plan will not be used in order to prevent traffic load;
- Drivers of construction vehicles will get traffic training which includes rules to be followed and sensitivities related to communities;
- Drivers' police records will be examined before recruitment;
- The Sub-project will adopt a policy of zero tolerance in relation to alcohol consumption, including immediate termination of employment agreement in case of violation;
- Local community of MZ Jajinci who lives nearby Vodice and Zavodska streets will be informed at least 1 month before the construction works.

7.7 Biodiversity

7.7.1 Introduction

Potential impacts of the proposed construction activities for the Sub-project on the biological environment are considered. These impacts could be in effect during both the construction and operation phases of the Sub-project. Potential impacts will affect flora-fauna directly or indirectly.

The following subsections define the potential impacts of the Sub-project considering the foreseen Sub-project activities during construction and operation. The potential impacts are assessed for flora and fauna. Mitigation measures to be taken in order minimize these impacts are also included in the assessments.

The impact of Sub-project activities on ecological components is related to the size of the impact and the vulnerability of the recipient. For flora-fauna species, size, and significance of the effects according to the matrices presented below have been determined in accordance with the criteria determined according to the ecological sensitivities of the species. It is known that the features of each step in the systematic classification of species are different from each other and accordingly the shapes and dimensions of the influence from the Sub-project will vary within themselves.

7.7.2 Legal Context

The Biodiversity Baseline studies have considered relevant Serbian (national) legislation, applicable standards and guidelines for international finance, and international agreements to which Serbia is a signatory. Applicable policy and legislation relevant to the Biodiversity Baseline studies are summarized below.

7.7.2.1 Standards and Guidelines for International Requirements

Ecology and Biodiversity part of the Sub-project is guided by the requirements of the World Bank’s Environmental and Social Standards (ESS) 6 to manage environmental risks and impacts on ecology and biodiversity. ESS6 aims that the protection of critical natural habitats and to be taken mitigation measure to minimizing habitat loss. As appropriate, the Sub-project will take the necessary measures and implement commitments.

In line with the ESS6, assessments of the baseline conditions and determined significance criteria for impacts assessments were detailed. ESS6 covers areas of biodiversity conservation, ecosystem services and sustainable management of living resources, which are all fundamental to achieve sustainable development. The objectives of ESS6 are outlined as follows:

- To protect and conserve biodiversity and habitats.

- To apply the mitigation hierarchy and the precautionary approach in the design and implementation of projects that could have an impact on biodiversity.
- To promote the sustainable management of living natural resources.
- To support livelihoods of local communities, including Indigenous Peoples, and inclusive economic development, through the adoption of practices that integrate conservation needs and development priorities.

The requirements of ESS 6 are applied to all projects that potentially affect biodiversity or habitats, either positively or negatively, directly, or indirectly, or that depend upon biodiversity for their success.

7.7.2.2 International Agreements

In evaluating the threat/protection status of species, CITES (Convention on International Trade in Endangered Species of Wild Fauna and Flora); Bern Convention (Convention on the Conservation of European Wildlife and Natural Habitats); and IUCN (International Union for Conservation of Nature) Red List Database; Bird Directive (2009/147/EC) and Habitat Directive (92/43/EEC) were used.

CITES

Species covered in CITES are given under three different appendices according to their conservation status;

- Annex I covers the species, which are under the threat of extinction. Trade in the specimens of these species is not allowed except under extraordinary circumstances.
- Annex II includes species, which are not threatened with extinction, but trade in specimens is restricted in order to prevent utilization incompatible with their survival.
- Annex III includes species, for which other parties of CITES is applied for assistance in controlling trade and which are conserved at least in one country.

Bern Convention

The Bern Convention aims at conserving and promoting biodiversity, developing national policies for the conservation of wild flora and fauna and their natural habitats, protection of the wild flora and fauna from planned development and pollution, developing training for protection practices, and promoting and coordinating all research made regarding this subject. It has been signed by 26 member states of the European Council (as well as Serbia) with the aim of conserving the wildlife in Europe. Species that are protected under the Bern Convention are classified according to the following categories:

- Appendix I: Strictly protected flora species

- Appendix II: Strictly protected fauna species
- Appendix III: Protected fauna species
- Appendix IV: Prohibited means and methods of killing, capture and other forms of exploitation

All parties to the Bern Convention have signed the Convention on Biological Diversity (CBD) as well. These parties are responsible from ensuring sustainable use of resources in line with their national development trends and conserving threatened species

<u>IUCN Red List of Threatened Species</u>

The International Union for Conservation of Nature (IUCN) Red List is published to draw attention to the species whose population is under risk or threatened. IUCN includes the species to the Red List after researching the reasons causing decrease in its population. IUCN Red List categories are given below:

- EX: Extinct
- EW: Extinct in the Wild
- CR: Critically Endangered
- EN: Endangered
- VU: Vulnerable
- NT: Near Threatened
- LC: Least Concern
- DD: Data Deficient
- NE: Not Evaluated

<u>Bird Directive (2009/147/EC)</u>

Bird Directive number 2009/147/EC is the directive of European Parliament and Commission for the protection of wild birds, and it was put into force in November 30, 2009 (as amendment of Directive 79/409/EEC). The Directive stipulates the protection of 194 detected bird species and sub-species that are threatened and require special protection measures. Distinct components are of concern for the application of the Directive (European Commission, 2014a):

- Annex-1: 194 species and sub-species are particularly threatened. Member States must designate Special Protection Areas (SPAs) for their survival and all migratory bird species.

- Annex-2: 82 bird species can be hunted. However, the hunting periods are limited and hunting is forbidden when birds are at their most vulnerable: during their return migration to nesting areas, reproduction and the raising of their chicks.

- Annex-3: overall, activities that directly threaten birds, such as their deliberate killing, capture or trade, or the destruction of their nests, are banned. With certain restrictions, Member States can allow some of these activities for 26 species listed here.

- Annex-4: the directive provides for the sustainable management of hunting but Member States must outlaw all forms of non-selective and large-scale killing of birds, especially the methods listed in this annex.
- Annex-5: the directive promotes research to underpin the protection, management and use of all species of birds covered by the Directive, which are listed in this annex.

Habitat Directive (92/43/EEC)

Habitat Directive 92/43/EEC was put into force in 1992 with the main aim to promote the maintenance of biodiversity, taking account of the economic, social, cultural and regional requirements. Directive contributes to the general objective of sustainable development; whereas rare, threatened and endemic approximately 450 fauna and 500 flora species are aimed to the protected. 200 rare and special habitat types are included in the protection targets considering their features (European Commission, 2014a).

Annex-I and Annex-II of the Directive comprises the habitat types and species that require the designation of special protection areas. Some can be regarded as “priority” habitats or species (under extinction risk). Explanations on Habitat Directive appendices are:

- Annex-I: Natural habitat types included in Community Importance that requires the designation of special protection areas
- Annex-II: Plant and animal species included in Community Importance that requires the designation of special protection areas
- Annex-III: Selection criteria for the areas suitable to be designated as special protection areas regarding Community Importance
- Annex-IV: Plant and animal species included in Community Importance that requires strict protection measures
- Annex-V: Plant and animal species included in Community Importance that requires management measures for exploitation and taking in the wild

7.7.2.3 National Environmental Legal and Policy Framework

In Serbia, nature conservation is regulated by the Law on Nature Conservation (Official Gazette of Republic of Serbia No. 36/2009, 88/2010 and 91/2010), which is harmonized with the EU Habitats Directive and the Birds Directive. Specific aspects of nature conservation are regulated by various by-laws. The Decree on Ecological Network (Official Gazette of Republic of Serbia, No. 102/2010) identifies ecological network areas in Serbia and sets the management, financing, monitoring and protection requirements.

Protection of habitats and species is regulated by the:

- Regulation on the criteria for separation of habitat types, habitat types, sensitive, vulnerable, rare, and for the protection of priority habitat types and protection measures for their preservation (Official Gazette of Republic of Serbia, No. 35/2010).
- Regulation on cross-border trade and trade in protected species (Official Gazette of Republic of Serbia, No. 99/2009, 6/2014).
- Regulation on special technical and technological solutions that enable undisturbed and safe communication of wild animals (Official Gazette of Republic of Serbia, No. 72/10).
- Regulation on control of use and trade of wild flora and fauna (Official Gazette of Republic of Serbia, No. 31/2005, 45/2005, 22/2007, 38/2008, 9/2010 and 69/2011).
- Rulebook on cross-border trade and trade in protected species (Official Gazette of Republic of Serbia, No. 99/2009, 6/2014).
- The Rulebook on the criteria for the evaluation and process of categorization of individual protected wild flora and fauna species in 2011 ("The Official Gazette of the Republic of Serbia", No. 24/2011, 24/2012, 21/2013, 23/2014).
- Rulebook on the Proclamation of Game Species Protected by Closed Season ("The Official Gazette of the Republic of Serbia", No. 9/2012).
- Regulation on the proclamation and protection of strictly protected and protected wild species of plants, animals and fungi (Official Gazette of Republic of Serbia, No. 5/2010, 47/2011, 32/2016 and 98/2016), which contains lists of strictly protected and protected wild species and protection measures:
    - Annex I: Strictly protected species
    - Annex II: Protected species

7.7.3 Impacts

The impact assessment process predicts and describes impacts that are expected to occur for different phases of the Sub-project. Where possible, impacts are quantified to the extent practicable, which may include size of habitat loss; loss of flora, etc. For each impact, its significance is evaluated by defining and evaluating two key aspects:

- The magnitude of the impact; and
- The sensitivity of the feature or receptor that will be impacted.

The sensitivity/vulnerability/importance designations themselves are universally consistent, but the definitions for these designations will vary on a resource/receptor basis. The universal sensitivity/vulnerability/importance designations are:

- Low;
- Medium; and
- High.

Receptor sensitivity definitions are provided in Table 7-51.

Table 7-51. Sensitivity/Vulnerability/Importance for Biodiversity Features

Value	Description
Low	Species and/or population has high capacity to absorb or adapt to change (i.e. has capacity to move away from or adapt to the project impact), and is potentially unaffected or marginally affected; Modified and artificial habitats
Medium	Internationally threatened species /protected area within the area impacted by the project activities outside of period of high sensitivity or during routine or reliably predictable peak presence. Species and/or population which has moderate capacity to absorb or adapt to change (i.e. has capacity to move away from or adapt to the project impact), leading to potential temporary but sustainable effect which does not substantially alter character or result in significant loss of ecological functionality; Species listed in the IUCN Red List with VU category. Natural habitats that are less likely to be inhabited by species of elevated conservation concern
High	Internationally threatened species /protected area within the area impacted by the project activities during period of high sensitivity (e.g. during breeding, spawning or nesting) and during routine or reliably predictable peak presence; Species and/or population which has little or no capacity to absorb or adapt to change (i.e. little or no capacity to move away from or adapt to the project impact), leading to potential for substantial change of character and/or loss of ecological functionality; Species listed in the IUCN Red List with EN and CR categories. IUCN Red List or endangered habitats or critical habitats or unique habitats or highly threatened and/or unique habitats

Receptor Sensitivity, Vulnerability and Importance are evaluated for each group in Table 7-52. Biodiversity feature with the highest sensitivity was taken into account in the sensitivity assessment.

Table 7-52. Receptor Sensitivity, Vulnerability, and Importance

Potential Receptor	Sensitivity		
	Sensitivity Score	Description of the Sensitivity	Sensitivity Value
Habitats	High	There is no sensitive habitat in the project area and its surroundings. According to the critical habitat assessment, there is no critical habitat in the project area and its surroundings	**5**
	Medium	There is no natural habitat in the project area and its surroundings.	**3**
	Low	**There are modified habitats in the project area and its surroundings.**	**1**
Flora	High	There is no any Critically Endangered (CR) or Endangered (EN) flora species within the project area and surroundings	**5**
	Medium	There is no any Vulnerable (VU) flora species within the project area and surroundings	3
	Low	**Remaining species are included in this group.**	**1**

Potential Receptor	Sensitivity		
	Sensitivity Score	Description of the Sensitivity	Sensitivity Value
Fauna	High	There is no any Critically Endangered (CR) or Endangered (EN) fauna species within the project area and surroundings	**5**
	Medium	***Falco vespertinus* is in the VU category according to the IUCN Red List and are included in this group.**	**3**
	Low	Remaining species are included in this group.	**1**

7.7.3.1 Impacts during Construction

In the construction phase of a Sub-project some direct or indirect impacts could be occurred. The loss of habitat and biodiversity are the most important examples to direct impacts. However, the planned Sub-project will be realized in an already modified area. There is not any critical natural vegetation which harbours wildlife, so there will not be any sensitive habitat and vegetation loss during the Sub-project construction activities.

Another direct impact of the construction phase will be the vehicle traffic for construction. The fauna species which have limited mobility will be prone to fauna mortality. The risk of crushing will increase as the animals cross the road.

Internationally Recognized and Nationally Protected Areas

There are not any internationally recognized and nationally protected areas within the Sub-project Area. There is no impact of construction activities on internationally recognized and nationally protected areas.

Flora

The most major impacts of this kind of projects on the environment are generally habitat and vegetation loss or damage. However, Sub-project will be built in modified habitat with poor vegetation. There are trees that were previously planted for landscaping purposes in the area where the Sub-project site is located. As part of land preparation, these trees will be removed from the area. There are a lot of human-made structures in the vicinity of Sub-project area. Therefore, there are no sensitive habitats or flora species, and such an effect will not be the issue.

The impacts of the construction activities will include dust. Dust generation may lead to effects on plant species within the vicinity of the Sub-project area, but will not long last. When necessary measures are taken and after the construction activity is over, it is expected that the composition of the plant species will return to its original state in time.

To conclude, the impacts on the biological environment during construction will be limited. It is considered that all the impacts will be minimized or eliminated completely if necessary precautions are taken. The impact of construction activities on flora species is assessed as negligible.

Fauna

The impacts of construction activities on fauna species in the region can be seen. These impacts will mostly consist of secondary effects. Due to the construction activities, mortalities may be observed due to disturbed fauna species and traffic collision. At the same time, noise, visual nuisance, and vibration due to construction activities may also have a negative impact on fauna species. All these effects can be eliminated by taking appropriate measures. The impact of construction activities on fauna species is assessed as low.

Table 7-53. Summary of Impact Significances of the Receptors for the Construction Phase

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)								
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)	Receptor Sensitivity	Impact Significance (Magnitude x Sensitivity)
Habitat Loss	Negative Direct and Indirect	Potential impact on vegetation will be directly and indirectly related to the construction activities. The direct impact is immediate destruction or damage of vegetation in the course of construction. The indirect impact is a change in the plant communities' growth conditions induced by the construction activities. The greatest impacts on habitats in the Sub-project area will include: • deforestation of the Sub-project site areas; • loss of plant resources; • inhibition of plant growth due to emissions of dust from construction activities and harmful substances;	Habitat loss will be in the Sub-project site and its impact will be in the Sub-project site	Construction activities at the Sub-project site will continue for 6 months.	Impacts related to Habitat Loss the impact can be detected or perceived but the effects are unlikely to cause tangible changes in environmental or social components	-	Habitat loss will occur due to the construction works to be carried out.	Potential Impacts related to Habitat Loss are expected to be reversible in the medium term.	The Sub-project area and its surroundings consist of modified habitats.	**Low**
		Score	Sub-project Site	Short	Low	N/A	Probable	Mid-term	Low	
		Value	1	2	2	-	5	3	1	
	Impact Magnitude (G+D+I+F (or L)) x R		**30**						**1**	**30**
Loss or damage of flora species	Negative Direct	Vegetation clearing during the construction phase may result in the destruction of floral species of conservation concern.	Impacts on plant species will be in the Sub-project site	Construction activities at the Sub-project site will continue for 6 months.	The impact on plant species is within legal standards or accepted practices and is likely to result in tangible changes	-	Loss of plant species will occur due to the construction works to be carried out.	Potential impacts related to plant species are expected to be reversible in the short to medium term.	There is no distribution of protected or sensitive flora species in the Sub-project area.	**Negligible**
		Score	Sub-project Site	Short	Medium	N/A	Likely	Short/mid-term	Low	
		Value	1	2	3	-	3	2	1	
	Impact Magnitude (G+D+I+F (or L)) x R		**18**						**1**	**18**
Loss of fauna species	Negative Direct	Small and less mobile species can become trapped, injured and killed during vegetation clearing and earth works. Fauna of particular concern in this context include: • Fossorial mammals; • Nesting birds (ground and tree nesting); and • Reptiles and amphibians. Other common causes of fauna injury, death or disturbance during the construction include: • Vehicle-fauna collisions. • Hunting, trapping and poisoning of fauna by construction workers and contractors; and • Fauna trapped/caught in infrastructure, such as fences and excavations. One species of conservation concern have been recorded in the Sub-project Area, *Falco vespertinus* as VU	Impacts on fauna species will be in the Sub-project site and its surroundings	Construction activities at the Sub-project site will continue for 6 months.	The impact on fauna species is within legal standards or accepted practices and is likely to result in tangible changes	-	Loss of fauna species unlikely to occur due to the construction works to be carried out.	Potential impacts related to fauna species are expected to be reversible in the short to medium term.	*Falco vespertinus* is in the VU category according to the IUCN Red List and can be found occasionally in the Sub-project area.	**Low**
		Score	Local	Short	Medium	N/A	Unlikely	Short/mid-term	Medium	
		Value	2	2	3	-	1	2	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**16**						**3**	**48**

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)								
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)	Receptor Sensitivity	Impact Significance (Magnitude x Sensitivity)
Disturbance and displacement of resident fauna due to noise, visual nuisance and vibration	Negative Indirect	The disturbance and displacement of resident fauna species within the footprint will primarily be caused by light, noise and vibration impacts during construction. Noise, light and vibration disturbances have the potential to influence breeding, roosting or foraging behaviour of fauna. During the construction phase temporary impacts from the Sub-project are expected. Noise will be the primary disturbance of this nature due to vegetation clearing, excavation, movement of materials and general construction activities. These activities will introduce noise sources to areas not currently exposed to these disturbances. In addition there may be vibration associated with activities and the movement of any vehicles/machinery.	Impacts related to noise, visual nuisance and vibration will be in the Sub-project site and its surroundings	Construction activities at the Sub-project site will continue for 6 months.	Impacts related to noise, visual nuisance and vibration is within legal standards or accepted practices and is likely to result in tangible changes	-	Impacts related to noise, visual nuisance and vibration likely to occur due to the construction works to be carried out.	Potential impacts related to fauna species are expected to be reversible in the short term.	*Falco vespertinus* is in the VU category according to the IUCN Red List and can be found occasionally in the Sub-project area.	**Low**
		Score	Local	Short	Medium	N/A	Likely	Short-term	Medium	
		Value	2	2	3	-	3	1	3	
	Impact Magnitude (G+D+I+F (or L)) x R				**10**				**3**	**30**
Impacts on flora due to dust emission	Negative Indirect	Land preparation has the potential to generate dust which may settle on vegetation adjacent to the construction area. Excessive dust deposition on flora may act to suppress growth through limiting photosynthesis and the dusted foliage may also become unpalatable to foraging fauna.	Impacts related to dust emission will be in the Sub-project site and its surroundings	Site preparation activities at the Sub-project site will continue for 2 weeks	Impacts related to dust emission can be detected or perceived but the effects are unlikely to cause tangible changes	-	Impacts related to dust emission likely to occur due to the construction works to be carried out.	Potential impacts related to flora species are expected to be reversible in the short term.	There is no distribution of protected or sensitive flora species in the Sub-project area.	**Negligible**
		Score	Local	Short	Low	N/A	Likely	Short-term	Low	
		Value	2	1	2	-	3	1	1	
	Impact Magnitude (G+D+I+F (or L)) x R				**8**				**1**	**8**
Spreading of Alien invasive species	Negative Direct	Clearance of vegetation and disturbances caused by earthworks can create conditions conducive to the establishment and rapid spread of alien invasive vegetation. If left uncontrolled, alien species can spread exponentially, suppressing or replacing native vegetation. This may lead to disruption of ecosystem functioning and loss of biodiversity. Alien invasive plants can potentially be established in all areas where construction activities will disrupt existing vegetation. Recognized alien invasive plant species commonly recorded in the study area that may become problematic include *Robinia pseudoacacia, Erigeron annus, Erigeron canadensis,* and *Datura inoxia.*	Spreading of Alien invasive species will be in the Sub-project site and its surroundings	Construction activities at the Sub-project site will continue for 6 months.	Impacts related to Spreading of Alien invasive species may result in exceedances of legal standards or accepted practices and/or is likely to cause very serious to catastrophic damage to environmental	-	Spreading of Alien invasive species unlikely to occur due to the construction works to be carried out.	In addition to the natural processes, with proper restoration potential impacts during construction is expected to be reversible in the medium term.	The Sub-project area and its surroundings consist of modified habitats.	**Low**
		Score	Local	Short	Very High	N/A	Unlikely	Mid-term	Low	
		Value	2	2	5	-	1	3	1	
	Impact Magnitude (G+D+I+F (or L)) x R				**30**				**1**	**30**

7.7.3.2 Impacts during Operation

Operational activities of the Sub-project are not expected to have a negative impact on flora and fauna. When the necessary preventive measures are taken during the construction phase, the wildlife will return to its former state.

7.7.4 Mitigation Measures

The mitigation measures to be taken to the possible impacts on the biologic environment from the Sub-project activities during the land preparation and construction phases are given below.

- Prior to the land preparation phase, definite working areas will be set up where activities and permanent structures will be established and the clearance of vegetation will be limited to the strip of land needed for the occupation of the Sub-project and the adjacent working width.
- During the construction, there may be a risk of disturbance or even damage to the fauna components living in the Sub-project area and even choosing the area as a breeding ground. In case the activities coincide the breeding period, there may be loss of nests, eggs, or nestlings. To prevent losses that may occur in this way, attention will be paid to the timing of the works, and this tree or bush form cuttings will be avoided during the breeding period; or before clearance and assembling, it will be ensured that wild fauna components are not found in these sections or that they are removed. While carrying out these procedures, support will be sought from persons or organizations who are experts in the subject.
- After cleaning the ground and transporting the amphibians, reptiles and mammals encountered on the construction site, surface soils will be striped carefully. While stripping, some amphibians, reptiles and mammals may be seen again in excavated soil. All these animals will be collected and transported to a suitable nearby habitat.
- If the beginning of the activity coincides with the general breeding period (mid-April to the end of June), precautions will be taken to keep wild forms away from possible nests or breeding areas in the areas that will be affected by the activity. One of the simplest and easiest practice to implement these measures is to mark the nest or breeding areas with moving bright bands at the beginning of the breeding season. These visual repellers will prevent animals from choosing these areas as nesting sites. In order to serve this purpose, the entrances of the works, which are used as nests in some sections, can be blocked with wire mesh or material that will serve the same purpose,
- Construction work will be done gradually so that it will have enough time to escape for possible fauna species to be found,
- If there is a nest of bird species, the nest will be marked with a safety strip about 3 meters in diameter and an expert ornithologist will be informed,

- If there is a species that has limited mobility, transfer to safer locations if encountered during construction,
- Construction sites will be fenced in order to prevent fauna species' entrance into these areas.
- Avoid and/or minimize dust emissions by lightly watering the immediate surroundings of construction sites, and wetting the stored material,
- Measures to reduce dust and air pollution are provided in Chapter 7.4 Air Quality for details,
- Measures to reduce noise are provided in Chapter 7.5 Noise for details,
- All areas that have been cleared of vegetation and/or where the soil surface has been disturbed need rehabilitation of the vegetation to minimise the establishment of alien invasive species,
- Any invasive flora species will be prevented from entering the Sub-project area and its surroundings. For this purpose, especially the tools used for plant cleaning and/or plant transfer will be washed/cleaned before use,
- Revegetation of disturbed sites will be implemented within the same spring season, or within the upcoming spring season for disturbances occurring during the dry season.
- Sub-project workers will not be allowed to bring any live animals or plants into the construction site to avoid the risk of pest/invasive species establishing in the Sub-project Area,
- Invasive species will not be used in replanting/reseeding works to be carried out due to the Sub-project. It should be ensured that the species to be used in replanting/reseeding studies are not invasive.
- In case of encountering an invasive species in the Sub-project area, eradication methods will be applied within the scope of the Invasive Alien Species Management Plan to be prepared.

Starting the activity outside the breeding period will greatly reduce the possibility of affecting 0onstruction phase, impacts on biodiversity can be effectively mitigated through good management practices and implementation of mitigation measures mentioned above.

In addition, the impact significances for the construction phase are given in the Table 7-54.

Table 7-54. Construction Phase Residual Impact Significances-Biodiversity

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							Receptor Sensitivity	Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)		
Habitat Loss	Negative Direct and Indirect	Score	Sub-project Site	Short	Low	N/A	Likely	Mid-term	Low	**Negligible**
		Value	1	2	2	-	3	3		
	Impact Magnitude (G+D+I+F (or L)) x R		**24**						1	**24**
Loss or damage of flora species	Negative Direct	Score	Sub-project Site	Short	Medium	N/A	Unlikely	Short/mid-term	Low	**Negligible**
		Value	1	2	3	-	1	2		
	Impact Magnitude (G+D+I+F (or L)) x R		**14**						1	**14**
Loss of fauna species	Negative Direct	Score	Local	Short	Low	N/A	Improbable	Short/mid-term	Medium	**Low**
		Value	2	2	2	-	0	2		
	Impact Magnitude (G+D+I+F (or L)) x R		**12**						**3**	**36**
Disturbance and displacement of resident fauna due to noise, visual nuisance and vibration	Negative Indirect	Score	Local	Short	Low	N/A	Unlikely	Short-term	Medium	**Negligible**
		Value	2	2	2	-	1	1		
	Impact Magnitude (G+D+I+F (or L)) x R		**7**						**3**	**21**
Impacts on flora due to dust emission	Negative Indirect	Score	Local	Short	Negligible	N/A	Unlikely	Short-term	Low	**Negligible**
		Value	2	1	1	-	1	1		
	Impact Magnitude (G+D+I+F (or L)) x R		**5**						1	**5**
Spreading of Alien invasive species	Negative Direct	Score	Local	Short	Negligible	N/A	Unlikely	Mid-term	Low	**Negligible**
		Value	2	2	1	-	1	3		
	Impact Magnitude (G+D+I+F (or L)) x R		**18**						**1**	**18**

7.8 Socio-economy

7.8.1 Introduction

This section provides an assessment of the potential socioeconomic impacts of the Sub-project. The socioeconomic baseline conditions of the Sub-project's social impact area are described and the relevant socioeconomic impacts of the Sub-project are assessed.

The socio-economic impacts of the Sub-project will have both positive and negative impacts. During the construction period, impacts such as temporary employment and triggered indirect employment are expected to be positive. Traffic and dust generation may create negative impacts in the impact area. In the operation period, there will be advantages such as access to medical care, quick response to materials such as kits and vaccines in cases such as pandemics. Due to the lack of information sharing during both construction and operation periods, public unrest may pose a risk.

This section describes how the socio-economic impacts will be assessed and managed against the national laws and World Bank Environmental and Social Standards:

- Law on Labor, ("Official Gazette of RS", No. 24/2005, 61/2005, 54/2009, 32/2013, 75/2014, 13/2017 - decision of the Constitutional Court, 113/2017 and 95/2018);
- Law on Occupational Health and Safety (Official Gazette of RS, No. 101/05, 91/15, 113/17)
- ESS 1: Assessment and Management of Environmental and Social Risks and Impacts;
- ESS 2: Labour and Working Conditions.

7.8.2 Impacts

7.8.2.1 Impacts during Construction

Laboratory construction requires skilled labour, engineering expertise, and the purchase of specialized equipment and materials. The Sub-project is expected to have a positive impact on employment, including direct (i.e. on-site employment), indirect (i.e. suppliers or support services) and induced employment (i.e. created due to spending by new employees). The estimated number of employees for the construction phase of the Sub-project is 40 at the highest level.

The Sub-project may create direct employment opportunities to provide services during the construction period. It will provide catering, hygiene materials and transport services for all employees. Local people and suppliers will be utilised for these services.

The Project Owner aims to source labour locally to the extent possible. Therefore, the provision of temporary employment could contribute to the local economy.

In addition to the direct employment benefits of the Sub-project, indirect and induced employment benefits will also arise. Indirect employment is created by the provision of goods and services during the construction phase, and induced employment benefits are created by the earnings of direct and indirect workers being spent in the economy.

The introduction of a limited number of 40 temporary labour during construction and the creation of a small number of permanent jobs (maximum 5 professionals) during operation will have no impact on the population of the region. The significance of the impact is considered to be negligible.

Construction workers will be provided information and necessary trainings in order to prevent any disturbance to daily life of nearby communities through Code of Conduct and LMP.

There will be no land acquisition and therefore no economic or physical displacement under the Sub-project. There is no expropriation of agricultural or pasture land from which economic income is generated, but impacts such as increased traffic and dust can lead to loss of income for businesses in the impact area.

According to the results of the FGD conducted with the representatives of local people stated that the settlement will not be affected in socio-economic terms. The influx of labour is small, so the demographic structure is unlikely to be disrupted. However, mitigation measures for labour influx are provided below. They also stated that they have no concerns about their livelihoods.

Table 7-55. Construction Phase Impact Magnitude

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)						
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)
Impacts related to direct and indirect employment opportunities	Positive Direct	Definition	Construction activities will create direct or indirect business opportunities regionally.	It is planned that the construction phase of the Sub-project will take 6 months. The duration of potential impacts is expected to be short.	Considering the number of people to be recruited and prioritizing local workers, positive effects are expected to be high.	-	The Sub-project will lead to employment opportunities.	Construction activities will take 6 months. There is the possibility of employment throughout this process.
		Score	Regional	Short	Medium	N/A	Probable	Short/-mid-term
		Value	3	2	3	-	5	2
	Impact Magnitude (G+D+I+F (or L)) x R		**26**					
Impacts related to labour influx	Negative Direct	Definition	The impact of the labour influx will remain local.	It is planned that the construction phase of the Sub-project will take 6 months. The duration of potential impacts is expected to be short.	The number of people to be recruited is low and the construction period is short.	-	The likelihood of such an event is low but could occur at any time during Sub-project implementation (construction and operation).	Construction activities will take 6 months. There is the possibility of employment throughout this process.
		Score	Local	Short	Low	N/A	Unlikely	Short/-mid-term
		Value	2	2	2	-	2	2
	Impact Magnitude (G+D+I+F (or L)) x R		**16**					
Impacts related to traffic and dust	See Chapter 7.4 and 7.6							
Impacts related to community misperception	See Operation Phase Impact Magnitude table							

Table 7-56. Impact Significances

Potential Impact	Impact Magnitude	Sensitivity Value	Total Value	Impact Significance	
				Score	Description
Impacts of direct and indirect employment opportunities on potential Sub-project workers	26	3	**78**	**Medium**	The construction phase of the Sub-project will lead to significant employment potential. The impact was evaluated as positive.
Impacts of labour influx on local community	16	3	**48**	**Low**	The construction period is relatively short and the number of workers is low. There will be no accommodation in the area. The impact of the labour influx on the local community is estimated to be low.

7.8.2.2 Impacts during Operation

Socio-economic related impacts for the operational period include the laboratory's health care benefits, community misperception and public unrest, and community health and safety issues. For CHS see section 7.9.

The establishment of a BSL-3 laboratory allows the development and utilisation of in-house tests for both diagnostic purposes and scientific research, as well as the implementation of new diagnostic procedures that cannot be performed in the current space of the BSL-2 laboratory.

Unlike commercial tests, the development and use of in-house (internal) diagnostic tests allows the laboratory to be independent in the diagnosis of pathogenic microorganisms and to provide a timely and effective response to an epidemic, pandemic or the emergence of a new "threatening" infectious agent. This is particularly important given that there can be major difficulties in the supply of commercial diagnostic kits at times of high global demand (such as during the SARS-CoV-2 pandemic).

A prerequisite for the development of in-house (internal) diagnostic tests for analysing the virus genome and determining the susceptibility of the virus to antiviral drugs is the isolation of the virus from patient samples. Initially, the isolation of viruses such as West Nile virus, dengue virus, SARS-CoV-2, hantaviruses and others is planned. Cultivation of bacterial infectious agents and determination of susceptibility to drugs are also planned. All these analyses contribute to improving the quality of the health system's response to the threat of infectious diseases, as they enable more effective prevention of the spread of the epidemic and better treatment of the consequences of infectious diseases.

The Sub-project will positively impact the laboratory R&D and production capacity and biomedical field for diagnostic purposes in public health, emerging and other communicable diseases. It will help to enhance access to advanced diagnostic services for vulnerable groups; improve capacity to provide referral diagnostic services; and strengthen laboratory-based disease surveillance to provide early warning of public health emergency.

The BSL-3 laboratory will be made available not only to the Institute "Torlak", whose primary field of activity is virology, but also to other diagnostic and scientific research institutions in Serbia. In addition, it is expected that access to test kits and vaccines will be easy and inexpensive in the event of a possible pandemic or other health-threatening situations.

The laboratory will be used for the development of in-house tests for both diagnostic and scientific research purposes. Research and development activities at the facility can further contribute to economic growth by attracting funding and collaborations.

Public unrest that may arise in the society due to lack of effective information is considered within the scope of the study. In the social surveys, the public, professionals and governmental organisations stated that they have no concerns about this issue and that they believe that if there is information sharing, there will be no problems in the future. Issues such as the increase in housing prices, the income of the businesses around the facility and the change in the demographic structure due to the influx of workers were also addressed in the social studies. Considering that the Torlak Institute has been operating in this campus for many years, 1 additional building will be constructed and 5 new employees will be recruited, no concerns regarding these issues were identified in the social studies. Still, these issues are considered as risks within the scope of the Sub-project and included in the impact assessment.

Table 7-57. Operation Phase Impact Magnitude

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)						
		Geographical Extent (G)		Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)
Impacts related to direct employment opportunities	Positive Direct	Definition	Operation activities will create direct or indirect business opportunities nationally.	It is expected that employment opportunities will disappear shortly after the commissioning of the laboratory.	Given the number of people to be recruited, positive impacts are expected to be low.	-	The Sub-project will lead to employment opportunities.	During this period, employment is probable, but the number of People is not high.
		Score	National	Short	Low	N/A	Probable	Short/mid-term
		Value	4	2	2	-	5	2
	Impact Magnitude (G+D+I+F (or L)) x R		**26**					
Impacts related to healthcare system in Serbia	Positive Direct	Definition	The laboratory will serve the whole country.	The period of operation of the laboratory will be more than 5 years.	It will be an important diagnostic, kit and vaccination centre for infectious diseases and in the 'vent of a pandemic again.	-'The laboratory will definitely be an important development for Serbia's healthcare system.	The impact on the health system is assessed as positive. The laboratory will serve the health system for many years.	
		Score	National	Very long	High	N/A	Probable	Long-term
		Value	4	5	4	-	5	4
	Impact Magnitude (G+D+I+F (or L)) x R		**72**					
Impacts related to livelihood	Negative Direct	Definition	The impact of the laboratory on livelihoods will be limited locally.	It is considered that the impacts on livelihoods during the operation period will be valid for a short period of time.	The impact of the P'oject on livelihoods is not expected to lea' to tangible changes.	-	The likelihood of the Sub-project's impact on livelihoods is low.	The Sub-project's impact on livelihoods may be restored soon after the source of impact is discontinued.
		Score	Low	Short	Low	N/A	Unlikely	Short-term
		Value	2	2	2	-	1	1
	Impact Magnitude (G+D+I+F (or L)) x R		**7**					

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)					
		Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)
Impacts related to CHSS including misperceptions	See Chapter 7.9						

Table 7-58. Impact Significances

Potential Impact	Impact Magnitude	Sensitivity Value	Total Value	Impact Significance	
				Score	Description
Impacts of employment opportunities on potential lab employees	26	3	**78**	**Medium**	The operation phase of the Sub-project will lead to significant employment potential. The impact was evaluated as positive.
Impacts on citizens of potential contributions to health services	72	5	**360**	**Very High**	The commissioning of the laboratory will have a significant impact on the people of Serbia.
Impacts on livelihoods of local people with the commissioning of the laboratory	7	5	**35**	**Low**	Impact on livelihoods during the operation period is low probability.

7.8.3 Mitigation Measures

The Sub-project may cause positive and adverse socio-economic impacts during construction and operation periods. These will be predominantly local and temporary impacts in the region where Sub-project activities are carried out. The mitigation and management measures presented in this section have been developed with the aim of avoiding or minimizing any negative socioeconomic impacts on the livelihoods of local people or, where this is not possible, balancing these impacts with remedial measures. Most of the projected economic and social impacts of the Sub-project are expected to be positive. A number of options potentially exist for the Sub-project to mitigate the few potential adverse socio-economic impacts, including the types of measures outlined below.

7.8.3.1 Construction Phase

It is expected that the Sub-project will create positive effects such as direct and indirect employment and local supply during the construction period. Traffic and dust generation can have a negative impact on the local community. The mitigation measures to be considered during the construction phase of the Sub-project include the following:

- The Sub-project will seek to maximise the benefits from the Sub-project to local communities in terms of direct and indirect employment and procurement of local goods and services during construction if technically and economically feasible.. This will include measures such as adopting local employment and procurement policies, opening tenders for the supply of subcontracted goods and services on a scale that local businesses can respond to, ensuring that opportunities are advertised locally. These clauses will be added to the Tender Document for contractor selection;

- The Project Owner will adopt a Human Resources policy that considers wage standards, working hours regulation, freedom of association and staff incentives in line with ESS 2. The policy will also include provisions prohibiting child labour and forced labour, discrimination on the basis of religion, language, sex or social status, bullying and harassment. This policy will be developed by the Project Owner to cover local employment and training of local people. It will also apply to Sub-project contractors;
- Priority will be given to the local labour where possible and practical;
- The Labour Management Procedure developed for the Sub-project will be implemented:
- The Sub-project should seek to maximise benefits for local communities in terms of both direct and indirect employment opportunities and procurement of local goods and services. Equipment, goods and services required for construction works will be sourced from local suppliers as far as possible;
- Code of Conduct will be developed in compliance with the Serbian legislation and international standards. Hard copies will be provided in Serbian and English. It will outline expected behaviour with respect to their daily interactions with local residents and users of public amenities. In particular, it will cover issues related to ban on alcohol and drugs use, GBV/SEA/SH, etc.;
- Sub-project workers will be made aware of laws and regulations that make GBV a criminal offense subject to criminal prosecution;
- The Project Owner will check companies' indebtedness and monetary relationships with local businesses before hiring contractors to work on site to prevent the risk of defrauding;
- Local communities will be informed on program and sequence of works;
- Implementation of the SEP will also contribute to maintaining regular communication with affected parties and timely identification of potential issues associated with workers' influx and relevant impacts;
- The contractor and Project Owner will establish and implement a grievance mechanism;
- In case of using local roads for transportation, repair works will be made in collaboration with the local authorities;
- Please see Section 7.6.5 for mitigation measures of traffic impacts;
- Please see Section 7.4.6 for mitigation measures of air quality impacts;
- Please see Section 7.5.5 for mitigation measures of noise impacts.

7.8.3.2 Operation Phase

Positive impacts are expected during the operation period of the Sub-project. The Sub-project is expected to serve the whole country in the field of health services.

Public unrest that may arise in the society due to lack of effective information is considered within the scope of the study. To avoid public unrest or communication problems the mitigation measures to be considered during the operation phase of the Sub-project include the following:

- Sub-project-specific SEP will be implemented and information sharing will continue throughout the operation period;
- A structured grievance mechanism for the community will be implemented and socio-economic impacts will be monitored;
- Sub-project staff will be made aware of laws and regulations that make GBV a criminal offense subject to criminal prosecution.

7.8.4 Residual Impacts

Direct and indirect employment impacts during construction and operation phases are assessed as positive. In addition, the laboratory is expected to make a significant contribution to the health system during the operational phase. Due to the nature of the impacts, there is no residual impact for positive impacts. The impact on livelihoods that may occur during the operation period has been determined as low.

7.9 Community Health, Safety and Security

7.9.1 Introduction

This chapter provides an assessment of the community health, safety and security aspects that may impact workers and nearby communities during the construction and operation phases and sets out the mitigation measures to avoid or minimize the risks together with the residual impacts. In accordance with the requirements of the World Bank ESS4: Community Health and Safety, potential risks and significant adverse impacts related to the air quality, noise, road traffic, community health and exposure to disease, community misperception due to insufficient information sharing, life and fire safety, infrastructure safety, labour influx, security and biosafety requirements are covered in this chapter.

The risks and impacts of the Sub-project in the context of health and safety of the nearby communities will be managed through a Community Health and Safety Management Plan to be implemented by contractors and MoH. This plan will include measures to address the identified risks and ensure the disclosure of relevant Sub-project-related information to enable the affected communities to understand the risks and impacts. Additional management plans and programs related to protection of community health and safety will be required including plans to prevent and respond to incidents and emergencies, as well as plans to protect the health, welfare and security of the community from any adverse effects related to generation of noise and dust, road traffic and security operations, as explained further below. The chapter covers specific background details on:

- National legislation framework and international standards, policy requirements and guidelines against which to assess the impacts of the Sub-project on community health, safety and security matters;
- Determines magnitude, sensitivity, and impact significance on community health, safety and security issues;
- Establishes biosafety and biosecurity management with all possible emergency scenarios during design, construction and operation of biosafety laboratories;
- Informs about dust and noise, waste management, biosafety and biosecurity, infrastructure safety, life and fire safety, security and traffic related requirements and emergency issues management including exposure of communities to disease/infections; and
- Final remarks on any residual impacts and monitoring and reporting.

7.9.2 Legal Context

7.9.2.1 National Regulations on Community Health, Safety and Security

All national laws and regulations related to Sub-project are provided in the Appendix-B. The main of these are as follows:

- Law on the Protection of Population against Infectious Diseases (Official Gazette of RS, No.15/2016)
- Law on Public Health (Official Gazette of RS, No. 15/2016)
- Law on Health Care (Official Gazette of RS, No. 25/2019)
- Law on Disaster Risk Reduction and Emergency Management (Official Gazette of RS, No. 87/18)

7.9.2.2 International Regulations on Community Health, Safety and Security

With respect to the certification of BSL laboratories, the Sub-project will majorly refer to the international standards, guidelines and regulations listed below, but not limited to:

- WHO Laboratory Biosafety Manual, 3rd edition, 2004 and 4th edition, 2020,
- CEN/CWA 15793:2008 Laboratory Biorisk Management Standard

- CDC-NIH Biosafety at Microbiological and Biomedical Laboratories (BMBL), 6th edition, 2020,
- NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (DRM), 2019,
- NIH Biosafety Level 3 Laboratory Certification Requirements, 2006.

7.9.3 Impacts

7.9.3.1 Impacts during Construction

Jajinci and Kumodraz-1 settlements are expected to be subject to environmental and social impacts. The construction period may affect the quality of life of local residents, such as disturbance due to traffic movement, waste management, dust and noise generation, risk of fire and accident, stress on infrastructure, inappropriate behavior of security guards.

It may raise concerns among local communities due to perceived risks associated with handling dangerous pathogens. Some community members may also express concerns about safety, potential pathogen release, and the proximity of the facility to residential areas.

Community misperception can have significant and important consequences to a project such are:

Opposition and resistance: Misperceptions can lead to community opposition and resistance, which may manifest as protests, legal challenges, or public campaigns against the project.

Delays and obstacles: Community misperception can create delays or obstacles in obtaining necessary approvals, permits, or community support, thus hindering the timely implementation of the project.

Damage to reputation: Negative perceptions can harm the reputation of the project proponents or organizations involved, affecting public trust, investor confidence, and stakeholder relationships.

Communication challenges: Misperceptions make it difficult to effectively communicate project objectives, benefits, and mitigation measures to the community. This can lead to misinformation, mistrust, and ineffective stakeholder engagement.

Social division and conflicts: Community misperception can cause social divisions, conflicts, or public unrest.

During the field study, questions were asked to local community representatives about this issue. Representatives stated that they have no reservations about this issue for the time being. They mentioned that if transparent communication and information sharing continues, public unrest and misunderstandings can be prevented.

During the construction phase of the Sub-project, fire safety risks may arise, particularly affecting construction workers and, depending on the area of fire spread, nearby residents. In addition, unauthorised access to the construction site may put life safety at risk. These risks will be managed through the implementation of various mitigation measures through the preparation and implementation of an Emergency Preparedness and Response Plan during construction phase activities.

Emergencies can cause serious damage to the environment, occupational health and safety, and assets, as well as causing the cessation or termination of operations. Emergencies consisting of accidents, explosions, fires, gas leaks, hazardous chemical/biological and liquid waste spills, disease outbreaks and similar events that occur unexpectedly due to equipment/infrastructure failures, employee errors, natural disasters (floods, landslides, earthquakes, storms), sabotage and similar reasons may pose a risk to public health.

Safety impacts and conflicts might occur in case of abuse of authority by security personnel. In particular, this is relevant if responsibilities of the security personnel are not clearly defined. The impacts may be caused by inadequate behavior of security personnel, e.g. inappropriate use of force, offensive language with regard to workers or local resident.

Dust generation is described in Section 7.4, noise generation in Section 7.5 and traffic in Section 7.6, waste management Section 7.3.

Table 7-59 shows the summary of the respective Community Health and Safety Impact assessment for construction phase of the Sub-project:

Table 7-59. Construction Phase Community Health and Safety Impact Significances

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)								Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)	Receptor Sensitivity	
Impacts on community health	Negative Direct	Definition	Community health impacts during the construction period will be regionally limited.	The construction period is limited to 6 months. With the completion of the construction, no impact on community health is expected due to construction activities.	Expected impacts on community health is within legal standards or accepted practices and is unlikely to result in tangible changes to the social component.	The public health impacts of the construction period are expected to last 6 months and events will be evenly or randomly distributed over time	-	Activities concerning community health during the construction period will end with the completion of the construction. However, if the necessary precautions are not taken, the initial condition of the component can be restored within a few months to one year after cessation of the impact source and/or with restoration activities..	Residential area and residential buildings in the vicinity of the Sub-project area	Low
		Score	Regional	Short	Medium	Recurrent	N/A	Short-term	Medium	
		Value	3	2	3	3	-	1	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**11**						**33**	
Impacts on life and fire safety	Negative Direct	Definition	Life and fire risks impacts during the construction period will be locally limited	The construction period is limited to 6 months. therefore, life and fire risks are limited to 6 months.	During the construction phase of the Sub-project, depending on the area where the fire has spread, risks may arise that may affect especially construction workers and local people. Risks to life may arise if adequate security is not provided at the construction site and the public is not prevented from entering this area.	-	The risk to life or fire is likely to occur at any time during the construction phase of the Sub-project.	After the finish of the construction works, there will be no risk associated with the construction of the Sub-project. It may not be possible to reverse the life safety and fire related impacts of the necessary plans and procedures are not followed.	Residential area and residential buildings in the vicinity of the Sub-project area	High
		Score	Local	Short	Very High	N/A	Likely	Irreversible	Medium	
		Value	2	2	5	-	3	5	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**60**						**180**	
Impacts on infrastructure safety	Negative Direct	Definition	Sub-project related seismic movements have the potential to have regional impact.	Considering that the construction period will take 6 months, the impacts will be limited to 6 months.	Expected impacts is within legal standards or accepted practices and is likely to result in tangible changes in social components.	-	If the designs do not take into account the resulting earthquake loads, it may cause high impact sizes.	With the completion of the construction, there will be no additional pressure on seismic risks.	Residential area and residential buildings in the vicinity of the Sub-project area	Low
		Score	Regional	Short	Medium	N/A	Likely	Short/mid-term	Medium	
		Value	3	2	3	-	3	2	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**22**						**66**	
Impacts related to security personnel	Negative Direct	Definition	Impacts related to security personnel during the construction period will be locally limited.	The construction period is limited to 6 months. With the completion of the construction, no impact expected.	Expected impacts is within legal standards or accepted practices and is likely to result in tangible changes in social components	-	If training for security personnel is disrupted, serious risks to the community can occur.	Potential impacts will disappear with the end of construction. Potential impacts can be reverted soon after the solution is found.	Residential area and residential buildings in the vicinity of the Sub-project area	Low
		Score	Local	Short	Medium	N/A	Likely	Short/mid-term	Medium	
		Value	2	2	3	-	3	2	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**20**						**60**	

7.9.3.2 Impacts during Operation

Impacts related to Occupational Health and Safety of Workers

During operation of the BSL-3 laboratory, there will be health and safety risks to the workers and local community posed by the storage and use of hazardous chemicals, solvents, disinfectants and flammable materials (such as formaldehyde, chloroform, phenol, ethyl alcohol, isopropyl alcohol, amyl alcohol and sodium hypochlorite) which will require effective management. Additionally, an array of non-hazardous and hazardous wastes will be generated including process/laboratory wastewaters and medical waste in the form of infection waste and sharps which may cause public health and environment risks. Since the operation phase involves laboratory work and working with biological organisms and cultures, impacts may include potential exposure of laboratory providers and personnel to infections and diseases and other potential infectious materials during transport, collection, handling, storage and treatment of pathogens, as well as disposal of medical or bio-waste. Failure of or unavailability of key equipment, such as HEPA filters and PPE can lead to infection of workers and transmission of pathogens outside the facility.

Impacts related to Accidental Release of Patogens

During the operation of the facilities, adverse impacts may occur on workers and communities in case of design and management failures such as inadequate biological risk management, unsafe laboratory practices, improper management of ventilation of the units, improper management of laboratory security, improper management of medical and laboratory wastes. Failure of or unavailability of key equipment, such as HEPA filters and PPE can lead to infection of workers and transmission of pathogens outside the facility Additional risks against which measures are needed during operation of the Sub-project (including during the transportation activities) includes accidents, emergencies, sabotage, terrorism and similar. Such occurrences may result in aerosol transmission of agents that can cause serious and potentially fatal infections, as well as diversion or release of biological materials that could be used to harm humans.

If biological risk management is not given due importance, it may appear as a regional epidemic, country-level epidemic or pandemic and cause public health problems that seriously affect the public and nations. The sensitivity of the receptors is rated high and magnitude of potential impacts if unmitigated is major. The resulting impact significance associated with potential biosafety and biosecurity risks is therefore critical.

Impacts related to Transport of Hazardous Materials

The transportation of hazardous materials, such as infectious samples or biological agents may lead to exposure of workers to pathogens and subsequent health risks for both workers and the community due to mishandling or accidents.

Impacts related to Community Perception and Concerns

The presence of a BSL-3 facility in a community may raise concerns and anxiety among residents. Lack of awareness or understanding about the safety measures in place could lead to fear, panic, mistrust and public unrest. If unmitigated, the above impacts are considered to be of critical significance, including the worst case scenario of a pathogen ending up in the population near the lab site, and spreading onwards. Therefore, a set of comprehensive mitigation measures will be required, as elucidated in the relevant sections.

The fact that the Sub-project is a biosafety laboratory could trigger public unrest and related protests. Questions were asked to local people, professionals, NGO representatives, the municipal authority and current employees. None of the respondents indicated that the operation of the laboratory would have an impact on public health.

Local people and professionals believe that the inhabitants of the settlement will not have any problems with the construction of the laboratory. They also stated that the residents are tolerant and the most important thing for them is that the construction of anything is completed within the planned timeframe.

Professionals hope that the new laboratory will enable Serbian experts to produce vaccines, which will be a very positive outcome of this Sub-project; if successful, the BSL-3 laboratory will serve the national interest, primarily economic and public health. NGOs and professionals are all of the opinion that the laboratory poses no environmental risk and can be built anywhere. They expressed concern that the building should be constructed in accordance with standards and that the legislation should be appropriate for the laboratory. Normative regulation and inspection issues are central to the safety of the laboratory (ECDC and CDC standards). All respondents encourage adequate public education and information to avoid misunderstandings.

Table 7-60 shows the summary of the respective Community Health and Safety Impact assessment for construction phase of the Sub-project:

Table 7-60. Operation Phase Community Health and Safety Impact Significances

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)								
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)	Receptor Sensitivity	Impact Significance (Magnitude x Significance)
Impacts on community health (Accidental Release of Pathogens, OHS)	Negative Direct	Definition	Community health impacts (accidental release of pathogens) will be regionally limited.	Impacts will cease after the operational life span of the Sub-project.	Accidental release of pathogens may result in exceedances of legal standards or accepted practices.	-	If the plans and procedures prepared for the Sub-project are not followed, the likelihood of impacts will increase.	If the necessary precautions are not taken, accidental release of pathogens can leave irreversible impacts for the communities.	Residential area and residential buildings in the vicinity of the Sub-project area	High
		Score	Regional	Long	Very High	N/A	Likely	Irreversible	Medium	
		Value	3	4	5	-	3	5	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**75**						**225**	
Impacts on community health (Transport of Hazardous Materials)	Negative Direct	Definition	Community health impacts (transport of hazardous materials) will be regionally limited.	Impacts will cease after the operational life span of the Sub-project.	Incidents during transport of hazardous materials may result in exceedances of legal standards or accepted practices.	-	If the plans and procedures prepared for the Sub-project are not followed, the likelihood of impacts will increase.	If the necessary precautions are not taken incidents during transport of hazardous materials can leave irreversible impacts for the communities.	Residential area and residential buildings in the vicinity of the Sub-project area	**High**
		Score	Regional	Long	Very High	N/A	Likely	Irreversible	Medium	
		Value	3	4	5	-	3	5	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**75**						**225**	
Impacts on community health (Community Misperception)	Negative Direct	Definition	Community health impacts (transport of hazardous materials) will be regionally limited.	Impacts will cease after the operational life span of the Sub-project.	Impact likely to lead to serious deterioration in social components.	-	If the plans and procedures prepared for the Sub-project are not followed, the likelihood of impacts will increase.	If necessary precautions are not taken, there may be serious impacts for the community.	Citizens of Serbia	**High**
		Score	National	Long	High	N/A	Likely	Long term	Medium	
		Value	4	4	4	-	3	4	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**60**						**180**	

7.9.4 Mitigation Measures

In addition to the mitigation measures given in the previous sections regarding labour influx, traffic movement, waste management, dust and noise generation which have the potential to affect communities, the following measures will be implemented:

- Implementation of good construction site practices in line with national regulations and international guidelines as outlined in the Construction Site Management Plan to be developed by the contractor during construction;
- Implementing the Community Health and Safety Plan and the Security Plan during construction and operation;
- Implementing the Emergency Preparedness and Response Plan during construction and operation;
- Implementing the Communication Plan during construction and operation;
- Strict adherence to the design codes and standards during construction and operation;
- Adherence to safety regulations and ongoing monitoring;
- Maintaining ongoing consultation and engagement with communities and stakeholders during construction and operation;
- Monitoring feedbacks and grievances received from communities and stakeholders during construction and operation.
- Implementing occupational health and safety program during construction and operation.

<u>Mitigation measures regarding Accidental Release of Pathogens</u>

<u>Strict adherence to Design Requirements</u>

The internationally accepted rules and guidelines to ensure biosafety and biosecurity in laboratories are published in the WHO Laboratory Biosafety Manual. The manual adopts a risk assessment approach and has been in broad use at all levels of laboratories and other biomedical sectors globally, serving as a de facto global standard that presents best practices and sets trends in biosafety. In addition to core requirements, design features and heightened control measures indicated in the 4th edition of the manual, design and operation considerations for BSL laboratories are detailed in the associated seven monographs.

The BSL-3 laboratory will be established in compliance with the facility design requirements of the WHO Laboratory Biosafety Manual. Code of practice, laboratory design and facilities and laboratory equipment requirements for the BSL-3 laboratory is provided in Chapter 2.3 of this report.

Commissioning and Certification of the BSL-3 Laboratory

The commissioning and certification of the Sub-project will be in line with WHO Biosafety Laboratory Biosafety Manual, 3rd edition, 2004 and 4th edition, 2020.

The commissioning of the BSL-3 laboratory is essential to systematically review and document to signify that specified laboratory structural components, systems and/or system components have been installed, inspected, functionally tested, and verified to meet national or international standards, as appropriate. Commissioning will be conducted to provide with a greater degree of confidence that the structural, electrical, mechanical and plumbing systems, containment and decontamination systems, and security and alarm systems will operate as designed, to assure containment of any potentially dangerous microorganisms being worked with in a particular laboratory. Commissioning of the BSL-3 laboratory is provided in Chapter 2.4 of the report.

Laboratory certification is the systematic examination of all safety features and processes within the laboratory (engineering controls, personal protective equipment and administrative controls). The certification process of the Sub-project will be conducted using the tools provided in Tables 5–7 (Laboratory Safety Surveys) of the WHO Biosafety Manual (3rd edition, 2004). Certification of the laboratory should not be completed, and the laboratory should not be declared functional, until deficiencies have been adequately addressed. It will be ensured that the certification of the BSL-3 laboratory will be performed by a team of professionals with experience in BSL-3 laboratory on a regular basis with adequate documentation. Certification of BSL-3 laboratory is provided in Chapter 2.4.4.

Biosafety Management

The aim in a biosafety program is to design and prevent infections and illnesses among personnel and to protect the public, the environment, and animal population from harm by preventing the inadvertent release of biological material. The details of Biosafety Management of BSL-3 laboratory is provided in Chapter 2.3.2.

Torlak Institute has decades of experience as a healthcare institution as one of the oldest institutions of this kind in the world. It has four national reference laboratories for diagnostics, three of which are certified by the World Health Organization. Torlak Institute will establish and oversee Laboratory Diagnostics Division implementing the biosafety management system for BSL-3 laboratory.

- BSL-3 laboratory will be established and operated ensuring specific design features, construction, containment facilities, equipment, practices and operational procedures in compliance with WHO Laboratory Biosafety Manual, 4th edition,

- BSL-3 laboratory practices will be performed according to well-documented and validated standard operating procedures and plans developed specific to the BSL-3 laboratory,
- Critical roles and responsibilities for successfully managing a biosafety programme at the BSL-3 laboratory will be assigned. The laboratory staff will have the competency with the required experience and qualifications for working at BSL-3 laboratory,
- Biosafety committee will be established which include members with sufficient experience and knowledge in biosafety and biosecurity practices. The committee will review and approve biosafety and biosecurity SOPs, risk assessments for working with biological materials, training of personnel, overseeing the compliance of BSL-3 laboratory practices with WHO Laboratory Biosafety Manual.

Biosecurity Management

Any intentional exposure to infectious pathogens will be prevented through a robust biosecurity management. Torlak Institute will develop institutional and personnel security measures designed to prevent the loss, theft, misuse, diversion or intentional release of biological agents being handled in the laboratory. Biosecurity management practices will also complement BSL-3 laboratory biosafety risk will management. The details of Biosecurity Management of BSL-3 laboratory are provided in Chapter 2.3.3.

Risk assessments will be conducted in the areas of Security of inventory, Security of information, Security policies for personnel, Physical security of BSL-3 laboratory, Security of transport of biological agents, Emergency/incident response protocols.

- Procedures will be developed including description of the biological agent(s), its quantities, storage location and use, the person responsible, documentation of internal and external transfers, and an inactivation and/or disposal of the materials.
- Sensitive information including research data, diagnostic results, lists of key personnel, security plans, access codes, passwords, storage locations and biological agent inventories will be identified, labelled and protected. Sharing sensitive information with unauthorized individuals will be strictly prohibited.
- Laboratory biosecurity training will be provided in addition to biosafety training for all personnel according to the outcomes of the risk assessment. The training will also include a review of relevant national standards and the institution-specific procedures. Security related roles and responsibilities of personnel in everyday and emergency scenarios will also be defined.
- Physical security counter measures will be established to prevent unauthorized access of outside adversaries (that is those who do not have a legitimate presence in the facility and have malicious intent such as criminals, terrorists and extremists/activists) and also to minimize the threat from insiders (that is those who have a legitimate presence in

the facility such as employees and approved visitors) who do not require access to a particular asset.

- The transfer of biological agents will comply with national and international rules for packaging, marking, labelling and documentation. The process will be controlled according to the assessed biosecurity risks of the biological agent being transported to ensure proper oversight within the biosecurity programme.
- An incident/emergency response protocol will be written and followed to ensure proper reporting, and to facilitate investigation, root-cause analysis, corrective action and process improvement.

Training

Laboratory personnel will receive specific training in handling pathogenic and potentially lethal agents, and they will be supervised by scientists competent in handling infectious agents and associated procedures. The training should include information on safe methods that are commonly encountered by all laboratory personnel and which involve:

- Inhalation risks,
- Ingestion risks when handling specimens, smears and cultures,
- Risks of percutaneous exposures when using syringes and needles,
- Handling potentially hazardous pathological materials,
- Decontamination and disposal of infectious material.
- Handling, storage and transport of hazardous materials
- Emergency response and preparedness procedures

Emergency Preparedness and Response

Emergency situations are incidents that cause the activities to cease, terminate and also cause serious damage on environment, occupational health and safety and assets. An “Emergency Preparedness and Response Plan” will be developed a part of ESMS (Chapter10) of the Sub-project for emergency situations that consist of incidents such as accidents, explosions, fires, gas leakages, hazardous chemical/biological and liquid waste spills, disease outbreaks and similar events that occur unexpectedly due to equipment/infrastructure failures, employee errors, natural disasters (flooding, landslides, earthquakes, storms), sabotage and similar, for the Sub-project in line with national regulations and international standards.

The emergency response and preparedness plan will be prepared with the involvement of the relevant departments of City of Belgrade.

The emergency response plan will be reviewed and updated regularly to include any changes, or based on lessons learned and advancements in biosafety practices. The employees will be informed on any updates.

Employees will be provided with trainings on emergency preparedness and response procedures.

The BSL-3 laboratory will develop an Emergency Preparedness and Response Plan which includes operational procedures on:

- Risk assessment (including identification of high-risk organisms, location of high-risk areas, e.g. laboratories, storage areas, identification of at-risk personnel and populations)
- Emergency response procedures (including incident-exposure and decontamination management, containment breaches or pathogen releases)
- Precautions against fire and natural disasters, e.g. flood, earthquake and explosion)
- Emergency evacuation procedures of people from the premises
- Emergency equipment (e.g. fire fighting equipment, PPEs, protective clothing chemical and biological spill kits, decontamination equipment and supplies)
- Lists of sources of immune serum, vaccines, drugs, special equipment and supplies
- Communication systems (how public and emergency response institutions will be informed to ensure a coordinated and effective response)
- Lists of treatment and isolation facilities that can receive exposed or infected persons
- Emergency medical treatment of exposed and injured persons
- Medical surveillance of exposed persons
- Clinical management of exposed persons
- Epidemiological investigation
- Post-incident continuation of operations.
- Transport of exposed or infected persons
- Roles and responsibilities: Identification of responsible personnel and their duties, e.g. biosafety officer, safety personnel, local health authority, clinicians, microbiologists, veterinarians, epidemiologists, and fire and police services

The Emergency Preparedness and Response Plan will include among others emergency procedures for microbiological laboratories:

- Puncture wounds, cuts and abrasions
- Ingestion of potentially infectious material
- Potentially infectious aerosol release (outside a biological safety cabinet)
- Broken containers and spilled infectious substances

- Breakage of tubes containing potentially infectious material in centrifuges not having sealable buckets
- Breakage of tubes inside sealable buckets (safety cups)
- Fire and natural disasters
- Emergency services (whom to contact)
- Emergency equipment

Mitigation measures regarding Occupational Health and Safety of Workers

Mitigation measures regarding occupational health and safety impacts are detailed in Chapter 7.10.5 Labor and Working Conditions Mitigation Measures. In summary; the impacts of exposure to infectious microorganisms and transmission of pathogens outside the facility will be mitigated through below measures;

- Strict adherence to design requirements will be ensured._To prevent infections among personnel and the public and protect the environment from harm by avoiding the inadvertent release of biological materials, the Sub-project will strictly adhere to national regulations and internationally accepted standards/directives. A comprehensive biosafety and biosecurity program will be adopted to be able to keep track of biological risks that may arise. A biosafety manual specific to the facility and SOPs will be implemented throughout the operation. The Sub-project will also employ qualified research and production personnel with specific training in BSL facility procedures, handling of pathogenic agents and wastes and operating equipment.
- The personnel will be provided with specific training on handling infectious agents and operating procedures. The personnel will also have trainings regarding waste handling, storage and transport. The trainings will also include biosecurity requirements as a part of biosafety management.
- All infectious microorganisms will be handled within BSCs.
- The ventilation of the BSL-3 laboratory will have HE laboratory practices are performed PA filters and ensure_that air from BSL-3 is not recirculated to other areas within the building. HEPA filters will be tested annually and replaced when necessary.
- Biosafety and biosecurity management will ensure that all laboratory practices are performed safely for the personnel, public, and the environment, in accordance with best practice and applicable national or international regulations.
- Decontamination of BSL-3 laboratory and equipment will be provided.
- Decontamination of infectious waste generated in the BSL-3 laboratory will be conducted by using an autoclave.

- Emergency preparedness and response plan developed for BSL-3 laboratory will include the risk assessment and response procedures regarding exposure to infectious microorganisms. The details on the Emergency Response and Preparedness Plan is provided Chapter 7.10.5 Labor and Working Conditions Mitigation Measures.
- Laboratory personnel will be provided with medical surveillance and offered appropriate immunizations for the handled agents.
- An autoclave will be available at the BSL-3 laboratory for decontamination of infectious wastes. Detailed assessment of impacts due to different types of waste during the commissioning and operation phases of the Sub-project and mitigation measures are given in Chapter 7.2 and 7.3 Waste and Wastewater Management of this ESIA report.

Mitigation Measures regarding Transport of Hazardous Materials

- The transfer of hazardous materials such as infectious samples will be conducted a way that minimizes the potential for drop, spillage, collision or similar events and in strict compliance with applicable national regulations and internationally accepted standards for packaging, labelling, and transport of hazardous materials and wastes including UN Model Regulations for the Transport of Dangerous Goods,
- SOPs will be developed for and implemented during transfer of infectious materials,
- Personnel will be provided with training on infectious materials handling, storage and transport,
- When infectious samples are transferred sealed containers, such as screw-capped tubes will be used,
- Appropriate and approved packaging designed for the specific type of infectious material will be used such as triple package,
- All containers will be labelled with biohazard symbols and necessary information regarding the contents, handling instructions, and emergency contact details will be provided.
- Access to the transportation area will be restricted to authorized personnel only. Implement Security measures to prevent unauthorized access will be implemented.
- Dedicated vehicles for transporting infectious materials to minimize the risk of cross-contamination with other items or passengers will be used. Regular maintenance of vehicles will be provided to prevent to prevent breakdowns and minimize the risk of accidental exposure due to vehicle issues.
- A clear emergency response plan regarding the case of spills, accidents, or any other incidents during transport will be developed and communicated. The plan will include procedures for containment, clean-up, and notification of relevant authorities.

- Effective communication channels between the sending and receiving laboratories, as well as transportation personnel, to coordinate the transportation process and handle any unexpected situations will be established.
- Personal protective equipment as well as emergency response equipment such as cleaning tools, disinfectants will be provided for transporting infectious materials.
- Accurate documentation of all transported materials, including sender and receiver information, date, time, and details of the transported materials will be maintained.

7.9.5 Residual Impacts

Mitigation measures are expected to minimise such impacts to short and intermittent events that will be reversible in a short-term by the effect of the natural processes. The Residual Impact Significances for the construction and operation phases are given in Table 7-61 and Table 7-62, respectively.

Table 7-61. Construction Phase Community Health and Safety Residual Impact Significances

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							Receptor Sensitivity	Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)		
Impacts on community health	Negative Direct	Definition	Considering potential impacts during the construction activities the geographical extent of the impact is expected to be local.	The construction period is limited to 6 months. With the completion of the construction, no impact on community health is expected due to construction activities.	Expected impacts intensity will be lowered with taking aforementioned mitigation measures during the construction phase of the Sub-project.	The public health impacts frequency will be lowered with taking aforementioned mitigation measures during the construction phase of the Sub-project.	-	Activities concerning community health during the construction period will end with the completion of the construction. However, if the necessary precautions are taken, the initial condition of the component can be restored within a few months to one year after cessation of the impact source and/or with restoration activities..	Residential area and residential buildings in the vicinity of the Sub-project area	Negligible
		Score	Local	Short	Low	Single event	N/A	Short-term	Medium	
		Value	2	2	2	1	-	1	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**7**							**21**
Impacts on life and fire safety	Negative Direct	Definition	Life and fire risks impacts during the construction period will be locally limited	The construction period is limited to 6 months. therefore, life and fire risks are limited to 6 months.	Expected impacts intensity will be lowered with taking aforementioned mitigation measures during the construction phase of the Sub-project.	-	The risk to life or fire will be lowered with taking aforementioned mitigation measures during the construction phase of the Sub-project.	After the finish of the construction works, there will be no risk associated with the construction of the Sub-project. It may not be possible to reverse the life safety and fire related impacts of the necessary plans and procedures are not followed.	Residential area and residential buildings in the vicinity of the Sub-project area	Medium
		Score	Local	Short	Medium	N/A	Unlikely	Irreversible	Medium	
		Value	2	2	3	-	1	5	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**40**							**120**
Impacts on infrastructure safety	Negative Direct	Definition	Sub-project related seismic movements have the potential to have regional impact.	Considering that the construction period will take 6 months, the impacts will be limited to 6 months.	Expected impacts is within legal standards or accepted practices and is likely to result in tangible changes in social components.	-	If the designs do not take into account the resulting earthquake loads, it may cause high impact sizes.	With the completion of the construction, there will be no additional pressure on seismic risks.	Residential area and residential buildings in the vicinity of the Sub-project area	Low
		Score	Regional	Short	Low	N/A	Likely	Short/mid-term	Medium	
		Value	3	2	2	-	3	2	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**20**							**60**
Impacts related to security personnel	Negative Direct	Definition	Impacts related to security personnel during the construction period will be locally limited.	The construction period is limited to 6 months. With the completion of the construction, no impact expected.	Expected impacts is within legal standards or accepted practices and is likely to result in intangible changes in social components	-	By training for security personnel, risks will be lowered	Potential impacts will disappear with the end of construction. Potential impacts can be reverted soon after the solution is found.	Residential area and residential buildings in the vicinity of the Sub-project area	Low
		Score	Local	Short	Low	N/A	Unlikely	Short/mid-term	Medium	

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)								
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)	Receptor Sensitivity	Impact Significance (Magnitude x Significance)
		Value	2	2	2	-	1	2	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**14**						**42**	

Table 7-62. Operation Phase Community Health and Safety Residual Impact Significances

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)							Receptor Sensitivity	Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)		
Impacts on community health (Accidental Release of Pathogens, OHS)	Negative Direct	Definition	Community health impacts (accidental release of pathogens) will be regionally limited.	Impacts will cease after the operational life span of the Sub-project.	Expected impacts intensity will be lowered with taking aforementioned mitigation measures	-	If the plans and procedures prepared for the Sub-project are followed, the likelihood of impacts will decrease.	If the necessary precautions are taken, accidental release of pathogens can leave irreversible impacts for the communities.	Residential area and residential buildings in the vicinity of the Sub-project area	Medium
		Score	Regional	Long	High	N/A	Unlikely	Long term	Medium	
		Value	3	4	4	-	1	4	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**48**						**144**	
Impacts on community health (Transport of Hazardous Materials)	Negative Direct	Definition	Community health impacts (transport of hazardous materials) will be regionally limited.	Impacts will cease after the operational life span of the Sub-project.	Incidents during transport of hazardous materials may result in exceedances of legal standards or accepted practices. Expected impacts intensity will be lowered with taking aforementioned mitigation measures	-	If the plans and procedures prepared for the Sub-project are followed, the likelihood of impacts will decrease.	If the necessary precautions are not taken incidents during transport of hazardous materials can leave long-erm impacts for the communities.	Residential area and residential buildings in the vicinity of the Sub-project area	**Medium**
		Score	Regional	Long	High	N/A	Unlikely	Long term	Medium	
		Value	3	4	4	-	1	4	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**48**						**144**	
Impacts on community misperception	Negative Direct	Definition	Impacts is expected to remain at the regional level.	With effective communication and implementation of SEP, the misperception of the community will be reduced in a short period of time.	If the plans and procedures prepared for the Sub-project are followed, the intensity of the impacts may decrease.	-	If the plans and procedures prepared for the Sub-project are followed, the likelihood of impacts will decrease.	After the source of impact has been cut off, community perception can be restored in a mid term.	Citizens of Serbia	Medium
		Score	Regional	Short	Low	NA	Unlikely	Mid-tern	Medium	
		Value	3	2	2	-	1	3	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**72**						**72**	

7.10 Labour and Working Conditions

7.10.1 Introduction

Sub-project workers may be exposed to some risks and impacts during the construction and operation periods. The risks identified for both construction and operation periods are discrimination, growing grievances due to lack of grievance mechanism and OHS risks. The most serious risk identified for the operational period is exposure to infectious pathogens.

This section defines the required workforce over the lifetime of the Sub-project and provides assessment of impacts and risks associated with labour and working conditions, as well as relevant mitigation and monitoring measures. The chapter is developed considering the following standards and documents:

- Labor Law, ("Official Gazette of RS", No. 24/2005, 61/2005, 54/2009, 32/2013, 75/2014, 13/2017 - decision of the Constitutional Court, 113/2017 and 95/2018);
- Law on Strikes: Law on Strike ("Official Gazette of RS", No. 57/2016);
- Law on Health and Safety at Work: ("Official Gazette of RS", No. 101/2005, 91/2015 - other law, 113/2017 - other law and 95/2018);
- ESS 2: Labour and Working Conditions;
- Labour Management Procedure.

7.10.2 Project Workforce

Pre-construction

The implementation of the Sub-project is conducted Project Coordination Unit (PCU) assigned by the Ministry of Health. The PCU is already staffed with a financial, management and procurement staff, environmental and social specialists.

The PCU will coordinate relevant technical units in the Ministry, and directly implement certain technical activities, including procurement of medical supplies, equipment, communication and monitoring. The PCU will report directly to the Minister of Health. PCU will follow environmental and social documents and practices throughout the life of the Sub-project.

Construction

The number of construction employees during the peak will be 40. The construction period of the Sub-project is expected to last around six (6) months.

Operation

The total number of workers to be employed during the operation phase of the Sub-project is around 5. In addition to the newly recruited workers, approximately 20 workers will be appointed from among those currently employed at the Torlak Institute. It is expected that the BSL3 Sub-project activities will require the following categories of workers:

- BSL3 facility staff (i.e. doctors, personnel, OHS personnel, laboratory workers). BSL3 laboratory staff are involved in research and development in the field of microbiology using viruses, bacteria and toxins;
- Civil servants. They are non-technical personnel in the facility. They are responsible for paperwork and contracts;
- Non-medical workers in BSL3 facility (e.g. facility and maintenance staff engaged in transport, delivery, technical maintenance, waste management).;
- Third party consultants/contractors. In the area of monitoring, evaluation, validation and maintenance, etc.

7.10.3 Labour and Working Conditions

7.10.4 Impacts

7.10.4.1.1 Construction Phase

Depending on the location, scale and nature of construction Sub-project, the impacts on labour and working conditions can vary and construction can have both positive and negative impacts and risks on labour and working conditions.

If working conditions are not well managed, the following impacts and risks may arise:

<u>Discrimination</u>

- Gender discrimination/gender based violence/sexual exploitation and abuse/sexual harassment (GBV/SEA/SH);
- Discrimination based on race, nationality, etc.

<u>Lack of a grievance mechanism</u>

- Failure to register complaints;
- Receiving complaints verbally;
- SEA/SH.

The risks are particularly relevant for the construction phase during the involvement of Sub-project (sub)contractors and gaps between national requirements and international standards.

In particular, the lack of a grievance mechanism and the failure to record grievances from workers may lead to adverse impacts not being addressed.

Occupational Health and Safety Impacts

There are several occupational health and safety risks that workers may face during the construction of a building. These risks can vary depending on the specific type of work being performed, the work environment, and the equipment being used. Some of the common occupational risks during building construction include:

- Falls from heights,
- Electric shock,
- Traffic accidents
- Burns,
- Exposure to hazardous materials,
- Musculoskeletal injuries from manual handling of heavy loads,
- Accidents involving heavy machinery and equipment,
- Risks related to working in confined spaces,
- Noise exposure,
- Exposure to extreme temperatures or weather conditions.

To mitigate these risks, proper training, use of personal protective equipment, and adherence to safety regulations and procedures are essential.

Table 7-63 shows the summary of the impact significances during construction phase. Impact significances are determined based on the methodology given in Chapter 5 of this ESIA Report.

Table 7-63. Construction Phase Labour and Working Conditions Impact Significances

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)								Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)	Receptor Sensitivity	
Impacts related to labour conditions	Negative Direct	Definition	The construction works will be in the Sub-project site, but considering the supply chain and transportation to the Sub-project site, the impact area is considered regional.	The construction period is limited to 6 months. With the completion of the construction, no impact on community health is expected due to construction activities.	Working conditions will be regulated according to legal standards, but it is likely to result in tangible changes in the social components.	-	Considering the low number of workers to work during the peak period, impacts related to working conditions can be expected.	Potential impacts related to labour conditions are expected to be irreversible.	Sub-project Workers (including contractors and suply chain etc.)	Medium
		Score	Regional	Short	Medium	N/A	Unlikely	Irreversible	Medium	
		Value	3	2	3	-	1	5	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**45**						**135**	
Impacts on life and fire safety	Negative Direct	Definition	Life and fire risks impacts during the construction period will be locally limited	The construction period is limited to 6 months. therefore, life and fire risks are limited to 6 months.	During the construction phase of the Sub-project, depending on the area where the fire has spread, risks may arise that may affect especially construction workers and local people. Risks to life may arise if adequate security is not provided at the construction site and the public is not prevented from entering this area.	-	The risk to life or fire is likely to occur at any time during the construction phase of the Sub-project.	After the finish of the construction works, there will be no risk associated with the construction of the Sub-project. It may not be possible to reverse the life safety and fire related impacts of the necessary plans and procedures are not followed.	Sub-project Workers (including contractors and supply chain etc.)	High
		Score	Local	Short	Very High	N/A	Likely	Irreversible	Medium	
		Value	2	2	5	-	3	5	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**60**						**180**	
Impacts related to health and safety	Negative Direct	Definition	Impacts on worker health and safety during the construction period will be limited to workers working at the Sub-project site.	The construction period is limited to 6 months. therefore, life and fire risks are limited to 6 months.	The impact on health and safety is within legal standards or accepted practices and is likely to result in tangible changes to the social component.	-	If necessary, precautions are not taken during the construction of the Sub-project, serious risks are likely to occur in terms of worker health and safety.	If necessary precautions are not taken and major accidents/injuries occur, the impact is irreversible.	Sub-project Workers (including contractors and supply chain etc.)	Medium
		Score	Sub-project Site	Short	Medium	N/A	Likely	Irreversible	Medium	
		Value	1	2	3	-	3	5	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**45**						**135**	

7.10.4.1.2 Operation Phase

Several of the impacts on working conditions identified during the construction period also apply during the operational period.

- Discrimination;
- Lack of a grievance mechanism.

Biomedical workers in BSL facilities: The expected risks are exposure to biohazards resulted in severe illness and death, physical and mental exhaustion, long shifts with little or no break and deprivation of sleep, occupational burnout, passing on infection to families and local communities and stigma, and exposure to infectious waste.

Non-medical workers in BSL3 facility: The expected risks are labor and OHS hazards, but not all members of this staff will be exposed to the same risk levels.

Occupational Health and Safety Impacts

The primary risk during the operation of the BSL-3 laboratory is exposure of laboratory workers to infectious microorganisms. The pathogenic microorganisms that will be handled in the BSL-3 laboratory have the risk to cause serious diseases through inhalation route of exposure. Exposure to hazardous materials, inadequate decontamination of BSL-3 laboratory, improper use of equipment, fire and electrical hazard are other potential risks commonly encountered by workers of a microbiological laboratory.

Table 7-63 shows the summary of the impact significances during operation phase. Impact significances are determined based on the methodology given in Chapter 5 of this ESIA Report.

Table 7-64. Operation Phase Labour and Working Conditions Impact Significances

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)								Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)	Receptor Sensitivity	
Impacts related to labour conditions	Negative Direct	Definition	During the operation phase, the works will be conducted at the Sub-project site.	During the operational period of the Sub-project, impacts on working conditions may occur.	Working conditions will be regulated according to legal standards, but it is likely to result in tangible changes in the social components.	-	Considering the number of workers, effects related to working conditions can be expected.	Potential impacts related to labour conditions are expected to be irreversible	Sub-project Workers (including contractors and supply chain etc.)	High
		Score	Sub-project Site	Very long	Medium	N/A	Likely	Irreversible	Medium	
		Value	1	5	3	-	3	5	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**60**						**180**	
Impacts related to health and safety (Exposure to infectious microorganisms)	Negative Direct	Definition	Impacts related to health and safety (exposure to infectious microorganisms) will be regionally limited.	Impacts will cease after the operational life span of the Sub-project.	Accidental release of pathogens may result in exceedances of legal standards or accepted practices.	-	If the plans and procedures prepared for the Sub-project are not followed, the likelihood of impacts will increase.	If the necessary precautions are not taken, accidental release of pathogens can leave irreversible impacts for the Sub-project workers.	Sub-project Workers (including contractors and supply chain etc.)	High
		Score	Regional	Long	Very High	N/A	Likely	Irreversible	Medium	
		Value	3	4	5	-	3	5	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**75**						**225**	

7.10.5 Mitigation Measures

Mitigation measures for general labour and working conditions during the construction phase:

- The Sub-project will develop a Staff Selection and Recruitment Procedure to cover both construction and operation phases of the Sub-project. This procedure will take into account unskilled, semi-skilled and skilled labour with the aim of providing opportunities for the employment of local labour to the extent possible;
- Employment capacity and qualifications required for construction will be publicised to avoid unrealistic expectations.
- The Project Owner will develop an HR Policy to cover the key provisions of ESS 2. The HR Policy will also apply to all Sub-project (contractors and will be included in all contracts concluded (including supply chain);
- Contractor staff to work on the Sub-project will also be recruited in accordance with this policy and equal rights and conditions for all employees will be ensured;
- Labour Management Procedure will be developed and implemented for the Sub-project construction stage;
- Equal conditions for all employees will be guaranteed by the HR policy and Labour Management Procedure;
- All mitigation measures provided within the scope of the Sub-project also apply to contractor and supply chain employees. The Project Owner is responsible for contractors' compliance with the specified standards and mitigation measures;
- The Project Owner will ensure that international standards are applied to the entire Sub-project workforce (including subcontractors' employees) and where Serbian legislation differs from international standards, the stricter one will be applied for the Sub-project;
- All prohibitions on child labour and forced labour will be stated in the HR policy;
- There will be no discrimination or reprisals against workers who are members of these trade unions and participate in collective bargaining. The right of employees to join trade unions and bargain collectively shall be guaranteed by the HR policy;
- In the event of dismissal in accordance with international legislation, the Project Owner, in consultation with workers, their organisations and in some cases the government, will develop a plan to mitigate the adverse effects of dismissal on workers. Information on redundancy will be provided in the HR policy;
- Workers will have contracts in place prior to commencement of work setting out their working conditions, terms of employment and EHS responsibilities;

- All Sub-project Workers, including subcontractors, will sign the Code of Conduct upon commencement of work, together with their employment contract, which includes punitive measures against GBV, SEA and SH;
- A labour grievance mechanism will be established and disclosed to all workers including contractors (see section 9.4.2).

Occupational Health and Safety Mitigation Measures

The Law on Safety and Health at Work of Serbia is the key legislative act in this area defines general principles of basic requirements and preventive measures that are related to occupational health and safety (OHS) at the workplace, the existing and anticipated risks, prevention of accidents and occupational diseases, training, informing, and consulting of the employees, and their equal engagement in the occupational health and safety protection issues. Torlak Institute will ensure that the requirements of all applicable health and safety legislation will be met during construction and operation phases of the Sub-project.

Torlak Institute and/or the Contractor will develop and implement procedures to ensure a safe working environment during both construction and operation phases in line with the Serbian legislation and ESS2. Project Owner and/or the Contractor will ensure occupational health and safety measures in general are designed and applied to ensure;

- Identification of potential hazards,
- Provision of preventive and protective measures also regarding hazardous conditions,
- Training of workers,
- Documentation and reporting of occupational accidents, diseases and incidents, training records,
- Emergency prevention and preparedness and response arrangements are in place,
- Remedies are defined for adverse impacts such as occupational injuries, deaths, disability and disease.

Some key mitigation measures to protect the health and safety of workers during construction phase include;

- Conducting a thorough job hazard analysis to identify and assess potential hazards and risks.
- Providing workers with proper training on construction safety procedures and protocols and potential hazards and risks.
- Ensuring that all workers are provided with and use appropriate personal protective equipment (such as hard hats, safety glasses, gloves, and protective footwear).

- Implementing safety measures to prevent falls from heights, such as guardrails, safety nets, and personal fall arrest systems.
- Ensuring that all equipment and machinery is regularly inspected and properly maintained.
- Providing workers with appropriate tools and equipment to reduce the risk of musculoskeletal injuries from manual handling.
- Properly storing and labeling hazardous materials to prevent exposure and contamination.
- Establishing and enforcing safety procedures and guidelines for working in confined spaces.
- Providing workers with access to adequate ventilation and respiratory protection when working with hazardous materials.
- Establishing and enforcing safety procedures and guidelines for working in extreme temperatures or weather conditions.
- Providing workers with access to adequate hydration and rest breaks to prevent heat-related illnesses.
- Conducting regular safety audits and inspections to identify potential hazards and risks.

These measures are intended to create a safe and healthy work environment for construction workers and minimize the risk of accidents, injuries, and illnesses.

Some key mitigation measures to protect the health and safety of workers during operation phase include;

Exposure to infectious microorganisms

The BSL-3 laboratory will be established in compliance with the facility design requirements of the WHO Laboratory Biosafety Manual. Code of practice, laboratory design and facilities and laboratory equipment requirements for a BSL-3 laboratory is provided in Section 2.3 of this report.

The laboratory will be equipped with Class III BSC in order to protect the operator and the environment from infectious aerosols generated:

- The Class III BSC is a closed-fronted design that provides complete separation between the material being handled and the operator/environment. Access to the work-surface is by means of strong rubber gloves attached to ports in the cabinet.
- Class III cabinets are airtight and both supply and exhaust air are filtered (with HEPA filter or equivalent) and high rates of air change are maintained within the cabinet.

Airflow is maintained by a dedicated exhaust system outside the cabinet, which keeps the cabinet interior under negative pressure compared to the surrounding space.

A controlled ventilation system that maintains a directional airflow into BSL-3 laboratory will be established. A visual monitoring device should be installed so that all times proper directional airflow into the laboratory room is maintained.

The building ventilation system will be so constructed that air from BSL-3 is not recirculated to other areas within the building. Air will be high-efficiency particulate air (HEPA) filtered, reconditioned and recirculated within that laboratory. When exhaust air from the laboratory (other than from biological safety cabinets) is discharged to the outside of the building, it must be dispersed away from occupied buildings and air intakes. Depending on the agents in use, this air may be discharged through HEPA filters. A heating, ventilation and air-conditioning (HVAC) control system may be installed to prevent sustained positive pressurization of the laboratory. Consideration should be given to the installation of audible or clearly visible alarms to notify personnel of HVAC system failure.

Medical Surveillance

The Project Owner is responsible for ensuring that there is adequate surveillance of the health of laboratory personnel. The objective of this surveillance is to monitor for occupationally acquired diseases. Appropriate activities to achieve these objectives are:

- Provision of active or passive immunization where indicated,
- Facilitation of the early detection of laboratory-acquired infections,
- Exclusion of highly susceptible individuals from highly hazardous laboratory work,
- Provision of effective personal protective equipment and procedures.

Decontamination

Decontamination of the BSL-3 laboratory will be provided in order to prevent any risks to workers handling infectious agents:

- In Sub-project activities, decontamination and sterilisation will be undertaken through use of chemical disinfection, autoclaving and pressurised rooms. To ensure an appropriate laboratory management system, factors for transmission of infection (e.g., aerosol generation, contact, indirect contact), methods for sterilization and disinfection, and levels of antimicrobial activity must be reviewed;
- To overcome the non-biological hazards arising from the use of chemical disinfectants, appropriate non-biological risk control measures must be applied;
- For sterilization of the equipment, steam (wet) sterilization will be applied at 121-134ºC for between 15-45 minutes and dry air sterilization will be applied at 300ºC for

3 minutes. Gas phase H_2O_2 (hydrogen peroxide) decontamination will be applied for room area decontaminations (The process is described in Appendix G) ;

- Protective clothing requirements will be adhered to in the clean room and BSL1, 2, 3 laboratories. In accordance with the GMP, health screenings, periodical health monitoring and vaccinations (based on product to be produced) of the personnel will be obligatory and followed by the quality assurance unit;
- Chemical disinfectants must be selected, stored, handled, used and disposed of with care, following manufacturers' instructions. PPE should be used to reduce the likelihood of exposure of personnel to both the chemical hazard and any biological agents present;
- Aerosol-generating procedures must be conducted in containment;
- The selection of an appropriate antimicrobial product and adherence to the product label instructions are critical to ensuring the product's performance against the target microorganism. Use of chemical agents for decontamination requires paying attention to instructions for their use and safety data sheets; ensuring they are used safely, and that appropriate precautions and protections are used;
- Gloves should be worn when handling biohazardous materials and hazardous chemicals, including those used in disinfection and decontamination. Hand hygiene should be performed after removing gloves, after touching potentially contaminated surfaces with bare hands, after completing work and before exiting the laboratory;
- Decontamination of the entire laboratory shall be considered when there has been gross contamination of the space, significant changes in laboratory usage, major renovations, or maintenance shutdowns. Selection of the appropriate materials and methods used to decontaminate the laboratory is based on a risk assessment;
- Decontamination processes must be verified on a routine basis;
- Decontamination of all cultures, stocks and other potentially infectious materials must be done before disposal, consistent with applicable institutional, local and national requirements. Mitigations and specifications related to medical waste are discussed in Decontamination, Waste and Wastewater Management in detail.

As mentioned in 7.9.4 Community Health, Safety and Security BSL-3 laboratory will be commissioned and certified according to the requirements of WHO Biosafety Laboratory Biosafety Manual, 3rd edition, 2004 and 4th edition, 2020. Biosafety and biosecurity programmes of the BSL-3 laboratory will be developed and implemented by the Project Owner. The workers will be provided with necessary training programmes including laboratory biosecurity training. Also an adequate Emergency Preparedness and Response Plan will be developed for the Sub-project.

Chemical Hazard

Occupational chemical exposure may result from laboratory procedures performing and handling of chemicals. All staff would have training in controlling of chemical hazardous and handling. Only limited amounts of chemicals necessary for daily use will be stored in the laboratory. Implementation of engineering and administrative control measures to avoid the release of hazardous substances into the work environment. Appropriately equipped first-aid stations will be easily accessible throughout the place of work, with Materials Safety Data Sheets.

Ergonomic Hazard

Laboratory workers are at risk for repetitive motion injuries during routine laboratory procedures such as pipetting, working at microscopes, operating machine and working on BSC workstations. By becoming familiar with how to control laboratory ergonomics-related risk factors, employers can reduce chances for occupational injuries. Selecting tools and designing work stations that reduce force requirements and holding times, and which promote improved postures, implementing administrative controls into work processes, such as job rotations and rest or stretch breaks.

Improper Use of Equipment

Laboratory workers are at risk for repetitive use of laboratory equipment such as pipetting, centrifuge, BSC homogenizers, shakers, blenders, sonicators, freezers, autoclave and other equipment. Certain items of equipment may create hazards when they are used, and the common hazards related to laboratory equipment are Aerosols, splashing and tube breakage rotors and impaired ultrasonic hearing, dermatitis, burning, splash and spillage. In addition, due to improper use equipment-related accidents might occur. The mitigation measures would be training of workers in equipment operating and handling techniques during operation, and operation of equipment, periodic maintenance and calibration would be according to the manufacturer's instructions.

Fire and Electrical Hazard and Mitigation Measures

Fire risks:

- Chemical spills or leaks that can ignite and cause fires
- Improper storage or handling of flammable or combustible materials
- Overloading electrical circuits, which can cause electrical fires
- Malfunctioning or improperly maintained lab equipment that can spark and cause fires
- Combustible materials located near ignition sources
- Blocked exits or pathways that can impede evacuation in the event of a fire.

Electrical Risks:

- Electrocution from contact with live wires or electrical sources
- Fires caused by electrical equipment or wiring
- Malfunctioning or improperly maintained lab equipment that can spark and cause fires
- Overloading electrical circuits, which can cause electrical fires
- Improper grounding of electrical equipment, which can lead to electrocution or electrical fires
- Electrical shocks or burns from faulty or damaged electrical equipment
- Electrical interference with sensitive lab equipment or instruments.

In order to minimize fire risks, laboratory safety protocols and procedures will be followed, all chemicals are properly labelled and stored, and a clean and clutter-free workspace will be maintained. Other steps to reduce fire risks include installing and maintaining fire suppression systems and equipment, regularly inspecting and maintaining electrical systems and equipment, and conducting regular fire drills to ensure that all laboratory occupants know how to respond in the event of a fire.

All electrical equipment will be properly grounded and maintained, and avoid overloading electrical circuits. Other steps to reduce electrical risks include regularly inspecting and maintaining electrical systems and equipment, using appropriate personal protective equipment (such as insulated gloves and safety glasses), and ensuring that all electrical equipment is properly labelled and meets safety standards.

7.10.6 Residual Impacts

Mitigation measures are expected to minimise such impacts to short and intermittent events that will be reversible in a short-term by the effect of the natural processes. The Residual Impact Significances for the construction and operation phases are given in Table 7-65 and Table 7-66, respectively.

Table 7-65. Construction Phase Labour and Working Conditions Residual Impact Significances

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)								Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)	Receptor Sensitivity	
Impacts related to labour conditions	Negative Direct	Definition	The construction works will be in the Sub-project site, but considering the supply chain and transportation to the Sub-project site, the impact area is considered regional.	The construction period is limited to 6 months. With the completion of the construction, no impact on community health is expected due to construction activities.	Expected impacts intensity will be lowered with taking aforementioned mitigation measures during the construction phase of the Sub-project.	-	Considering the low number of workers to work during the peak period, impacts related to working conditions can be expected.	Activities concerning labour conditions during the construction period will end with the completion of the construction. However, if the necessary precautions are taken, the initial condition of the component can be restored within within one to five years after cessation of the impact source and/or with restoration activities	Sub-project Workers (including contractors and supply chain etc.)	Low
		Score	Regional	Short	Low	N/A	Unlikely	Mid-term	Medium	
		Value	3	2	2	-	1	3	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**24**						**72**	
Impacts on life and fire safety	Negative Direct	Definition	Life and fire risks impacts during the construction period will be locally limited	The construction period is limited to 6 months. therefore, life and fire risks are limited to 6 months.	Expected impacts intensity will be lowered with taking aforementioned mitigation measures during the construction phase of the Sub-project.	-	The risk to life or fire will be lowered with taking aforementioned mitigation measures during the construction phase of the Sub-project.	After the finish of the construction works, there will be no risk associated with the construction of the Sub-project. It may not be possible to reverse the life safety and fire related impacts of the necessary plans and procedures are not followed.	Sub-project Workers (including contractors and supply chain etc.)	Medium
		Score	Local	Short	Medium	N/A	Unlikely	Irreversible	Medium	
		Value	2	2	3	-	1	5	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**40**						**120**	
Impacts related to health and safety	Negative Direct	Definition	Impacts on worker health and safety during the construction period will be limited to workers working at the Sub-project site.	The construction period is limited to 6 months. therefore, life and fire risks are limited to 6 months.	Expected impacts intensity will be lowered with taking aforementioned mitigation measures during the construction phase of the Sub-project.	-	If necessary, precautions are taken during the construction of the Sub-project, serious risks are unlikely to occur in terms of worker health and safety.	If major accidents/injuries occur, the impact is irreversible.	Sub-project Workers (including contractors and supply chain etc.)	Medium
		Score	Sub-project Site	Short	Low	N/A	Likely	Irreversible	Medium	
		Value	1	2	2	-	1	5	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**30**						**90**	

Table 7-66. Operation Phase Labour and Working Conditions Residual Impact Significances

Potential Impact	Impact Type	Nature of Impacts (Magnitude designations)								Impact Significance (Magnitude x Significance)
			Geographical Extent (G)	Duration (D)	Intensity (I)	Frequency (F)	Likelihood (L)	Reversibility (R)	Receptor Sensitivity	
Impacts related to labour conditions	Negative Direct	Definition	During the operation phase, the works will be conducted at the Sub-project site.	During the operational period of the Sub-project, impacts on working conditions may occur.	Working conditions will be regulated according to legal standards, but it is unlikely to result in tangible changes in the social components if mitigation measures are applied.	-	Considering the number of workers, effects related to working conditions can be expected.	Potential impacts related to labour conditions are expected to be irreversible. However if the necessary precautions are taken, the initial condition of the component can be restored within a few months to one year after cessation of the impact source and/or with restoration activities.	Sub-project Workers (including contractors and supply chain etc.)	Low
		Score	Sub-project Site	Very long	Low	N/A	Likely	Short/Mid-term	Medium	
		Value	1	5	2	-	3	2	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**22**						**66**	
Impacts on life and fire safety	Negative Direct	Definition	Impacts is expected to remain at the local level.	Life and fire safety risks will exist throughout the operational period.	If the plans and procedures prepared for the Sub-project are followed, the intensity of the impacts may decrease.	-	If the plans and procedures prepared for the Sub-project are followed, the likelihood of impacts will decrease.	It may not be possible to reverse the life safety and fire related impacts of the necessary plans and procedures are not followed.	Sub-project Workers (including contractors and supply chain etc.)	High
		Score	Local	Very long	Medium	NA	Unlikely	Irreversible	Medium	
		Value	2	5	3	-	1	5	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**55**						**165**	
Impacts related to health and safety **(Exposure to infectious microorganisms)**	Negative Direct	Definition	Impacts related to health and safety (exposure to infectious microorganisms) will be regionally limited.	Impacts will cease after the operational life span of the Sub-project.	Expected impacts intensity will be lowered with taking aforementioned mitigation measures	-	If the plans and procedures prepared for the Sub-project are followed, the likelihood of impacts will decrease.	If the necessary precautions are taken, accidental release of pathogens can leave long-term impacts for the communities.	Sub-project Workers (including contractors and supply chain etc.)	Medium
		Score	Regional	Long	High	N/A	Unlikely	Long term	Medium	
		Value	3	4	4	-	1	4	3	
	Impact Magnitude (G+D+I+F (or L)) x R		**48**						**144**	

8 CUMULATIVE IMPACT ASSESSMENT

8.1 Introduction

Cumulative impacts are defined as the impacts that occur together with other impacts resulting from concurrent or planned future third-party activities to affect the same receptors as the proposed Torlak Institute BSL-3 Subproject. This Chapter presents the Cumulative Impact Assessment (CIA) for the Sub-project including applicable CIA guidance, CIA methodology, CIA scoping and impact assessment. The CIA herein takes into account the existing and proposed projects and their further operational considerations in the vicinity of the Sub-project site.

8.2 International Guidance and Requirements

World Bank Group Environmental and Social Standard 1, Assessment and Management of Environmental and Social Risks and Impacts, defines cumulative impact as “the incremental impact of the project when added to impacts from other relevant past, present and reasonably foreseeable developments as well as unplanned but predictable activities enabled by the project that may occur later or at a different location”.

In addition to the WBG ESSs, the guidance document “Good Practice Handbook: Cumulative Impact Assessment and Management” of International Finance Corporation (IFC), the private sector arm of the WBG published in 2013 is also taken into consideration during the CIA. The good practice handbook highlights the importance of a defined scope for CIA by introducing the concept of Valued Environmental and Social Components (VEC[32]s). According to the Guideline, the VECs are considered as environmental and social attributes that are considered to be important in assessing risks listed below among others:

- Physical features, habitats and wildlife populations;
- Ecosystem services;
- Natural processes (e.g. water and nutrient cycles, microclimate);
- Social conditions (health, economics); and
- Cultural aspects.

8.3 Methodology

Assessment of cumulative impacts considers the effects of other past, present and planned projects with similar impacts on the project area of influence. The key point in determining the need for cumulative impact assessment is to identify one or more impact topics which are affected by different developments.

[32] Originally described by Beanlands and Duinker as “Valued Ecosystem Components” in 1983.

Cumulative effects can occur as interactions between actions and the environment, and between components of the environment. These “pathways” between a source and an effect are often the focus of an assessment of indirect or cumulative impacts. The magnitude of combined effects along a pathway can be equal to the sum of the individual effects (additive effect) or can be an increased effect (synergetic effect).

The objective of the assessment of cumulative impacts is to identify and focus on significant impacts, and to ensure that these impacts are taken into consideration in the decision-making process. In order to make the assessment effective, at first, these main impacts should be analyzed. They can be generally defined as follows.

Cumulative Impacts: These impacts are incremental effects of past, present or future activities together with the proposed project.

Indirect Impacts (Secondary Impacts): These impacts are not directly caused by project. Indirect impacts occur in complex pathways or away from the project.

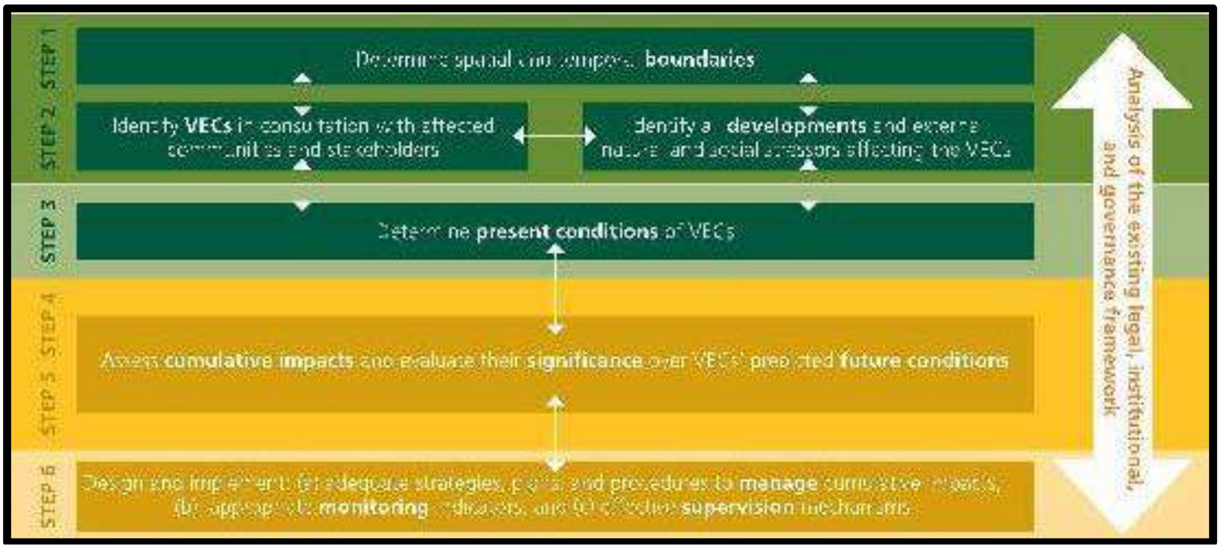
Impact Interactions: These impacts (e.g. reaction of emissions of proposed project and an existing plant) are the results of reactions between impacts of proposed project or other actions.

The approach to this CIA has been undertaken in line with the IFC Good Practice Handbook, Cumulative Impact Assessment and Management Guidance for the Private Sector in Emerging Markets. CIA can be considered when the challenges are due to:

- Lack of baseline data related to the other project developments;
- Uncertainties associated with anticipated developments; and
- Limited and emergent, strategic regional, sectoral, or integrated resource planning schemes.

The assessment should be commensurate with the incremental contribution, source, extent, and severity of cumulative impacts anticipated. The assessment also focuses only on potentially significant cumulative impacts, and on cumulative impacts where the Project’s contribution to cumulative impact is considered to be significant.

The CIA methodology follows the steps indicated in Figure 8-1.



(Source: IFC Good Practice Handbook: Cumulative Impact Assessment and Management)

Figure 8-1. Steps of CIA

The CIA process predicts cumulative impacts to which the Project may contribute. The assessment is based on consideration of the status of the activities/developments in the vicinity of the Project site and the nature of the information available in order to predict the magnitude of the impact arising from the other activities/developments. The focus is the condition of the VECs and the scope of the expanded spatial and temporal boundaries for the analysis.

The CIA methodology comprises the following:

- Scoping phase, which is to: (i) determine spatial and temporal boundaries, ii) identify VECs and identify all other activities/ developments affecting VECs;
- Baseline condition of VECs;
- Assessment of cumulative impacts and evaluation of the significance over VECs' predicted future conditions;
- Mitigation measures and management strategies.

It is important to note that since the impacts and mitigation measures are detailed in the ESIA Report, the assessment given in this section is focused on the residual impacts from the Sub-project after taking necessary mitigation measures.

It is only possible to define the impacts resulting from other activities/developments through the readily available and published documents using the impact assessment methodology described in *Chapter 5: Scope and Methodology.*

Significance criteria

The significance of potential cumulative effects has been determined in accordance with the criteria set out in Table 8-1.

Table 8-1. Combined and cumulative effects' significance

Significance category	Typical Description of Effect
Very High (typically adverse only)	Where the cumulative impacts of the Project in association with other developments upon a single of a number of environmental and/or social receptors would be very very high and/or effects would be permanent for receptors of very high value.
High (adverse or beneficial)	Where the cumulative impacts of the Project in association with other developments upon a single of a number of environmental and/or social receptors would be (positive or negative): • widespread/large scale for a receptor of high value; • permanent for a receptor or receptors of high value; • localised for a receptor or receptors of very high value; or • temporary for a receptor or receptors of very high value.
Medium (adverse or beneficial)	Where the cumulative impacts of the Project in association with other developments upon a single of a number of environmental and/or social receptors would be (positive or negative): • permanent for a receptor or receptors of medium value; • localised for a receptor or receptors of high value; or • temporary for a receptor or receptors of high value.
Low (adverse or beneficial)	Where the cumulative impacts of the Project in association with other developments upon a single of a number of environmental and/or social receptors would be noteworthy but not significant (positive or negative). Effects would be: • permanent for receptors of low value; • localised for a receptor or receptors of medium value; or • temporary for a receptor or receptors of medium value.
Negligible	Where the cumulative impacts of the Project in association with other developments upon a single of a number of environmental and/or social receptors would be not significant (positive or negative).

8.4 Identification of Boundaries and VECs

In general, the temporal boundary of the CIA covers the entire Project life-cycle, from construction through long-term operations. On the other hand, the CIA process is limited with the prediction of the future activities and developments such as the planning/implementation of other relevant projects in the region. Therefore, for the purpose of this CIA, consideration is given to the pre-construction, design and construction phase and for operation phase is only considered to the extent feasible for discussion and assessment of cumulative impacts with the other projects.

The spatial boundary of the CIA has considered the Sub-project characteristics and the assessment is made based on the study areas defined in Chapter 5: Scope and Methodology of this ESIA report. The spatial boundaries may be flexible and may vary from the space occupied by a small VEC feature (e.g. air quality) to a larger geographical region depending on the characteristics of the VEC. The relevant spatial boundaries are essentially the same as the geographical extent in Chapter 7, where it varies between Sub-project area to Belgrade city depending on the baseline feature.

In this ESIA report, VECs that may be potentially affected by the Sub-project are considered. The VECs have been identified based on the available information obtained for the activities/developments in the vicinity of the Sub-project site and considering the environmental and social conditions of the study area. Since the stakeholder engagement activities are integral part of the ESIA study and play an important role for the identification of the environmental and social resources, the results of the stakeholder engagement activities are considered and included in the cumulative impact assessment. The details of the stakeholder engagement activities are summarized in *Chapter 4: Scope and Methodology of ESIA and Stakeholder Engagement* and presented in Stakeholder Engagement Plan (SEP). The environmental and social aspects which affect the VECs are identified as follows:

- Air quality,
- Environmental noise,
- Water and wastewater,
- Waste,
- Community health and safety,
- Occupational health and safety,
- Social
- Biodiversity.

The assessment for the VECs only considers the residual impacts (i.e. impacts following the application of mitigation measures) arising from the Sub-project. The summary of impact assessment made in the relevant chapters of the ESIA report and identified residual impacts on the selected VECs considering the construction and operation phase of the Sub-project are presented in Table 8-2. As such, the *negligible* residual impacts are scoped out of the CIA, residual impacts having *low* significance have been reviewed for potential cumulative impacts; and residual impacts with *medium, high* and *very high* significance are evaluated as part of the CIA.

Table 8-2. Specific VECs for the Sub-Project

Environmental and Social Aspects	Topics / VECs	Potential Impacts	Residual Impacts
Air Emissions	**Air quality at nearby settlements**	Fugitive dust and PM emissions due to construction activities, Exhaust emissions from the movement of construction machinery and vehicles	Negligible
Noise	**Background noise levels at nearby settlements**	Noise from the construction machinery and vehicles. Noise from potential noise generating equipment (depending on location of ventilation system, type of generator etc.) during operation phase	Low
Wastewater	**Water and soil contamination**	Contamination risk due to improper wastewater management	Low
Waste	**Water and soil contamination**	Contamination risk due to improper waste management	Low
Biodiversity	**Terrestrial ecology**	Clear-cut of trees within Sub-project area during construction activities	Low
Community misperception	**Community**	Public unrest	Medium
Community Health and Safety	**Community**	Escape of infectious pathogens during operation, transport of hazardous materials, life and fire safety	Medium
Occupational health and safety	**Workers**	Exposure risk to infectious pathogens during operation, life and fire safety	Medium

8.5 Developments in the Vicinity of the Sub-Project Site

8.5.1 Existing Facilities

The existing facilities in the close vicinity of the Sub-project are Torlak Institute and Faculty of Pharmacy.

Background environmental and social measurements include impacts from existing facilities, therefore the study area is not likely to experience cumulative impacts resulting from existing activities.

8.5.2 Ongoing and Planned Developments

The study area might experience cumulative impacts resulting from ongoing construction activities on the 300 m west of the Sub-project Area. The location of the ongoing construction area of the building is given in Figure 8-2.

3

Figure 8-2. Sub-Project Location and Ongoing Construction Area

The construction activities of the Sub-project and the planned development will be conducted concurrently.

Planned BIO4 Campus

The Serbian government approved in 2021 to set up a BIO4 Campus in Belgrade which will house scientific institutions and faculties, research and development departments of pharmaceutical and biotechnology companies, an extension of the Belgrade Science and Technology Park for the development of startups, scientific centers, a conference and multimedia exhibition center, and other facilities including a BSL-3 laboratory (*BIO4 Campus - Serbia*).

The BIO4 Campus will focus on 4 key topics:

- Biomedicine,
- Biotechnology,
- Bioinformatics,
- Biodiversity

Although the details are not yet known, the construction works for BIO4 Campus are planned to start at the end of 2023 and the official start of the campus is planned at the end of 2025 (*BIO4 Campus - Serbia*).

BIO4 Campus will be located along the Vojvode Stepe Street on the right and also left side, close to Torlak Institute and will occupy approximately 20 hectares.

Figure 8-3. Location of BIO4 Campus (*Reference: BIO4_Campus.pdf*)

According to the available information, the BSL-3 Laboratory Subproject is significantly small, and its impacts are expected to be relatively limited compared to the planned BIO4 Campus therefore, cumulative impacts regarding BIO4 Campus are not discussed in this ESIA report. Neverthless the communication plans and procedures which will be prepared for BSL-3 Laboratory Subproject will take into account the planned BIO4 Campus and ensure common measures and responses are in place where necessary. Besides, the ESIA report and management plans generated for BSL-3 Laboratory Subproject can be used as supportive documents when conducting environmental and social studies for the BIO4 Campus Project.

8.6 Cumulative Impact Analysis of the Developments

Cumulative impacts are defined as the impacts that occur together with other impacts resulting from concurrent or planned future third-party activities to affect the same receptors (specific VECs) as the proposed Sub-project.

Table 8-3. Cumulative Impact Assessment of the VECs

Environmental and Social Aspects	Topics/VECs	Project Under Assessment	Ongoing Development	Cumulative Impact Predicted
Noise	**Background noise levels at nearby settlements**	X	X	Yes
Wastewater	**Water and soil contamination**	X	X	Yes
Waste	**Water and soil contamination**	X	X	Yes
Community Health and Safety	**Escape of infectious pathogens during operation, transport of hazardous materials, life and fire safety**	X	-	No
Occupational Health and Safety	**Exposure to infectious pathogens, life and fire safety**	X	-	No
Community misperception	**Public unrest**	X	-	No
Biodiversity	**Terrestrial ecology**	X	X	No

8.7 Mitigations for Cumulative Impacts of the Developments

A qualitative assessment of potential cumulative impacts on the identified VECs is provided below in Table 8-4.

Table 8-4. Mitigations for Cumulative Impacts of the Developments

Environmental and Social Aspects	Topics / VECs	Cumulative Impacts	Mitigation
Noise	Background noise levels at nearby settlements	Environmental noise resulting from the construction and operation phases of the existing and proposed Sub-projects.	Mitigation measures were identified in the relevant chapters of the ESIA report (Chapter 7 Environmental and Social Impact Assessment and ESMP).
Wastewater	Water and soil contamination	Contamination risk due to improper wastewater management	Mitigation measures were identified in the relevant chapters of the ESIA report (Chapter 7 Environmental and Social Impact Assessment and ESMP).
Waste	Water and soil contamination	Contamination risk due to improper waste management	Mitigation measures were identified in the relevant chapters of the ESIA report (Chapter 7 Environmental and Social Impact Assessment and ESMP).
Community Health and Safety	Escape of infectious pathogens during operation, transport of hazardous materials, life and fire safety	Infectious pathogens, life and waste risks	Mitigation measures were identified in the relevant chapters of the ESIA report (Chapter 7 Environmental and Social Impact Assessment and ESMP).

Environmental and Social Aspects	Topics / VECs	Cumulative Impacts	Mitigation
Occupational Health and Safety	Exposure to infectious pathogens, life and fire safety	Infectious pathogens, life and waste risks	Mitigation measures were identified in the relevant chapters of the ESIA report (Chapter 7 Environmental and Social Impact Assessment and ESMP).
Community misperception	Public unrest	Social unrest due to lack of information	Mitigation measures were identified in the relevant chapters of the ESIA report (Chapter 7 Environmental and Social Impact Assessment and ESMP).

8.8 Conclusion

The cumulative impact assessment was undertaken considering the programme, distance to the Sub-project site and development features of the proposed activities in order to understand the Sub-project's potential to contribute to cumulative impacts during the construction and operation phase. As discussed in the previous sections, the Sub-project will have the potential to interact with the ongoing construction activities on the 300 m west of the Sub-project Area that can lead to cumulative impacts.

The cumulative impacts on the surrounding area/communities that would result from the combination of the Sub-project and other nearby development consist of impacts related to the air quality, environmental noise, wastewater, waste, community health and safety and biodiversity.

The assessment shows that expected level of the cumulative impacts are same as the Sub-project impacts given in Chapter 7, and in general low and negligible. Therefore, no specific recommendations are made for monitoring or measurements of potential impacts in the field due to fact that mitigations suggested in the assessment overlaps with mitigations stipulated in the ESMP.

9 STAKEHOLDER ENGAGEMENT

Public consultation and information sharing is crucial during the construction and operation periods of the BSL-3 laboratory. A transparent communication strategy with the public should be built to manage public misperception and related unrest. At the same time, complaints, suggestions and requests for information from the public should be carefully analysed and relevant measures and explanations should be made in a timely manner.

Transparent information disclosure, stakeholder engagement, and GRM are proactive measures to prevent or minimize risks and impacts by fostering open communication, addressing concerns, and facilitating the resolution of issues. These measures ensure that affected communities have access to accurate information, can express their opinions, and are involved in the decision-making process.

The ultimate goal of stakeholder engagement is to create a mutually beneficial relationship between the Sub-project and its stakeholders among which are the citizens of the Belgrade. It aims to ensure that decisions and actions are informed by a diverse range of perspectives, leading to better outcomes, improved understanding, and increased trust and support from stakeholders.

Identification and analysis: Identifying and understanding the stakeholders relevant to a project or organization, assessing their interests, influence, and potential impacts.

Communication: Establishing effective communication channels to share information, updates, and project details with stakeholders, as well as receiving input and feedback from them.

Consultation and involvement: Actively involving stakeholders and citizens in general in decision-making processes, seeking their input, and considering their perspectives and concerns.

Accountability and responsiveness: Being accountable to stakeholders and citizens in general by addressing their concerns, providing timely responses, and keeping them informed about the outcomes of their engagement.

Stakeholder engagement is an integral and crucial part of an ESIA process, aimed at providing an opportunity for affected and/or interested individuals, groups and organizations to express their views and concerns about the project which are taken into account during the assessment of impacts and identifying mitigation measures. Stakeholder engagement helps to:

- Build and maintain a constructive relationship with the stakeholders, especially affected communities;
- Promote improved environmental and social performance through effective engagement with the stakeholders;

- Promote and provide means for adequate engagement with affected communities and to ensure that meaningful environmental and social information is disclosed to such communities and to other stakeholders;
- Ensure that all stakeholders have ways to access information and raise issues;
- Ensure that project-affected communities have accessible means to raise issues and grievances, and the Project Owner responds to and manage such issues and grievances appropriately.

A stand-alone Stakeholder Engagement Plan (SEP) has been developed for the construction of BSL 3 laboratory, to help structure a systematic communication with the stakeholders during the ESIA study. The details of stakeholder engagement activities undertaken as part of the ESIA study are presented below.

The SEP also includes a grievance mechanism for community members and other stakeholders to raise any concerns and problems related to the Sub-project. The Grievance Mechanism (GM), which is one of the most important tools of stakeholder engagement, has also been developed within the scope of the SEP.

Stakeholder engagement is an ongoing process, and the SEP will be regularly monitored and updated throughout all stages of the Sub-project. This version of the SEP is related with the consultation activities of Environmental and Social Impact Assessment (ESIA) study which is being prepared for the Sub-project. SEP will be published on the Project Company's website at the same time as the Final Draft ESIA Report in order to provide an opportunity for people to comment on the plans related to engagement as well as on the Sub-project. The SEP is the responsibility of the Project Company and Project Company is fully committed to undertaking necessary engagement activities in a manner that is consistent with international good practice as outlined in next sections.

This chapter includes the following key topics:

- Identifying key stakeholders for the Sub-project;
- Stakeholder engagement activities carried out to date;
- Planned stakeholder engagement activities;
- Grievance mechanism.

9.1 The Sub-Project Social Area of Influence

The locations of nearby neighbourhoods and sensitive receptors in the vicinity of the Sub-project site are illustrated in Figure 9-1.

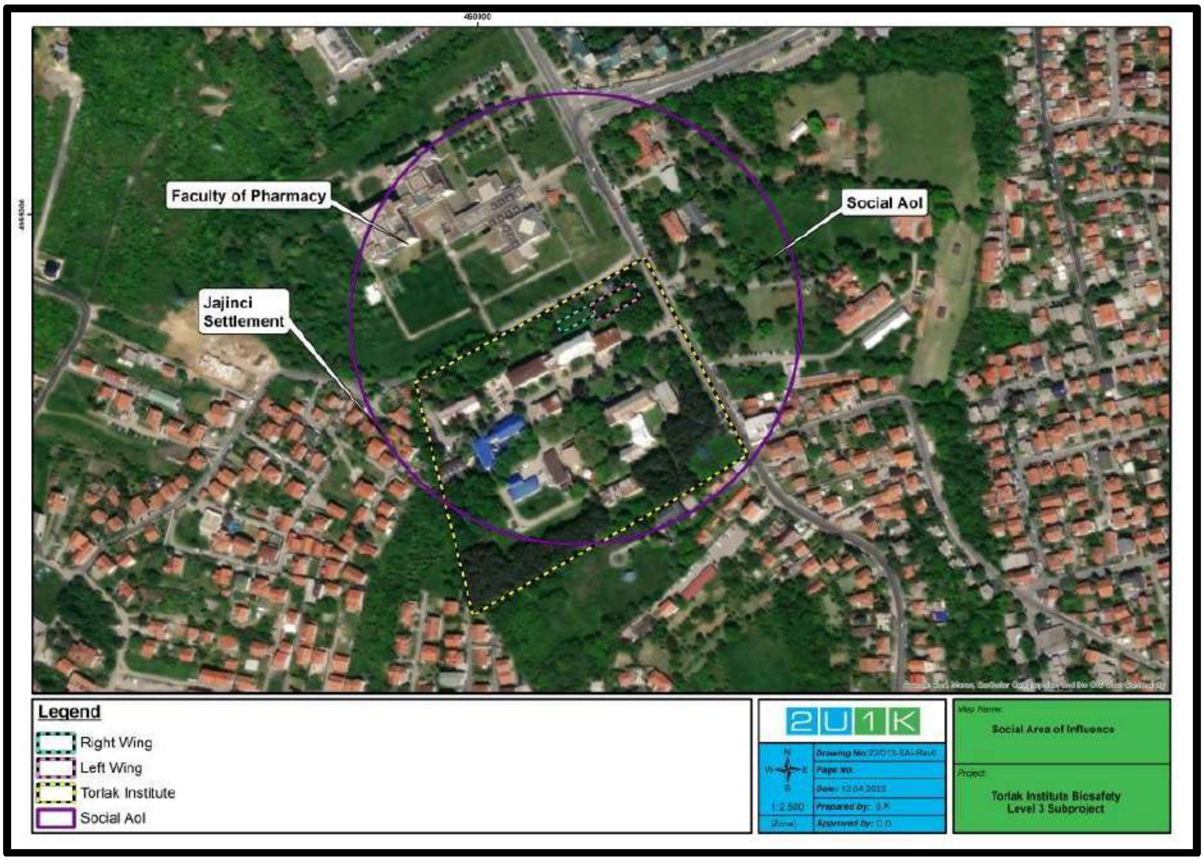


Figure 9-1. Nearby neighbourhoods and sensitive receptors in the vicinity of the Sub-Project Area

9.2 Stakeholder Identification

Stakeholder identification is a key step in managing the overall stakeholder engagement process.

According to WB ESS-10, the process to identify stakeholders includes the following, as appropriate: (a) First, at the beginning of the environmental and social assessment for the project, the Borrower develops a list of project-affected and other interested parties, paying special attention to identifying disadvantaged or vulnerable groups. Information from any preliminary social impact assessment can inform this list. (b) Second, other interested parties are identified by listing relevant interest groups, and considering historical issues, social relations, relationships between local communities and the project implementer, and any other relevant factors related to the sector and location that help anticipate local and external responses to the project. (c) Third, it is advisable to conduct discussions with representatives of the stakeholders identified and with persons knowledgeable about the local, country, and sector contexts. In some circumstances, media and social media searches may help to verify the list and identify any other project-affected or interested parties and to contact them. Specific attention should be paid to identifying any disadvantaged or vulnerable groups.

Project stakeholders are divided into 3 key groups: affected parties, interested parties and vulnerable groups. Vulnerable groups are crosscutting and can be found in both groups.

Affected parties include stakeholders that might be directly or indirectly affected by a project. Interested parties include individuals, groups or institutions that will not be directly affected by the project but whose interests might be affected. This category describes government bodies, NGOs and educational institutions, etc. Vulnerable groups are people who might be directly and differentially or disproportionately affected by a project because of their disadvantaged or vulnerable status. This disadvantaged or vulnerable status may stem from an individual's or group's race, color, sex, language, religion, political or other opinion, national or social origin, property, birth, or other status.

Table 9-1. Stakeholder Groups

Stakeholder groups		Level of interest	Level of influence	Level of engagement	Nature of Interest
Project Affected Parties	**Project Workers**				
	• Contractors and workers; • Health Care Workers and supportive staff; • Institute management.	High	High	Partner	Interest in OHS and management plans during construction and operation periods of the project.
	Technical				
	• Project designer; • ESIA Consultants.	High	Medium	Consult	Potential concerns over regarding environmental and social impacts and project designs
	NGO's				
	• NGOs especially ones dealing with social dialogue, community health and safety, ecology and vulnerable group.	High	Medium	Consult	Potential changes in potential environmental and social conditions
	Local Communities				
	• Local communities within the Project area	High	Medium	Consult	Concerns about health, safety, traffic, construction related impacts (noise, dust, damages, emissions, vibrations)
	Nearby Businesses and Government Institutions				
	• Local Businesses; • Schools and Faculty of Pharmacy; • Healthcare Institutions.	Medium	Low	Inform	Concerns about disruption of business and operation activities
Project Interested Parties	**Government / Authorities**				
	• Ministry of Health; • Ministry of Environmental Protection; • Ministry of Construction, Transport and Infrastructure; • Ministry of Labour and Social Policy;	High	High	Partner	Institutional and legal arrangements, regulations

	Stakeholder groups	Level of interest	Level of influence	Level of engagement	Nature of Interest
	• Vozdovac Municipality; • Academic Institutes.				
Project Interested Parties	**Scientific institutions in the field of infective diseases**				
	• University of Niš Faculty of Medicine; • Clinical Center Niš, hospital; • Faculty of Pharmacy; • Institute of Molecular Genetics and Genetic Engineering; • Clinical Center Belgrade; • Infectious Diseases Clinic, Niš; • Infectious Diseases Clinic, Belgrade; • VMA Belgrade; • University of Belgrade Faculty of Medicine; • Infectious Diseases Clinic KCV, Novi Sad; • University of Novi Sad Faculty of Medicine; • Clinical Center Vojvodine.	Low	Low	Inform	Institutes and clinics that can be co-operated with
Vulnerable Groups	**Vulnerable Groups/Individuals (directly affected by the project)**				
	• Front line health staff; • Women staff; • Staff with disabilities; • Waste pickers.	High	Medium	Consult	Access to participation activities, greater exposure to potential adverse impacts
	Vulnerable Groups/Individuals (might be affected)				
	• Retired elderly and people with disabilities and chronical diseases in home lockdown; • Disabled; • Households below poverty line that could not afford medicine, private doctors services, adequate nutrition; • Homeless persons; • Single parent headed households, male and female (with children up to 14 years; without some other relatives in the household); • Roma population living in unhygienic settlements (enclaves) without water facilities, sewage, improvised houses.; • Migrants; • Youths; • LGBT persons ;	Medium	Medium	Consult	Access to participation activities, greater exposure to potential adverse impacts

Stakeholder groups		Level of interest	Level of influence	Level of engagement	Nature of Interest
	• Persons with chronic diseases living in Torlak surrounding communities.				

9.3 Stakeholder Engagement Activities during ESIA Study

9.3.1 Preliminary Stakeholder Engagement Activities

Under the Serbia Emergency Covid-19 Response Project As required by the World Bank (WB) Environmental and Social Standard 10 (ESS10) – Stakeholder Engagement and Information disclosure, during the preparation of draft ESMF and SEP documents for the Serbia Emergency Covid-19 Response Project (SECRP) the Borrower carried out public consultations with relevant stakeholders.

The draft documents and invitation to the public consultations were also available on the MoH website: https://www.zdravlje.gov.rs/tekst/en/228/covid-19.php.

On 24 February 2021, at 11:00 AM (local time), public consultations and presentation of the draft ESMF and SEP for SECRP documents were organized at the premises of the Project Coordination Unit (PCU), Pasterova 1, III floor, Belgrade. The meeting was attended by a diverse group of 17 stakeholders, including the representatives of MoH, the National Health Insurance Fund (NHIF) and PCU implementing SECRP and "Second Serbia Health Project" (SSHP).

The consultation consisted of two parts. In the first, introductory part, Ms. Biljana Kozlovic, PCU Coordinator, explained the goal and components of the SECRP and introduced the PCU members. In addition, participants were informed in general about the ESF and the purpose of ESMF and SEP documents during the project implementation. It was also emphasized that all activities supported under the Project shall be environmentally and socially sound, sustainable, and consistent with WB ESS and Serbian national legislation.

In the second part, a presentation of ESMF and SEP documents was held. Environmental Specialist and Social Specialist presented SEP and ESMF documents and explained the expected environmental and social impacts of the project.

For the subproject, on 31.10.2022, face-to-face introductory meetings were held between officials from 2U1K and Enacta Environmental and Social departments and officials from the Ministry of Health and Torlak Institute. The meeting before noon was between the Ministry of Health, 2U1K, Enacta, while the second meeting took place in the afternoon at the Torlak Institute with the participation of the Institute officials. The purpose of the meetings was to introduce the Scoping, ESIA and SEP documents to be prepared by 2U1K and this business process and to request technical information from the authorities that they will need in this process.

The second meeting was held at the Sub-project site in February 2023. In order to conduct due diligence, preliminary information about the location of the Institute and the structure and capacity of the Sub-project building to be constructed was obtained and the Sub-project site was observed.

9.3.2 Follow-up Stakeholder Engagement Activities

A public participation meeting (PPM) was organised after the Scoping Report was finalised. The meeting was originally scheduled to be face-to-face on 5 May 2023, but due to unusual circumstances in Serbia (the attack on Vladislav Ribnikar primary school in Belgrade and the armed attack in Dubona village) it was held online. Below is the list of participants of the meeting held on 22 May 2023:

- Representative of BIRODI (Bureau of Social Research);
- USPON, the centre for education, inclusion and social development:
- ALIMS representatives (Serbian Agency for Medicines and Medical Devices);
- IJZS Batut (Institute of Public Health of Serbia, Dr Milan Jovanović Batut).

The meeting chronology is given below:

- Welcome speech to all participants and parties
- A brief introduction to the Sub-project and the process
- Torlak presentation with brief information about the history, activities, capacities and future of the laboratory
- Main PPM presentation
- Call for additional information about the Sub-project and questions from participants
- No questions were asked by the participants
- Closing of the meeting

In addition, some of the participants did not have any information about the laboratory during the fieldwork process. The Sub-project brochure was presented to the participants and a brief explanation was given during the interviews and FGDs to receive their views, concerns and questions.

9.3.3 ESIA Disclosure

Following the completion of the ESIA document, ESIA, ESMP, SEP and NTS were published on the website of the Serbian Ministry of Health. In addition, ESIA disclosure meeting (2nd PPM) was held on 20.10.2023.

The meeting took place face-to-face and online at Savski Venac Health Center. A total of 30 people participated in the meeting. The people who were personally present in the meeting room are listed below[33]:

[33] There were 6 people who participated in the meeting online.

MEETING PARTICIPANT LIST

Date	: 20.10.2023
Place	: DZ SAVSKI VENAC, BEOGRAD/BELGRADE

Participants:

Name and Surname	Residence / Institution / Company	~~Signature~~ E-mail
[redacted]	2U1K	taskin.onurali@2u1k.com.tr
[redacted]	2U1K	ahmet_carhan@hotmail.com
[redacted]	ENACTA	d.kovacevic@enacta.rs
[redacted]	2U1K	ozenirler.gural@2u1k.com.tr
[redacted]	Institut „Torlak"	jprohic@torlak.rs
[redacted]	Institut Torlak	kilic@torlak.rs
[redacted]	ИНСТИТУТ ТОРЛАК	mknezevic@torlak.rs
[redacted]	HORSK	ivana.bogdanovic@zdravlje.gov.rs
[redacted]	HORSK	tamara.novakovic@zdravlje.gov.rs
[redacted]	HORSK	biljana.trivic@zdravlje.gov.rs
[redacted]	HORSK	ZANACVETKOVIC@ZDRAVLJE.GOV.RS
[redacted]	MINISTRY OF HEALTH ~~FBT~~ SECRP	ana.milicic@zdravlje.gov.rs
[redacted]	MoH	OLIVERA_JOVANOVIC@zdravlje.gov.rs
[redacted]	КОНСУЛТАНТ CБ	ZORICAJJ@GMAIL.COM
[redacted]	SECRP	svetlana.micic@zdravlje.gov.rs

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Revizyon Tarihi
Revision Date :02.01.2020

Revizyon Numarası
Revision Number :03

2U1K Mühendislik ve Danışmanlık A.Ş.
Tepe Prime İş ve Yaşam Merkezi
Mustafa Kemal Mahallesi Dumlupınar Bulvarı
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☎: (312) 287-2507
☎: (312) 287-2508
🖷: (312) 287-2509

2U1K Mühendislik ve Danışmanlık A.Ş.

MEETING PARTICIPANT LIST

Date :	20.10.2023
Place :	

Participants:

Name and Surname	Residence /Intstitution	Signature /E-mail
[illegible]	SECRP	[illegible]
[illegible]	SECRP	[illegible]
[illegible]	ICA	[illegible]
[illegible]	MZ	[illegible]
[illegible]	MZ	[illegible]
[illegible]	SECRP	[illegible]
[illegible]	SECRP	[illegible]
[illegible]	SECRP	[illegible]
[illegible]	SECONS/ENACTA	[illegible]

The meeting proceeded with a chronology similar to the first PPM. The Main PPM presentation was prepared and presented including potential impacts and mitigation measures. There were no questions, suggestions or requests from the participants at the end of the meeting.

9.3.4 Planned Stakeholder Engagement Activities

The project owner will notify the communities located in the impact area two days in advance of any possible temporary road closures caused by construction works. Similarly, the project owner will inform the affected local people of the future works on the notice platforms two days in advance. Information will be provided through notices posted in public areas such as bus stops, website announcements, and local media channels.

Likewise, businesses, schools and/or hospitals that are potentially affected by construction activities will be notified of the works two days in advance, and activities will be driven by the feedback received from stakeholders so that businesses and/or services are not disrupted.

The Project Owner will be responsible for engagement with stakeholders as an on-going process throughout the life of the Sub-project. All stakeholders will be able to share their views and grievances through a range of options such as the Sub-project owner's website, telephone number, letters and face-to-face meetings. There will also be grievance boxes at the institute entrances for local communities. All grievances will be logged by the designated focal point and recorded as described in the Grievance Mechanism section.

The grievance mechanism will be advertised and announced to affected stakeholders so that they are aware of the process, know they have the right to submit a grievance, and understand how the mechanism will work and how their grievance will be addressed.

9.4 Grievance Mechanism

9.4.1 Public Grievance Mechanism

Grievances should be reviewed as soon as possible to give priority to resolution. Regardless of general response and resolution times, some important grievances may require immediate action, such as an urgent safety issue or issues affecting public health.

There are 6 steps that supplement the Public Grievance Mechanism. This process is described by the steps provided below:

Table 9-2. Public Grievance Mechanism

Steps	Scope	Details
Step 1	**Identify grievances**	*Regardless of general response and resolution times, some important grievances may require immediate action, for example an urgent safety issue or issues regarding local people's livelihoods.*
Step 2	**Record grievances in the system**	*After determining the urgency level of the grievances, it will be ensured that the grievances is recorded.*
Step 3	**Determine specific actions for grievances and report them to relevant units / supervisors for resolution**	*Requests that require urgent support will be responded to and given support within the same day, and all outstanding grievances/requests will be approved within 2 days, and responded to within 10 days. The suitable resolution for the complaint will be accordingly communicated to the complainant within the 2 working days of completing the grievance investigation phase.*
Step 4	**Develop a response to grievances**	*A response will be developed by the delegated team within 10 days with input from relevant units and supervisors, excluding complaints involving emergencies. The response should identify a suitable resolution to the grievance, which could involve further information to clarify a situation, taking measures to mitigate problems.*
Step 5	**Communicate the response developed for grievances**	*The official appointed for the Project grievance handling will adopt and implement the most accurate approach to the communication of the relevant response. The response will also contain an explanation of how the person that raised the grievance can proceed with the grievance in case the outcome is not satisfactory.* *In case the grievance is raised anonymously, a summary of the grievance and resolution should be posted on the ministry's website and on notice boards located around the Project building as well as in the headman's offices in the settlements that are anticipated to be*

Steps	Scope	Details
		affected. In addition, the neighborhood headmen should be contacted regarding anonymous grievances and resolutions.
Step 6	**Close grievances**	*Based on the potential effects of the grievance, the complainant can be allowed time to respond and the complainant's response will be recorded, to help assess whether the grievance is closed or whether further action is required.* *Final approval will be provided after the relevant Project officials assess whether the grievance can be closed.* *Closed grievance files will be recorded in a systematic way, and will be submitted to the authorities during third party inspections when necessary.*

In case the grievance is raised anonymously, a summary of the grievance and resolution should be posted on the Ministry's website and on notice boards located around the Sub-project Administrative Building as well as in the settlements that are anticipated to be affected.

9.4.2 Worker Grievance Mechanism

The Workers Grievance Mechanism is defined as grievances from the Sub-project workers (including both direct and indirect workers). This mechanism should be structured to be an effective approach to early detection, assessment and resolution of complaints throughout the life of the Sub-project. It will be ensured that any employee who makes a complaint under the Grievance Mechanism is not subject to retaliation.

The scope of the Worker's Grievance Mechanism can be summarized as, but not limited to; occupational health and safety, conditions of employment, wages, problems with the local community or co-workers, hygiene problems in common areas, inadequate food and/or worker safety. The Grievance Mechanism will be communicated to the employees of all the Sub-project through written and verbal communication. Every employee should be briefed on the grievance mechanism at the time of employment and should have easy access to detailed information on how this mechanism works, for example in employee handbooks. Confidentiality is very important to some employees; therefore, workers can submit their grievances anonymously.

There are 5 steps that supplement the Worker Grievance Mechanism. This process is described by the steps provided below:

Table 9-3. Worker Grievance Mechanism

Step 1	**Identify grievances**	*The grievance will be raised through the Ministry official to be assigned. This could be in person, by phone, letter, grievance boxes or email.*
Step 2	**Record grievances in the system**	*Once the grievance is received and recorded, the Ministry official to be assigned based on the subject and issue will identify the department, management or personnel responsible for resolving the grievance.*
Step 3	**Follow up grievances**	*The Ministry official to be assigned and the relevant units should assess the facts relating to the grievance. This should be aimed at establishing and analyzing the cause of the grievance and identifying suitable mitigation measures. The analysis of the cause will involve assessing various aspects of the grievance, such as the background of the employee, frequency of the complaint occurrence, managerial practices, recent incidents in the workplace, etc.* *When needed, the Ministry official to be assigned may also undertake confidential discussions with the concerned parties to develop a more detailed understanding of the issue at hand. A site visit may be deemed necessary to gain first-hand understanding of the nature of the complaint and to verify the validity and severity of the grievance.* *After the details of the grievance are escalated to the relevant management unit, the said grievance will be discussed jointly by the employee and the regional and/or line manager.* *The investigation phase should be completed not later than 10 days of the grievance receipt.*
Step 4	**Resolve and close grievances**	*This is concluded based on the process developed in consultation between the assigned Ministry official and the related departments or management. The suitable remedy for the grievance should be communicated to the complainant within 10 days of the completion of grievance investigation phase.* *If the grievance is beyond the duty of the assigned Ministry official, the grievance should be escalated to the Project Management Unit to so that it can be resolved at managerial levels within 7 days of the escalation.*
Step 5	**Close Grievances**	*The assigned Ministry official, having received the necessary signatures, will close the grievance once the grievance is resolved and the result is communicated to the complainant. The current status of the grievance and the details regarding how the grievance is resolved will be recorded in the Grievance Log. The purpose of recording further information in the grievance log is to provide a baseline for any similar grievances that may arise in the future.* *If the grievance is raised anonymously, a summary of the grievance and resolution should be posted on the Ministry's website and on notice boards located in common areas of the facility, and should be announced through tool-box or weekly meetings.*

10 ENVIRONMENTAL AND SOCIAL MANAGEMENT

This chapter describes the arrangements for management of environmental, occupational and community health and safety, social and labour related *(altogether described as "environmental and social")* risks and impacts during the construction and operation phases of the Sub-project. A management system is proposed to be developed in order to manage these risks and also to meet applicable Serbian laws and regulations and European Union (EU) directives as well as the WBG Requirements.

Project Owner will establish an integrated management system *(referred to here as the Environmental and Social Management System - ESMS*) for the construction and operation phases of the Sub-project together with the main construction work contractor and the product and service provider of the Sub-project. The ESMS will enable management of the environmental and social risks and impacts by: (i) implementing, monitoring and reviewing identified mitigation measures, (ii) providing continuous control of the processes and (iii) improving environmental and social performance.

The ESMS will be developed and implemented separately for the construction and operation phases. Decommissioning activities will be covered by specific management plans to be developed during the Operational Phase. The ESMS will be prepared in line with the following international good practice and guidelines:

- International Organization for Standardization (ISO) 14001:2004 - Environmental Management System;
- ISO 45001: 2018[34] - Occupational Health and Safety Management System;
- World Bank's ESF - ESS1: Assessment and Management of Environmental and Social Risks and Impacts;
- International Finance Corporation (IFC) Performance Standard (PS) 1 - Assessment and Management of Environmental and Social Risks and Impacts;
- Equator Principles IV.

The following issues/documents will be taken into account during the establishment of the ESMS:

- Relevant Serbian laws and regulations;
- EU directives;
- WB ESF (ESSs);
- Equator Principles IV;

[34] ISO 45001 builds on the success of earlier international standards in this area such as OHSAS 18001, the International Labour Organization's ILO-OSH Guidelines, various national standards and the ILO's international labour standards and conventions.

- IFC PSs;
- World Bank Group (WBG) Environmental, Health and Safety Guidelines (EHS);
- Environmental and Social Management Plan (ESMP) prepared within the scope of the Environmental and Social Impact Assessment (ESIA) study.

The ESMS will integrate planning, implementation, control and review of the processes in relation to environmental and social impacts. The scope of the ESMS will be clearly defined in an *"ESMS Manual"* to be developed. This chapter has been prepared to identify and describe the outline structure of the ESMS and the relevant documentation. The ESMS will cover the following issues:

- **10.1:** Environmental, Health and Safety and Social (EHSS) Policy;
- **10.2:** Planning of the ESMS;
- **10.3:** Implementation of the ESMS;
- **10.4:** Control of the ESMS (including monitoring and audit);
- **10.5:** Stakeholder Engagement;
- **10.6:** Grievance Management.

As described in Chapter 2 Project Description, a diagnostic laboratory building with Biosafety Level 3 (BSL-3) will be constructed within the existing Torlak Institute of Virology, Vaccines and Sera in Belgrade, Serbia.

10.1 Environmental, Health and Safety and Social Policy

The senior management of The Project Owner will officially define a written "*EHSS Policy"*. The Policy will be relevant and compatible with the activities and environmental and social issues of the Sub-project in order to provide a framework for the determination and review of environmental and social targets and objectives. In addition, a Sub-project specific "Human Resources (*HR) Policy"* will be developed to set values and principles including active and competent participation of all employees in management and decision-making processes, and equal employment opportunity to all employees, as well as other issues defined by the WB ESS2.

A Common EHSS Policy and HR Policy will be developed by the Project Owner for construction, operation and decommissioning phases of the Sub-project. The EHSS and HR policies will apply to the Project Owner, contractors and all (sub)contractors engaged in the Sub-project. The Project Owner will ensure that the EHSS Policy and HR Policy are applied by all the Sub-project-related parties through agreements made between these parties.

The EHSS and HR policies will encompass the following:

- Compliance with environmental protection requirements and EHS legislative requirements;
- Occupational health and safety and human resources management requirements;
- Lender's requirements;
- Commitment to engagement with affected communities and other stakeholders;
- Commitment to continuous development and improvement of service quality.

Both policies will be disclosed to the public on the Sub-project website.

10.2 ESMS Planning

10.2.1 Environmental Social Management Plan (ESMP)

The ESIA process has identified key environmental and social impacts and risks associated with the Sub-project and requiring implementation of mitigation and management measures.

The purpose of this ESMP is to establish how the mitigation commitments made through the ESIA process will be implemented, monitored and managed. The content of the ESMP is essential to bridge the findings of the ESIA with implementation of the mitigation measures and to provide an early framework of management and monitoring that will ensure the implementation of these ESIA commitments.

The ESMP also provides information and instructions on how environmental and social commitments of the Sub-project will be managed from design, pre-construction through the construction and operation phases. The ESMP is a living document which:

- Incorporates the environmental and social mitigation measures identified as a result of the ESIA process into a comprehensive framework to facilitate and ensure appropriate management throughout the Sub-project life cycle;
- Provides a framework to incorporate commitments into the Sub-project plans and procedures for construction and operation activities;
- Presents the division of responsibilities for achieving the ESMP requirements including the provision of training;
- Provides a framework for the implementation of specific management plans that will meet the requirements of the national legislation, as well as the requirements of the WB ESSs;
- Provides the monitoring/verification and reporting program (including corrective actions).

This ESMP is applicable to the following stages of the Sub-project's lifecycle:

- Design;
- Construction; and
- Operation.

This ESMP represents a commitment by the Project Owner to environmental and social sustainability, and this commitment will also apply to the Sub-project (sub)contractors. Relevant commitments are also made with regard to the Sub-project supply chain.

10.2.2 Environmental, Social Management System (ESMS)

The identification of the EHSS aspects, significant risks and impacts of the Sub-project is considered to be the principal stage of the planning of an effective ESMS. Significant impacts of the Sub-project have been identified within the scope of the ESIA study and an ESMP has been developed for the Sub-project in order to manage these significant impacts as set out in Annex C (and as explained in more detail in Section 10.3.4).

10.2.3 Legal and Other Requirements

A detailed "*EHSS Legislation Review"* has been prepared as part of the ESIA study (presented in Appendix B) which can be used as a basis for the implementation of the Sub-project. This will provide an understanding of the legal (i.e. permits) requirements as much as possible. The list will be the part of ESMS of the Sub-project and be updated in case of any amendments in the legislation/other requirements or any change in the Sub-project. Updates of this document will be reflected to the Sub-project especially by means of the Environmental and Social Aspects and Risk Assessment, and accordingly additional plans and procedures will be developed as needed.

10.2.4 Targets, Objectives and Programs

EHSS objectives and targets will be set for the Sub-project to comply with legal requirements and obligations for continuous improvement of the environmental and social quality targets and objectives of the Sub-project. Targets and objectives will cover issues such as efficient use of raw materials, auxiliary materials/matters, natural resources/energy consumption and reduction, improvement of awareness of employees and reduction of health and safety incidents. Targets and objectives will be specific, measurable and feasible and supported by the programs. Deadlines and responsible party for each program established to achieve desired results will be assigned. Environmental and social targets and programs will be documented and monitored.

10.3 Implementation of the ESMS

10.3.1 Overall Governance of the Sub-Project and Responsibilities

Project Owner is responsible for financing, construction, and operation of the Sub-project. Torlak Institute Management, in collaboration with contractors and suppliers, will establish, maintain and promote, as required, a Sub-project-specific organizational structure that defines roles, responsibilities and authority for the implementation of Environmental and Social Management Plan (ESMP) as provided as a model in Figure 10-1 Specific personnel with clear boundaries of responsibility and authority should be appointed, including management representatives. The Sub-project-specific organizational structure to be developed will include executives who will coordinate and manage the Sub-project, the Technical and Financial Experts who will be in charge of construction and operational phases of the Sub-project, and at least one Social Expert (responsible for communication), one Environmental Expert and one Occupational Health and Safety Expert. The social expert will be assisted by public relations staff within the Ministry. Core environmental and social responsibilities should be well defined and communicated to the relevant personnel and the rest of the Project Organization Unit. Additionally, personnel should have adequate knowledge, skills and experience to competently and efficiently take specific measures and actions required under ESMP. Torlak management will be responsible for risk management. Overall organization chart of the governance structure for Torlak Institute is given in Figure 10-2. Detailed responsibilities for the Head of Laboratory Diagnostics Division, Assistant Head of Serodiagnostics and Molecular Diagnostics Department, and Doctor of Medicine, Specialist in Microbiological Diagnostics in Serodiagnostics and Molecular Diagnostics Department are given in Appendix E.

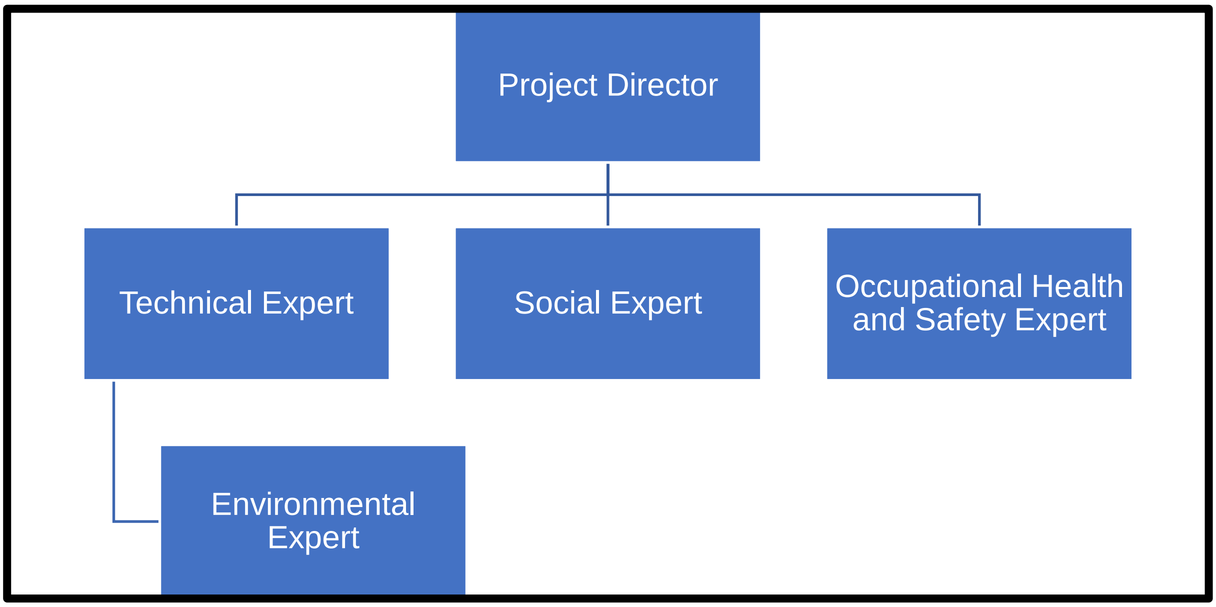

Figure 10-1. Project Management Unit Organizational Chart

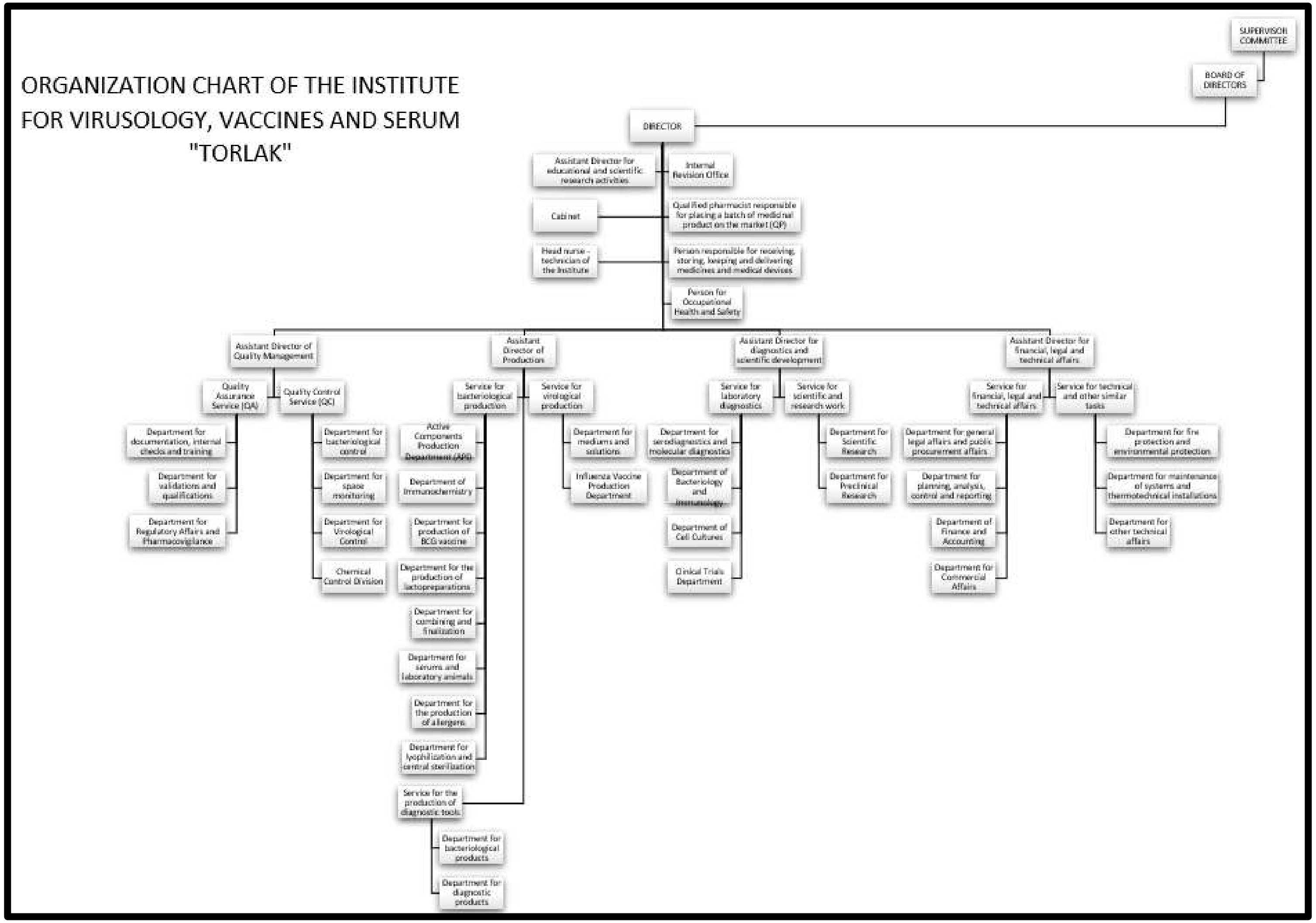

Figure 10-2. Institute of Torlak Organizational Chart

For the overall responsibility for the establishment, implementation, maintenance and effectiveness of ESMS, necessary human and financial resources and technical infrastructure will be provided by the Project Owner for all phases of the Sub-project.

Project Owner has the following responsibilities:

- Develop and implement the EHSS Policy and HR Policy;
- Manage the Sub-project in line with all relevant international and national environmental, health and safety legislation and commitments as detailed in the ESIA;
- Prepare policies, procedures and plans within the scope of national and international requirements and standards to which the Sub-project is subject, to ensure their implementation, and to inform all relevant parties;
- Establish and maintain Sub-project-specific organizational structure;
- Ensure that the Sub-project-specific organizational structure has appropriate mandate, capacity and Environmental and Social (E&S) assurance process;
- Employ Social Expert to maintain regular communication with affected communities and other stakeholders in line with the Sub-project SEP, and manage, review and monitor social commitments within the Environmental and Social Management Plan (ESMP), and Stakeholder Engagement Plan (SEP);
- Ensure SEP is developed and implemented and that grievance redress mechanism is in place both for workers and external stakeholders (communities, etc.);
- Employ technical (Environmental, Health and Safety) experts to manage, review and monitor the environmental, occupational health and safety programs to meet Sub-project requirements, including commitments within the ESMP;
- Establish a policy/procedure on internal reporting that includes incident reporting and investigation, system to record observations, non-conformance and actions that includes ESMP performance indicators;
- Review the (sub)contractors' site-specific implementation plans to ensure they meet the requirements of and support the implementation of the ESMP;
- Conduct periodic review of the ESMP effectiveness in line with the provisions of this plan;
- Employ Social/Human Resources Expert to manage, review and monitor the human resources programs to meet Sub-project requirements, including commitment within the ESMP;

10.3.2 Management of Construction and Operation Works

As it is stated above, Project Owner and (sub)contractors play important roles and hold responsibilities for execution of the Sub-project during its construction and operation stages. The Project Owner will employ experts in order to ensure effective collaboration between these parties and to meet environmental and social requirements of the Sub-project during construction and operation stages.

Responsible parties and terms of references are shown in Table 10-1.

Table 10-1. Sub-Project Organizational Management

Responsible Party	Terms of Reference
Project Owner	• MoH is the Project Owner and Institute of Torlak is beneficiary of this Project. • The Project Owner will be responsible for supervision of contractors and overall risk management for the Sub-project. In addition, it will be responsible for providing technical and data support during the preparation of technical and financial feasibility reports. The Project Owner will check both the technical and administrative progress of contract packages and the implementation of the points provided in ESMP and SEP on site together with Environmental, Social and Occupational Health and Safety Experts (at least one Social Expert, Environmental Expert and Occupational Health and Safety Expert) who will be involved in the Project Organizational Chart. • In addition to on-site inspections, the Project Owner will review the Environmental and Social Monitoring reports to be submitted by contractors on a monthly basis, and will submit these reports to MoH and WB quarterly.
Supervisory Consultant/Advisor	The Project Owner will appoint a Supervisory Consultant having a range of specialties to inspect the contractor's activities on a daily basis. The Supervisory Consultant will appoint the personnel given below: • The **Supervisory Contract Manager** will be responsible for inspecting the contractor to ensure that the recommendations and requirements given in the Sub-project disclosure package are fulfilled. They will be responsible for continuously monitoring processes and actions undertaken by the contractor and for identifying the measures to be taken by the contractor to deal with any areas of non-conformity. This includes periodic audits, inspections and/or on-site checks of Sub-project areas or worksites and/or records and reports compiled by contractors. • The **Environmental Expert** will be responsible for supervising the implementation of all environmental and biodiversity measures provided in the Sub-project disclosure package and for reporting to the Project Owner regularly. The environmental expert is expected to be a graduate of a University or similar institution in relevant disciplines (a master's degree would be an asset) and to be fluent in English and Serbian (both written and spoken). • The **Health and Safety Expert** should be certified for recognized international safety competency, for example the National General Certificate of Occupational Health and Safety or equivalent. Graduation from a university or a similar institution in the relevant discipline would be an asset. • The **Social/Human Resources Expert** will be responsible for supervising the implementation of all health, safety and social measures provided in the Sub-project disclosure package, as well as the implementation of SEP, and for reporting to the Project Owner regularly. The expert is expected to be a graduate of a university in relevant disciplines (a

Responsible Party	Terms of Reference
	master's degree would be an asset) and to be fluent in English and Serbian (both written and spoken). The expert is responsible for regularly reporting to the Project Owner.
Contractors	• The construction works under the contract packages included in the scope of the Environmental and Social Management Plan will be carried out by contractors. • Contractors will be responsible for observing the liabilities provided in the Environmental and Social Management Plan, LMP and SEP. Issues related to the implementation of the plans will be examined by the contractor during the preparation of the bid, and proposals will be submitted considering the ESMP prepared by the Contracting Authority. • The Environmental and Social Management Plan includes the monitoring tables that describe the possible negative effects of the operations to be carried out during the construction phase of the Sub-project and the measures to be taken to minimize these effects and the conditions for putting these measures into action. Additionally, the said tables include the entities and organizations (Sub-project stakeholders) responsible for the aforementioned items. • During the construction phase, the contractor will provide training to the personnel who will take part in the Sub-project, including the measures within the scope of ESMP, to raise awareness of environmental, occupational and worker health and safety, public health and safety and social issues. • As part of ESMP, implementation of the measures identified for the construction phase will be coordinated by Environmental, Social and Occupational Health and Safety Experts (at least one Social Expert, Environmental Expert and Occupational Health and Safety Expert) who will be involved in the Project Organizational Chart. The said experts will be responsible for taking actions required to eliminate/minimize environmental and social impacts in line with ESMP and for putting monitoring plans into practice. • In the event of unforeseen circumstances such as environmental, social and labor issues or accidents or loss of time, the contractor will immediately notify the Project Owner, who will in turn notify the ministry and the World Bank immediately. The immediate incident report on the root causes of the incident and corrective measures to be taken will be submitted to the ministry and the World Bank within 48 hours.
World Bank	• During the construction and operational phase, the officials from the World Bank will supervise the Project Owner's performance regarding compliance with the provisions set out in the ESMP managed by the Project Owner. • MoH, on the other hand, will inform the World Bank about environmental and social performance through monitoring reports every 3 months. In addition to this information, the World Bank will audit the Sub-project activities and progress through on-site inspections that will be conducted by the World Bank at least biannually.

10.3.3 Contractor Management

The Project Owner will ensure that contractors working on the Sub-project site meet the ESMS requirements by adopting and implementing an appropriate contractor management system. The contractor management shall include the following:

i) assessment of environmental and social risks associated with contracted works and services and incorporating relevant ESMS conditions;

ii) overseeing that contractors have the knowledge and skills to perform their tasks in accordance with contractual environmental and social conditions;

iii) monitoring contractor compliance with contractual environmental and social conditions;

iv) requiring contractors to have equivalent environmental and social arrangements with their subcontractors.

10.3.4 Communication

Project Owner will develop procedures to establish and maintain an effective and strong internal and external communication within the scope of the Sub-project.

A Stakeholder Engagement Plan (SEP) has been developed for the Sub-project during Scoping phase of the ESIA studies that covers engagement activities during all phases of the Sub-project and will be updated on regular basis (not less than annually). Communication methods/tools defined in the SEP will be considered in the establishment of this procedure and these methods/tools will be updated as necessary as the Sub-project proceeds.

The Sub-project will also establish grievance mechanism to ensure effective ongoing communication with stakeholders. Grievances, requests and suggestions coming from all parties (personnel, community and other stakeholders) will be received, recorded, evaluated and solved/responded.

10.3.5 Documentation and Document Control

A *"Document and Data Control Procedure"* will be established within the scope of construction and operation phases ESMS to control and approve any document before it is issued, to determine the writing format and numeration system to be used; to determine the approval system; to provide controlled distribution, review and update of documents; to provide relevant and updated documents; to abolish invalid documents and to manage external documents.

10.3.6 Operational Control

An *ESMP* has been developed for the Sub-project in order to manage the adverse impacts on the environment. The ESMP is prepared based on the international standards and best practices as well as national laws and regulations. The ESMP of the Sub-project is presented in Appendix C of this ESIA report. The ESMP includes description of the mitigation measures to avoid, minimize or compensate adverse impacts during the construction and operation phases of the Sub-project; responsible parties for the implementation of the mitigation measures; the timing of implementation; monitoring and audit requirements. The ESMP focuses on the avoidance of impacts, and where this is not possible, presents technically and financially feasible and cost-effective mitigation measures to minimize possible impacts to acceptable levels. The ESMP is based on the results of the ESIA study and is a framework document that specifies the necessary work to be conducted for the Sub-project such as preparation of detailed management plans for each topic (e.g. air quality control and monitoring, noise control and monitoring, traffic management). The ESMP will be kept up to date with any required additional mitigation throughout the Sub-project lifecycle and to reflect the requirements of new and/or amended laws and regulations.

The following plans are described in the ESMP. A number of plans and policies, including but not limited to the following, will be developed to achieve EHSS objectives for both construction and operation phases:

For All Phases of the Sub-Project (under the Responsibility of the Project Owner):

- HR Policy;
  - Code of Conduct;
- EHSS Policy;
- Stakeholder Engagement Plan
- Chemical and Hazardous Materials Management Plan
- Air Quality and Noise Management Plan
- Waste and Wastewater Management Plan (including Infection Control and Medical Waste Management Plan)
- Fire and Safety Plan
- Pollution Prevention Plan
- Construction site Traffic Management Plan
- Human Resources Management Plan
- Community Health and Safety Plan
- Occupational Health and Safety Plan
- Sampling and Analysis Quality Assurance/Quality Control (QA/QC) Plan
- Labour Management Procedure
- Construction Emergency Preparedness and Response Plan
- Operation Emergency Preparedness and Response Plan
- Biodiversity Management Plan
- Invasive Species Management Plan
- Biosafety Management Plan
- Biosecurity Management Plan
- Security Management Plan
- Communication Plan
- Chance Find Procedure

These plans will be supported by operational procedures and related instructions, as necessary, as part of the ESMS. The ESMS procedures and plans will be periodically (or when necessary) reviewed and revised. Additional procedures and plans will be developed as the Sub-project progresses, as necessary and included in the ESMS.

10.3.7 Environmental and Social Emergency Preparedness and Response

An *"Emergency Preparedness and Response Plan"* will be developed for emergency situations that consist of incidents such as accidents, explosions, fires, gas leakages, hazardous chemical/biological and liquid waste spills, disease outbreaks and similar events that occur unexpectedly due to equipment/infrastructure failures, employee errors, natural disasters (flooding, landslides, earthquakes, storms), sabotage and similar, for the Sub-project in line with national regulations and international standards. Emergency situations are incidents that cause the activities to cease, terminate and also cause serious damage on environment, occupational health and safety and assets.

The following needs to be detailed in the procedure:

- Emergency Response Team and first aiders (Name, Title, Responsibilities and Key Features);
- Emergency Response Plan, Emergency Drills, Internal Trainings (The drill scenarios should be conducted for different emergency cases);
- Maintenance and Control of Emergency Response Equipment (Fire Emergency Equipment, Pollution Prevention Materials, First Aid Cabinet, Safety Data Sheets, Personal Protective Equipment, Warning and Guiding Signs etc.);
- Measures to be taken in case of Emergencies/Natural Disasters (Communication in case of Emergency, Disease Outbreaks, Liquid Chemicals/Hazardous Liquid Wastes Spills, Gas Leakage (O_2), and Explosion, Flash/Fire, Earthquakes).

10.4 ESMS Control

10.4.1 Monitoring, Measurement and Review

For effective environmental and social management, the ESMS should be continuously monitored and periodically reviewed. The Project Owner will monitor:

- The compliance of the ESMS with the environmental and social provisions of the legal and other requirements as well as the commitments given in the ESMP;
- Overall implementation of the ESMP and other plans and procedures;
- Improvements achieved as the Sub-project progresses.

Tools employed for this purpose will include periodic internal and external audits, regular site inspections and measurements, impact monitoring, regular audits of the overall implementation of the ESMP and site inspections. Monitoring and review will be undertaken in accordance with requirements of ESMS and relevant legislation. Realization of environmental targets and objectives, environmental and social performance, equipment calibration, emissions, energy, natural source consumption, noise, waste amounts, environmental and social complaints and similar issues will be monitored, measured and evaluated. Conformance with legal and other requirements will be periodically evaluated and recorded.

Internal audits will be conducted in line with an *"Internal Audit Process Procedure"* to be developed within the scope of the ESMS. The "*Legal and Other Requirements Follow-up List"* will be used to evaluate conformance with the legal and other requirements. Other relevant and required procedures for the monitoring and measurement processes will be established for the Sub-project as needed.

10.4.2 External Reporting

All external reporting will be managed by the Project Owner within their obligations to the government entities under the national legislation and to WBG.

10.4.3 Internal Reporting

Internal reporting with regards to the commitments within the ESMP will be managed jointly by Social, Environmental, Occupational Health and Safety Experts. The Sub-project will share, as appropriate, inspection and audit findings with their suggested measures regularly with the Project Owner and employees. To maintain an open communication between the employees and management on occupational health, safety, environmental and social issues the following tools will be used:

- Team Briefings;
- On-site work group meetings;
- Work Specific Instructions.

10.4.4 Non-conformities and Corrective, Preventive, and Improving Actions

Non-conformities detected during inspections carried out by the Project Owner, (sub)contractors are subject to a process adapted to the severity of the situation. The non-conformities will be defined as deviations from the requirements of the contract, the ESMP and supporting EHSS documentation. Non-conformities are divided into 4 categories as follows:

Level 1 non-conformity: Non-conformities that do not represent a serious immediate EHSS risks. The non-conformity is the subject of a report addressed to the Contractors and shall be resolved within 5 days. The Contractor addresses to the Project Owner a report explaining how the non-conformity has been corrected. Further to an inspection and a favorable evaluation of effectiveness of the corrective action, the Project Owner (experts) signs a close-out report for the non-conformity. In all cases where a non-conformity of level 1 is not resolved within one (1) month, the severity of the non-conformity is raised to level 2;

Level 2 non-conformity: apply to all non-conformities that represent a risk with major consequences to health and/or the environment, social or safety. The same procedure as for level 1 non-conformities is applied. Corrective action shall be taken by the Contractor within 3 days. The Contractor issues a report explaining corrective actions implemented. All level 2 non-conformities, which are not resolved within 1 month, are raised to level 3.

Level 3 non-conformity: apply to all non-conformities that have resulted in damage to health or the environment, or which represent a high safety hazard or high social risk. The highest levels of the Contractor's management and the Project Owner are informed immediately and the Contractor has 24 hours to address the issue. A level 3 non-conformity results in the staged reduction of interim payments until the non-conformity has been resolved. Following the resolution of the Level 3 non-conformity the reduction(s) will be included in the next Interim Payment Certificate for payment. No interest will be paid on any reductions or suspended payment amounts. If the situation requires, the Project Owner can order the suspension of work until the resolution of the non-conformity.

Notification of observation of minor non-conformity: The non-conformity results in a notification to the Contractor followed-up by a signed notification of the observation prepared by the Project Owner. The multiplication of notifications of observation, or absence of corrective actions by the Contractor can result in the severity of the non-conformity being raised to that of level 1.

10.4.5 Data Control

Any information and data relevant to the ESMS will be recorded in line with a *"Document and Data Control Procedure"* to be developed for the Sub-project, which will set out procedures and principles related to establishment, prevention, maintenance, and disposal of the data records.

10.4.6 Management Review

Management reviews will be conducted (at least once a year) to maintain effectiveness of the ESMS and to determine the modification requirements and improvement opportunities in line with a "*Management Review Procedure"*. Internal and external audit results, conformance of the Sub-project with legal and other requirements, external notifications including grievances, ESMS performance (e.g. achievement level to targets and objectives), corrective and preventive actions taken, decisions/actions coming from previous meetings, improvement recommendations will be subject of management reviews. Based on the results generated from the reviews, senior management will take the necessary and appropriate actions to ensure that the provisions of environmental and social policy are met, and procedures and plans are effectively updated.

10.5 Stakeholder Engagement

Stakeholder engagement has started during the ESIA study. Consultation activities will continue during the construction and operation phases of the Sub-project aiming to maintain constructive relationships with the local communities and other stakeholders. The following principal activities will be undertaken during the construction and operation phases of the Sub-project:

Construction Phase

- Sub-project information will be disclosed at the Sub-project website, media and in the Sub-project leaflets distributed which will be updated as deemed necessary;
- A noticeboard will be kept present at the entrance of the Sub-project site in order to share the Sub-project information with the local people and to provide the name of site manager or Social Expert where complaints can be submitted in person, not only in writing;
- Meetings, as deemed necessary, with national and local authorities will continue during construction phase related to permitting and other issues;
- The stakeholder list will be regularly updated and any new stakeholder identified will be included in the list;
- Any activities likely to cause particular disturbance (such as noisy activities etc.) to the nearby neighbourhoods will be announced. This information will also be provided on the Sub-project website;
- All comments and grievances will be managed in accordance with the Grievance Mechanism;
- The security staff at the construction site will be informed about the Grievance Mechanism and in case a local person wants to submit a comment or grievance, the security personnel will be able to convey this person to the responsible staff;
- In order to ensure maintenance of the grievance mechanism, there will be clear and visible information on the Sub-project website and phone numbers for people to submit their grievances. In addition, phone numbers and website information will be posted on the construction site signs.

Operation Phase

- The Sub-project website will be updated to include information on operation activities and any changes in environmental policy, plans and procedures that are followed;
- Ongoing meetings, as deemed necessary, will be conducted with the national and local communities to inform them of any changes in Sub-project activities and related to permitting;
- The stakeholder list will be regularly updated and any new stakeholder identified will be included in the list;
- All comments and grievances will be managed in accordance with the Grievance Mechanism;

- The security staff at the facility will be informed about the Grievance Mechanism and in case a local person wants to submit a comment or grievance, the security personnel will be able to convey this person to the responsible staff;
- In order to inform people widely about the grievance mechanism, there will be clear and visible information on the Sub-project website.

More detailed information on stakeholder engagement at each stage of the Sub-project will be provided in SEP to be updated on annual basis.

10.6 Grievance Management

A Workers' Grievance Mechanism (as part of Labour Management Plan) and Public Grievance Mechanism (as part of the SEP) will be established in order to ensure that all comments, suggestions and objections received from the Sub-project stakeholders, especially from nearby surrounding communities and facilities, are dealt with appropriately and in a timely manner. The Project Owner will be responsible for the overall management of grievances.

Local communities will be informed about the grievance mechanism during the consultation and disclosure activities. All grievances will be recorded, responded to and resolved within a defined timeframe. The grievance mechanism is currently at the planning stage. It is expected that comments and grievances will be sent to The Project Owner via mail, e-mail or fax during the construction and operation stages as well as through the Sub-project website and telephone numbers. The anticipated procedure to handle grievances during construction and operation phases is described below:

1. All verbal and written grievances submitted by the stakeholders will be considered. Verbal grievances will be recorded on grievance forms by the responsible person (i.e. Social Expert for the external grievances);
2. All grievances will be reflected in a grievance log(s) to ensure that each grievance is assigned an individual number and that consistent tracking and corrective actions are carried out. The grievance log will contain:
    - Date of submission of the grievance;
    - Reference number;
    - Contact details of the complainant (unless it is anonymous);
    - Content of the grievance;
    - Identification of parties responsible for the resolution;
    - Dates when the investigation was initiated and completed;
    - Findings of the investigation;
    - Proposed corrective action;
    - Status of implementation of corrective action;
    - Date of response sent to the complainant (unless it is anonymous);
    - Statement of satisfaction of the complainant;

- Date of closing out the grievance;
- Any outstanding actions for non-closed grievances.

3. The grievance will be formally acknowledged within a week after submission. If the grievance is not well understood or if additional information is required, the complainant will be contacted for clarification;
4. The grievance will first be evaluated by the responsible person (Social Expert, etc.) and then conveyed to the relevant staff and management, if necessary, to identify what actions need to be taken, and an appropriate response will be developed. The complaint action form will be filled in;
5. The complainant will be informed about the proposed corrective action in writing three weeks after the grievance is acknowledged and the date of response to the complainant will be recorded in the grievance log;
6. The complainant will be contacted through telephone or face-to-face meeting, if needed, to confirm that the proposed corrective action taken is satisfactory, and the complainant's response will be recorded in the grievance log;
7. The grievance will be closed out and the close-out date will be recorded, if the complainant is satisfied with the action taken. If not, further assessment is needed and re-evaluation of the grievance is required;
8. It is envisaged that the grievances will be resolved within one month after receipt. If this is not possible, the complainant will be informed about the progress on a regular basis;
9. Any grievances related to subcontractors' activities will be managed in line with the mechanism described here. Furthermore, an interface will be established between the individual grievance mechanisms of the various subcontractors in order to effectively collate all Sub-project-related grievances, including those from subcontractor employees.
10. The Ministry official who will manage the Grievance Mechanism will be knowledgeable about the guidelines prepared by the World Bank to prevent sexual exploitation, abuse and harassment cases for the projects financed under construction works. Grievances of gender-based violence, exploitation and harassment can result in a culture of silence due to negative reactions from the community. For the avoidance of this, it is highly important that the stakeholders raise the grievances involving these issues about the Project anonymously. In addition, the authorities handling the grievances will address such issues with in confidence and by an unbiased approach[35].

More detailed information on the grievance mechanism is to be provided in SEP.

[35] https://thedocs.worldbank.org/en/doc/741681582580194727-0290022020/original/ESFGoodPracticeNoteonGBVinMajorCivilWorksv2.pdf

APPENDIX A

Official Letter

APPENDIX A-I

EIA – Out of Scope

Република Србија
Град Београд
ГРАДСКА УПРАВА ГРАДА БЕОГРАДА
СЕКРЕТАРИЈАТ ЗА ЗАШТИТУ ЖИВОТНЕ СРЕДИНЕ
V-04 број: 501.4-80/22
02. 08. 2022. године
Београд
Карађорђева 71

Градска управа града Београда, Секретаријат за заштиту животне средине, на основу члана 101. Закона о општем управном поступку („Службени гласник РС", бр. 18/16 и 95/18 – аутентично тумачење), чл. 26. и 47. Одлуке о градској управи града Београда („Службени лист града Београда", бр. 126/16, 2/17, 36/17, 92/18, 103/18, 109/18, 119/18, 26/19, 60/19, 85/19, 101/19, 71/21, 94/21 и 111/21), а у вези са чланом 4. Закона о процени утицаја на животну средину („Службени гласник РС", бр. 135/04 и 36/09) и у складу са Уредбом о утврђивању Листе пројеката за које је обавезна процена утицаја и Листе пројеката за које се може захтевати процена утицаја на животну средину („Службени гласник РС", број 114/08), а поступајући по захтеву за одлучивање о потреби процене утицаја на животну средину пројекта изградње дијагностичко – истраживачког објекта са лабораторијом BSL-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак" у улици Војводе Степе 458, на катастарској парцели број 1554/2 КО Кумодраж, на подручју градске општине Вождовац у Београду, који је поднео Дарко Тодоровић из Београда, Паунова 67, по овлашћењу носиоца пројекта Министарства здравља Републике Србије, Немањина 22-26, доноси

РЕШЕЊЕ

I - ОБУСТАВЉА СЕ ПОСТУПАК одлучивања о потреби процене утицаја на животну средину пројекта изградње дијагностичко – истраживачког објекта са лабораторијом BSL-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак" у улици Војводе Степе 458, на катастарској парцели број 1554/2 КО Кумодраж, на подручју градске општине Вождовац у Београду (носиоца пројекта Министарства здравља Републике Србије, Немањина 22-26), **јер нема услова да се даље води поступак.**

II – Носилац пројекта је у обавези да при планираној изградњи и редовном коришћењу предметног објекта примени мере и услове заштите животне средине које је утврдио Секретаријат за заштиту животне средине Градске управе града Београда, Решењем V-04 број 501.2-141/2022 од 05. 05. 2022. године, као и посебне услове које су утврдили други овлашћени органи и организације.

III – Налаже се носиоцу пројекта, да у случају пренамене пројекта из тачке I овог решења, поднесе захтев надлежном органу за одлучивање о потреби процене утицаја на животну средину.

Образложење

Секретаријату за заштиту животне средине Градске управе града Београда, као надлежном органу, дана 14. 07. 2022. године, достављен је захтев Дарка Тодоровића из Београда, Паунова 67, по овлашћењу носиоца пројекта Министарства здравља Републике Србије, Немањина 22-26, за одлучивање о потреби процене утицаја на животну средину пројекта изградње дијагностичко – истраживачког објекта са лабораторијом BSL-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак" у улици Војводе Степе

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458, на катастарској парцели број 1554/2 КО Кумодраж, на подручју градске општине Вождовац у Београду.

Уз поднети захтев, приложено су:

- Локацијски услови за изградњу дијагностичко – истраживачког објекта са лабораторијом bsl-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак“ у улици Војводе Степе 458, на катастарској парцели број 1554/2 КО Кумодраж у Београду (инт. бр. IX-20 бр. 350-290/2022 од 30 .05. 2022. године), Секретаријат за урбанизам и грађевинске послове Градске управе града Београда;
- Решење о утврђивању мера и услова заштите животне средине за потребе издавања Локацијских услова за изградњу дијагностичко – истраживачког објекта са лабораторијом bsl-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак“ у улици Војводе Степе 458, на катастарској парцели број 1554/2 КО Кумодраж у Београду (V-04 број 501.2-141/2022 од 05. 05. 2022. године), Секретаријат за заштиту животне средине Градске управе града Београда;
- Услови за израду техничке документације за изградњу објекта и услови за извођење радова у заштитном појасу гасовода у циљу издавања локацијских услова за изградњу дијагностичко – истраживачког објекта са лабораторијом bsl-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак“ у улици Војводе Степе 458, на катастарској парцели број 1554/2 КО Кумодраж у Београду (број 06-07-11/1525 од 05. 05. 2022. године), ЈП „Србијагас“;
- Услови за потребе издавања локацијских услова за изградњу дијагностичко – истраживачког објекта са лабораторијом bsl-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак“ у улици Војводе Степе 458, на катастарској парцели број 1554/2 КО Кумодраж у Београду (број 49/112 од 28. 04. 2022. године), ЈКП „Зеленило – Београд“;
- Услови за пројектовање и прикључење, а за потребе издавања Локацијских услова за изградњу дијагностичко – истраживачког објекта са лабораторијом bsl-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак“ у улици Војводе Степе 458, на катастарској парцели број 1554/2 КО Кумодраж у Београду (број 5470 од 26. 04. 2022. године), ЈКП „Градска чистоћа“;
- Услови за пројектовање и прикључење за изградњу дијагностичко – истраживачког објекта са лабораторијом bsl-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак“ у улици Војводе Степе 458, на катастарској парцели број 1554/2 КО Кумодраж у Београду (број 81110 SM, 49/11, 1135-1/22 и 1135-2/22 од 19. 04. 2022. године и 20. 05. 2022. године), „Електродистрибуција Србије“ д.о.о;
- Услови за пројектовање и прикључење, у процедури издавања локацијских услова за изградњу дијагностичко – истраживачког објекта са лабораторијом bsl-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак“ у улици Војводе Степе 458, на катастарској парцели број 1554/2 КО Кумодраж у Београду (IV-08 бр. 344.5-167/2022 од 24. 03. 2022. године), Секретаријат за саобраћај Градске управе града Београда;
- Услови канализације за израду локацијских услова за изградњу дијагностичко – истраживачког објекта са лабораторијом bsl-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак“ у улици Војводе Степе 458, на катастарској парцели број 1554/2 КО Кумодраж у Београду (број К-209/2022 од 21. 03. 2022. године), ЈКП „Београдски водовод и канализација“;
- Услови водовода за израду локацијских услова за изградњу дијагностичко – истраживачког објекта са лабораторијом bsl-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак“ у улици Војводе Степе 458, на катастарској парцели број 1554/2 КО Кумодраж у Београду (број В-286/2022 од 21. 03. 2022. године), ЈКП „Београдски водовод и канализација“;

- Услови у погледу мера заштите од пожара и експлозија за изградњу дијагностичко – истраживачког објекта са лабораторијом bsl-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак“ у улици Војводе Степе 458, на катастарској парцели број 1554/2 КО Кумодраж у Београду, према достављеном Идејном решењу (број 217-150/2022 од 11. 03. 2022. године), Министарство унутрашњих послова РС – Сектор за ванредне ситуације;
- Обавештење ЈКП „Београдске електране“, од 15. 03. 2022. године;
- Копија катастарског плана за катастарску парцелу број 1554/2 КО Кумодраж (број 952-04-231-4288/2022 од 07. 03. 2022. године), Републички геодетски завод - Служба за катастар непокретности Вождовац;
- Идејно решење ИДР - пројекат архитектуре са графичким приказима (број техничке документације 2021У012_А2_ИДР-А01, јун 2022. године, носилац израде „Машинопројект Копринг“ а.д. Београд);
- Овлашћење Министарства здравља Републике Србије дато Дарку Тодоровићу, бр. лк. 007662637 да може у име и за рачун Министарства здравља извршити припрему и предају захтева за одлучивање о потреби процене утицаја на животну средину планираног дијагностичко – истраживачког објекта са лабораторијом BSL-3, у оквиру Института за вирусологију, вакцине и серуме „Торлак“ у улици Војводе Степе 458, на катастарској парцели број 1554/2 КО Кумодраж у Београду (број: службено од 24. 06. 2022. године);
- графички прилози (планирана намена површина из Плана детаљне регулације подручја Јајинци – целина А2, општина Вождовац, приказ објекта са урбанистичким параметрима).

Увидом у поднети захтев и приложену документацију констатовано је да је предметним пројектом планирана изградња дијагностичко – истраживачког објекта са лабораторијом BSL-3, која би омогућила руковање патогенима који захтевају BSL-3 (ниво билошке безбедности) и у којој ће се изводити и креирати in house тестови, како у дијагностичке сврхе, тако и у научно – истраживачке. Предметни објекат, укупне БРГП 4792,02 m^2, спратности По+Пр+3 ће се састојати из две правоугаоне функционалне целине, леве, спратности По+Пр+3 и десне спратности Пр+3 које ће бити међусобно повезане. У предметном објекту је предвиђено дневно и вештачко осветљење, инсталације водовода и канализације, електроенергетске инсталације, телекомуникационе и сигналне инсталације, машинске инсталације и инсталације за заштиту од пожара. За третман потенцијално контаминираног инфективног отпада, предвиђена су два аутоклава. Ваздух који ће се испуштати у спољашњу средину ће двоструко пролазити кроз HEPA филтере, који ће се мењати према одређеној прописаној динамици за њихову употребу методом двоструке вреће, те ће се употребљени филтери у врећи деконтаминирати. У предметном објекту, неће се обављати никаква производња основних фармацеутских производа уз примену хемијских или биолошких поступака, као ни производња уопште.

Анализом расположивих података о предметној локацији, карактеристикама пројекта и могућим значајним утицајима предметног пројекта, а узимајући у обзир врсте пројеката и критеријуме прописане у Листи II Уредбе о утврђивању Листе пројеката за које је обавезна процена утицаја и Листе пројеката за које се може захтевати процена утицаја на животну средину, овај секретаријат је утврдио да предметни пројекат није наведен ни на Листи I пројеката за које је обавезна процена утицаја, као ни на Листи II пројеката за које се може захтевати процена утицаја на животну средину, односно одлучивати о потреби процене утицаја на животну средину.

Имајући у виду наведено, Секретаријат за заштиту животне средине Градске управе града Београда, на основу поднетог захтева носиоца пројекта и увида у достављену документацију, а применом одредаба члана 101. Закона о општем управном поступку, а у вези са чланом 4. Закона о процени утицаја на животну средину и у складу са Уредбом о утврђивању Листе пројеката за које је обавезна процена утицаја и Листе пројеката за које се може захтевати процена утицаја на животну средину – одлучио је као у диспозитиву овог решења.

Носилац пројекта Министарство здравља Републике Србије, сходно одредбама члана 18. Закона о републичким административним таксама („Службени гласник РС", број 43/03, 51/03, 53/04, 42/05, 61/05, 42/06, 47/07, 54/08, 05/09, 54/09, 35/10, 50/11, 70/11, 55/12, 93/12, 47/13, 65/13, 57/14, 45/15, 83/15, 112/15, 50/16, 61/17, 50/18, 95/18, 38/19, 86/19, 90/19, 98/20, 144/20 и 62/21), ослобођен је обавезе плаћања републичке административне таксе.

Упутство о правном средству: Против овог решења допуштена је жалба. Носилац пројекта може изјавити жалбу Министарству заштите животне средине у року од 15 дана од дана обавештавања о решењу. Жалба се подноси преко првостепеног органа.

Решење донето у Секретаријату за заштиту животне средине Градске управе града Београда, под V-04 број 501.4-80/22, дана 2. августа 2022. године.

ЗАМЕНИК НАЧЕЛНИКА
ГРАДСКЕ УПРАВЕ ГРАДА БЕОГРАДА
секретар Секретаријата
Ивана Вилотијевић

Достављено:
- Носиоцу пројекта;
- У Јавну књигу о спроведеним поступцима процене утицаја;
- Архиви.

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APPENDIX B

Environmental, Health, Safety and Social (EHSS) Legislation Review

Table 1. Summary of Environmental, Health and Safety and Labour Legislation in Serbia that are applicable to the Sub-Project

National Law			VEC
Name/Date/Number	**Section**	**Description**	
Constitution of Serbia (Official Gazette of RS, No. 98/06, 115/21, 16/22)	Article 74	Everyone has the right to a healthy environment and to timely and complete information about its condition. Everyone is obliged to preserve and improve the environment.	People's rights
Law on Public Health (Official Gazette of RS, No. 15/16)	Article 1	It governs the radius of effect of public health, competences, planning, implementation of activities related to the preservation and improvement of the population's health, as well as the method of financing. The goal is to achieve the public interest, by creating conditions for preserving and improving the health of the population through comprehensive activities of the society.	Introduction
	Article 8	Implementation of public health in the field of environment and population health (the state of the environment is monitored and analysed, i.e. analysis of water (surface and underground water, water used for drinking and recreation), air, soil, noise, vibrations, ionizing radiation, non-ionizing radiation, waste water and waste, ...).	Operation areas
	Article 9	Implementation of public health in the field of the working environment and the health of the working population. Determination of professional-medical positions in the field of occupational medicine, epidemiological surveillance, health promotion at work, monitoring and study of working conditions, study of professional risks (qualification and assessment) and their impact on the health of exposed employees, improvement of working conditions, health protection of employees.	Operation areas
Law on Health Care (Official Gazette of RS, No. 25/19)	Article 1	Regulates the health care system in the Republic of Serbia, its organization, social concern for the health of the population, general interest in health care, supervision over the implementation of this law.	Introduction
	Article 3	A person who is permanently settled or temporarily resides in the Republic of Serbia has the right to health care and the duty to protect and improve his and other citizens' health, as well as the conditions of the living and working environment.	Right to health care
Law on Medicines and Medical Devices (Official Gazette of RS, No. 30/10, 107/12, 113/17 - other law, 105/17 - other law)	Article 1	Governs the conditions and procedure for issuing a license to put a medicine on the market, i.e. the entry of medicines into the registers maintained by the Agency for Medicines and Medical Devices of Serbia, the production and circulation of drugs and medical devices and supervision in these areas, the work of the Agency for Medicines and Medical Devices of Serbia	Introduction
Law on the Protection of the Population from Infectious Diseases	Article 1	Regulates protection of the population from infectious diseases and special health issues, defining infectious diseases that threaten the health of the population of the	Introduction

National Law			VEC
Name/Date/Number	**Section**	**Description**	
(Official Gazette of RS, No. 15/16, 68/20, 136/20)		Republic of Serbia and whose prevention and suppression is of general interest for the Republic of Serbia, implementation of epidemiological surveillance and measures, the manner of their implementation and provision of means for their implementation, supervision over the execution of this law, as well as other issues of importance for the protection of the population from infectious diseases.	
Regulation on establishing the Crisis Management Plan (Official Gazette of RS, No. 90/15)	Article 1	Establishes the Crisis Management Plan, which is an integral part of this Regulation.	Introduction
	Article 2	The plan for managing crisis situations in particular contains the organization, measures and the way of implementing measures for the suppression of certain infectious diseases of animals, as well as the procedure for their control, in accordance with the Law on Veterinary Medicine.	Description
Public health strategy in the Republic of Serbia 2018–2026 (Official Gazette of RS, No. 61/18)	Summery	The Strategy's mission is to develop and implement a system of knowledge, skills and activities aimed at improving health, preventing and suppressing diseases, prolonging and improving the quality of life through organized measures of society.	Introduction
Regulation on measures for early detection, diagnosis, prevention of spread, suppression and eradication of African swine fever (Official Gazette of RS, No. 32/10)	Article 1	Determines measures for early detection, diagnosis, prevention of spread, suppression and eradication of the infectious disease of African swine fever, as well as the way of their implementation.	Introduction
Expert-methodological instructions for conducting fever surveillance West Nile (GZN) in the human population on the territory of the Republic of Serbia in the summer/autumn 2017 season	Summery	The basic public health goal of the surveillance system for neurotropic ARBO viruses is the prevention of the occurrence of diseases in the human population. Other Objectives of epidemiological surveillance in the human population are: - Monitoring trends in the frequency of illness and death from the neuroinvasive form West Nile fever in order to determine the burden of the disease on society; - Identification of risk factors for infection, development of neuroinvasive form diseases and determining the population at high risk; - Identification of seasonal and geographical distribution of cases of illness from neuroinvasive forms of West Nile fever	Introduction
Program for control, prevention, suppression and eradication of avian influenza in the Republic of Serbia, Ministry of Agriculture, Forestry and Water Management of RS, 2006	Summery	For prevention, detection, suppression and eradication avian influenza, the Program for the control, prevention, suppression and eradication of avian influenza in the Republic of Serbia was adopted. Depending on the degree of expansion and distribution of avian influenza, as well as the degree of threat to the territory of the Republic of Serbia, the Program is divided into five phases:	Introduction

National Law			VEC
Name/Date/Number	Section	Description	
		Favourable epizootiology situation: Phase 0 - Absence of avian influenza in the region (neighbouring countries, countries of the Balkans and Central Europe) Unfavourable epizootiology situation: Phase 1 - Immediate threat to the Republic of Serbia from avian influenza due to suspected or confirmed presence of avian influenza in the region Phase 2 - Existence of suspicion that there has been an outbreak of avian influenza in the Republic of Serbia Phase 3 - Confirmed presence of avian influenza in the Republic of Serbia Phase 4 - Preventing the spread, suppression and eradication of avian influenza in the Republic of Serbia	
Law on Environmental Protection (Official Gazette of RS, No. 135/04, 36/09, 36/09 - other law, 72/09 - other law, 43/11 - US, 14/16, 76/18, 95/18 - other law)	Article 10	In order to protect the natural values and environment, special laws and other regulations are governed such as protection of air, water, soil, forests, geological resources, waste management and so on.	Environment
	Article 11 Article 12 Article 13 Article 14 Article 15 Article 16 Article 17 Article 18	Natural values, which are natural resources, protected natural goods and public natural goods, management shall be carried out by planning sustainable utilization and preservation of their quality and versatility, in accordance with the conditions and measures of environmental protection set out in this law and in special laws. As a strategic document, the national strategy is conducted to protect environment, natural resources, cultural heritage and ecology. Moreover, it mentions rehabilitation and remediation of the degraded environment.	Environment/ Natural Resources/ Cultural Heritage/ Ecology
	Article 19	Development and spatial plans shall determine construction zones at certain locations depending on environmental capacity and the degree of load, as well as on the objectives of the construction within certain parts of those locations. In certain zones where protected distance or area has been established, it shall be allowed to carry out the activities in a way determined by special regulations in accordance with the nature of the load to the environment.	Land
	Article 20	Public green areas are inhabited places and they should be maintained in a sense of preservation and development of natural and man-made values. If a public green is destroyed, it must be compensated under relevant conditions.	Land/Public

National Law			VEC
Name/Date/Number	Section	Description	
	Article 22	Protection of land area and its sustainable use shall be achieved through the measures of systematic monitoring of land quality, monitoring of indicators for the assessment of risk of land degradation, as well as through the implementation of remediation programmes for removing consequences of land contamination and degradation, regardless if they occur naturally or are caused by human activities.	Land/Soil
	Article 23	Water may be used and loaded, and wastewaters discharged in water by applying adequate treatment, in a way and up to the level which shall not represent threat towards natural resources or quality and quantity of water renewal and which shall not reduce the possibility of their multi-purpose usage. Protection and use of water shall be realized within the integral water management through implementation of measures for preservation of surface and groundwaters and their reserves, quality and quantity, as well as through protection of riverbeds, waterfronts and courses in accordance with special law. Measures of water protection shall ensure prevention or restriction of introduction of hazardous, waste and other harmful substances into the water, monitoring and research of quality of surface and ground water, as well as quality of wastewaters and their treatment.	Water/ Pollution
	Article 24	Air protection shall be ensured through undertaking measures of systematic air quality monitoring, reducing pollution of air with pollutants below the prescribed limit values and by undertaking technical-technological and other necessary measures for emission reduction, by monitoring polluted air impact on the human health and environment. Measures of air protection shall ensure overall atmosphere preservation with all of its processes and climatic characteristics.	Air
	Article 25	For the purpose of protection and enhancement of forest ecosystems, forests shall be administered in a manner that shall ensure rational forest management, genetic fund preservation, and improvement of the structure and realization of forests priority functions.	Forests/ Ecology
	Article 26 Article 27 Article 28	Biosphere preservation shall comprise protection of organisms, their communities and habitats including preservation of natural processes and balance within the ecosystem, ensuring their sustainability. Biodiversity and biological resources shall be protected and used in a way that shall enable their survival, diversity, renewal and improvement in case of disturbance. In order to protect biodiversity and biological resources, the Ministry, other competent organizations shall control import and growth of plant and animal species of foreign origin. The trans boundary movement and trade in specimens of wild flora and fauna and their developed forms and parts may be performed provided that	Ecology

National Law			VEC
Name/Date/Number	**Section**	**Description**	
		import and/or export is not prohibited and/or that the quantity and number of specimens of wild flora and fauna subject to the trans boundary movement and trade do not endanger the survival of the species, and other conditions imposed by law.	
	Article 29	Management of hazardous materials should be carried out under the conditions and in the manner that ensures reduction of risk from their properties dangerous to the environment and human health in the process of production, storage, utilization and disposal.	Hazardous Materials
	Article 30	Waste management should be implemented according to the prescribed conditions and measures of waste treatment within the system of collecting, transportation, storage, preparation for reuse and recovery, treatment and disposal of waste, including supervision of these activities and care for the installations for waste management after their closure.	Waste
	Article 31	Usage of noise sources shall be allowed according to the prescribed conditions with the application of prescribed measures of protection by which noise emissions, i.e. the use of installations, devices, machines, means of transportation and apparatus causing noise are reduced. Protection against vibrations shall be enforced by undertaking measures by which threat to the environment from effects of mechanical, periodical and individual vibrations caused by human activity is prevented and eliminated.	Noise/ Vibration
	Article 33	During planning and construction, preventive measures should be taken like spatial planning. Furthermore, it is for ensuring preservation of built-up areas and establishing measures of environmental protection.	Environment
	Article 34	Spatial and urban plans shall ensure measures and conditions of environmental protection, and in particular; determining areas of endangered parts of the environment like polluted areas, natural areas; also, determining measures of integrated protection and planning of landscape, aimed at regulating long-term conception.	Land
	Article 35	Strategic Environmental Impact Assessment (SEIA) implies that strategies, plans, programmes and master plans in the field of spatial and urban planning or land utilization, agriculture, forestry, fishing, hunting, energy, industry, traffic, waste management, water management, telecommunications, tourism, infrastructure systems, protection of natural and culture goods, plant and animal life and their habitats etc.	Impact Assessment
	Article 36	The environmental impact assessment of the project should be carried out for the projects that are planned and implemented in an area, including changes in technology, reconstruction, expanding of capacities or termination of operations, which may result in significant environmental pollution or which constitute risk to human health in the fields of	Impact Assessment

National Law			VEC
Name/Date/Number	Section	Description	
		industry, mining, energy, traffic, tourism, agriculture, forestry, water management, waste management and utility activities.	
	Article 37	Integrated Pollution Prevention and Control indicates that for the operation of new and existent installations and activities that may have negative impact on human health and environment or material goods, an integrated license shall be required, which ensures the prevention and control of the environmental pollution. Types of activities and installations, conditions and procedures of issuing an integrated license, supervision and other issues relevant for integrated prevention and control of environmental pollution shall be governed by special law.	Pollution
	Article 38	The operator of the Seveso installation/establishment where activities are performed, in which one or more hazardous materials is present or may be present in the prescribed quantities, shall undertake all the necessary measures for preventing chemical accident and limiting impact of such accident on the life and health of humans and on the environment for the purpose of creating conditions for risk management, in accordance with this Law.	Chemical Accident Protection
	Article 39	In the Republic of Serbia, the requirements should be determined with respect to the environmental quality, i.e. limit values of the level of pollutants, noise, radiation and energy and limit values of their emissions into air, water and soil, including emission from mobile sources of pollution.	Limit Values
	Article 40 Article 41	Requirements related to environmental quality and requirements related to emissions. In order to prevent emission of pollutants or energy, concentrations or levels shouldn't exceed the prescribed limit values.	Environment Genera/ Limit Values
	Article 42	If any exceeding of limitations of pollution criteria, the public should be warned by the Ministry.	Warnings of the Public
	Article 43	The Government should define criteria for determining the state of endangered environment and for determining priorities for rehabilitation and remediation. The Ministry determines the state of endangered environment and priorities for rehabilitation and remediation for areas of local significance on the territory of autonomous province.	Endangered Environment
	Article 44	In the manner of Environmental Protection Management System, Serbian standards for the management and certification of the environmental management system should apply in the Republic of Serbia. Legal persons, organizations and other legal entities may certify their environmental management system in accordance with standard SRPS ISO 14001.	Environmental General

National Law			VEC
Name/Date/Number	Section	Description	
	Article 53	Ecological label should be established for products intended for general consumption, except foodstuffs, agricultural and other products obtained in accordance with regulations governing organic production, production of beverages, production of pharmaceutical products and medical equipment. Ecological label should also be established for products and services that are less polluting to the environment.	Ecology
	Article 54 Article 55	Ecological label is valid for 3 years. The right to use ecological label shall be withdrawn if the product or service ceases to fulfil one of the conditions for granting the label. Awards for contribution to the environmental protection might be preventing pollution and contribution in the area of nature protection.	Awarding and Withdrawal of Ecological Label
	Article 57	The main aim is that prohibiting of the importation of hazardous waste. License for import, export or transit of waste should be issued by the Ministry in accordance with law and other regulations.	Importation, Exportation and Transit of Waste/ License
	Article 58	In case of any chemical accident might occur, very detailed report should be prepared in advanced about what will be done; for example, limiting impact of such accident on life and health of humans and the environment, specified in such documents.	Chemical Accident
	Article 61 Article 62	Public should be warned about any chemical accident. Report on Safety and Seveso installations/establishments whose activities may cause chemical accident with trans boundary effects.	Health and Safety
	Article 63 Article 66	For the purpose of preventing further spreading of pollution caused by an accident, legal and natural person shall immediately undertake rehabilitation measures according to protection plans at its own cost. If the polluter-responsible is determined, sanction is applied.	Environment/ Rehabilitation
	Article 64	In the course of National Programme, it should provide integrated environmental protection like general environmental protection, implementations and long-term and short–term measures for prevention, mitigation and control of pollution.	Environment
	Article 67	Action and rehabilitation plans shall contain in particular: status, measures, impact assessment on human health in case of the endangered environment, proponents, manner, dynamics and funds for the implementation of plans.	Environment
	Article 72	The operator of the installation/establishment, which represents source of emissions and environmental pollution, shall, in accordance with law, through the responsible authority, authorized organization or independently, if it meets the conditions prescribed by law,	Pollution

National Law			VEC
Name/Date/Number	Section	Description	
		perform monitoring. The polluter shall prepare a plan for monitoring performance, keep good records on monitoring and submit reports, in accordance with this Law.	
	Article 73 Article 74	For the purpose of efficient identification, classification, processing, monitoring and record keeping of natural values and environmental management in the Republic of Serbia, an information system for environmental protection shall be established.	Data
	Article 75	National and local registers of sources of environmental pollution shall be maintained in accordance with this Law for the purpose of monitoring the qualitative and quantitative changes in the environment and undertaking measures for the protection of the environment. National register of sources of environmental pollution shall be maintained by the Environmental Protection Agency.	Pollution
	Article 76	The Government shall annually submit to the National Assembly a report on the state of the environment in the Republic of Serbia. The Environmental Protection Agency shall draft the report referred to in paragraph 1 of this Article on the basis of collected and available data and information no later than 31 May of the current year.	Environmental Report
	Article 80	After public authorities took necessary measures, they should share this information on electronic databases, which everyone can easily access.	Distribution of Environmental Information
	Article 81 Article 82	The public has the right to participate in the process of decision making on Strategic Environmental Impact Assessment of plans and programmes and other assessment or programmes. However, for sake of national security, the Government can limit public participation in decision-making.	Participation of the Public in Decision-Making
	Article 83	To finance environmental protection, the Republic of Serbia should provide for financing implementation of the environmental protection objectives. Environmental protection funds may also be provided from donations, loans, international aid resources, foreign investment resources intended for environmental protection, resources from instruments, programmes and funds of the EU, UN and international organizations.	Financing
	Article 85	The polluter should be obliged to pay a charge for environmental pollution. The criteria of the charge is determined according to type, quantity or characteristics of emissions from individual source/ produced or disposed waste and content of substances which are harmful to the environment in a raw material, semi-finished product and product.	Environmental Pollution Charge
	Article 86	The Payer shall be entitled to refund of the already paid charge for environmental pollution, i.e. to relief or reduction of the payable charge if it uses the funds for the implementation of measures for adjusting to the prescribed limit values or implements	Refund, Relief or Reduction of the Charge for

National Law			VEC
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		other measures contributing to reduction of environmental pollution below the prescribed level. The Government should determine criteria and conditions for refund, relief or reduction of payable charge	Environmental Pollution
	Article 89 Article 90	Financing environmental protection is implemented by applying the principles 'user pays', 'polluter pays' and 'liability'. The Green Fund of the Republic of Serbia shall be established as budgetary fund designed to track the allocation of assets earmarked for financing the preparation, implementation and development of programmes, projects and other activities related to the protection, sustainable use and improvement of environment.	Funds for Financing Environmental Protection
	Article 101	Taxation, customs and other relief or exemption from the payment may be determined, under the conditions and in a manner specified in special law, for legal and natural persons applying technologies, producing and placing on the market products that have more favourable effect than similar ones, i.e. using renewable energy sources (sun, wind, biogas, etc.), equipment and devices directly protecting the environment.	Economic Incentive Measures
	Article 102 Article 103	Legal and natural persons should be obliged to ensure environmental protection in the course of performing their activity particularly applying and implementing regulations on environmental protection, sustainable use of natural resources and energy and checking activities posing risk to human health and environment etc. The polluter causing environmental pollution shall be responsible for the occurred damage under the principle of objective responsibility. Legal and natural persons that through illegal or irregular acting have enabled or allowed environmental pollution shall also be responsible for environmental pollution.	Pollution and Liability
	Article 104 Article 105 Article 106	When polluter causes pollution, the polluter immediately must take necessary measures in the Accident Protection Plan and Rehabilitation Plan to reduce further risks and hazards. If the damage cannot be rehabilitated by appropriate measures, the polluter must pay punishment or payment. The polluter whose installation or activity represents high degree of threat to human health and the environment must be insured against liability in the case of damage made to third parties due to an accident.	Obligation and Liability
	Article 107	Any person that has suffered damage shall have the right to reimbursement.	Reimbursement of Damage
	Article 109	The Ministry shall supervise work of the Environmental Protection Agency, authorities responsible for environmental protection in the autonomous province and responsible	Supervision

National Law			VEC
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		authorities of the local self-government unit, as well as authorized legal persons, in the performance of delegated tasks.	
Law on Air Protection (Official Gazette of RS, No. 36/09, 10/13, 26/21- other law)	Article 1	This law regulates the management of air quality and determines the measures, way of organizing and controlling the implementation of protection and improvement of air quality as a natural value of general interest that enjoys special protection. The provisions of this law do not apply to pollution caused by radioactive substances, industrial accidents and natural disasters.	Introduction
	Article 56	A newly constructed or reconstructed stationary source of pollution for which there is no obligation to issue an integrated permit, i.e. to prepare an environmental impact assessment study, may start operating after obtaining a permit to operate. The work permit establishes that the conditions for air protection against pollution have been met, approves the operation of a stationary source of pollution and, based on the results of the measurements, determines the frequency of measurement of emissions and/or pollutant levels.	Operator obligation
	Article 58	The operator is obliged to: 1) submit data on the stationary source of pollution and any change (reconstruction) thereof to the competent authority; 2) ensure regular monitoring of the emission and keep records thereof; 3) provide continuous emission measurements when prescribed for specific pollutants and/or sources of pollution independently; 4) provide emission control measurements through an authorized legal entity, if emission measurements are performed independently; 5) provide prescribed periodic emission measurements, through an authorized legal entity, twice a year, if continuous emission measurements are not performed; 6) ensure monitoring of air quality by order of the competent inspection body; 7) keeps records on the type and quality of raw materials, fuel and waste in the incineration process; 8) keeps records of the operation of devices for preventing or reducing the emission of polluting substances, as well as measuring devices for measuring emissions. 9) implement measures to reduce pollutant emissions determined by the plan for his stationary sources of air pollution at his own expense.	Operator obligation
Regulation on limit values of emissions of pollutants into the air from stationary	Article 1	This Regulation prescribes: emission limit values of polluting substances into the air from stationary sources of pollution, except for combustion plants, content of the emission	

National Law			VEC
Name/Date/Number	**Section**	**Description**	
sources of pollution, except for combustion plants (Official Gazette of RS, No. 111/15, 83/21)		balance report and method of submitting data on emissions for the needs of the information system and deadlines for submitting data	
	Article 8 Article 9 Article 10 Article 11 Article 12	These articles are prescribing mass flows limit values, covering particulate matters, gas pollutants, organic substances, mercury and its compounds and parameters for waste gas as well.	Mass flows
	Annex 1 Annex 2	Emission limit values are prescribed for certain plant types (Annex 1), but also basic emission limit values for other cases (Annex 2).	Limit values
Law on Climate Change (Official Gazette of RS, No. 26/21)	Article 1	This law regulates a system for limiting gas emissions of GHG, adaptation programs to altered climatic conditions, monitoring and reporting on the low-carbon development strategy and its promotion, issuance of GHG emission licenses, and other issues of importance for the limitation of GHG emissions.	Introduction
	Article 2	This law shall apply to GHG emissions caused by human activity and sectors and systems exposed to the influences of climatic changes. The following GHGs are covered: Carbon dioxide (CO_2), Methane (CH_4), Nitrous oxide (N_2O), Hydrofluorocarbons (HFCs), Perfluorocarbons (PFCs), Sulfurhexafluoride (SF_6) and Nitrogen trifluoride (NF_3).	GHGs
Law on Environmental Impact Assessment (Official Gazette of RS, No. 135/04, 36/09)	Article 1	Regulates the impact assessment procedure for projects that may have significant impacts on the environment, the content of the study on environmental impact assessment, the participation of interested authorities and organizations and the public, cross-border notification for projects that may have significant impacts on the environment of another country, as well as supervision.	Introduction
	Article 3	The impact assessment is carried out for projects in the fields of industry, mining, energy, transport, tourism, agriculture, forestry, water management, waste management and communal activities, as well as for projects planned on protected natural assets and in the protected environment of immovable cultural assets. The subject of the impact assessment is projects that are planned and executed, technology changes, reconstructions, capacity expansion, cessation of work and removal of projects that may have a significant impact on the environment.	Subject of EIA
	Article 5	The holder of a project for which an impact assessment is mandatory and a project for which the need for an impact assessment has been established cannot proceed to the	Approval

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		realization, i.e. construction and execution of the project without the consent of the competent authority on the impact assessment study.	
	Article 8	The holder of a project for which an impact assessment may be required submits a request for a decision on the need for an impact assessment (hereinafter: a request on the need for an impact assessment) to the competent authority. The request for the need for an impact assessment is submitted on the prescribed form. The minister in charge of environmental protection shall specify the content of the request on the need for an impact assessment in more detail.	Screening Application
	Article 12	The holder of a project for which an impact assessment must be performed and for which the competent authority has determined the obligation of an impact assessment submits a request for determining the scope and content of the impact assessment study (hereinafter: request for determining the scope and content). The request for determining the scope and content is submitted on the prescribed form. The minister prescribes in more detail the content of the request for determining the scope and content of the impact assessment study.	Application for scope and content
	Article 16	The project holder submits a request for consent to the impact assessment study (hereinafter: request for consent) to the competent authority. The project holder is obliged to submit the request for consent no later than one year from the date of receipt of the final decision determining the scope and content of the impact assessment study.	Approval
	Article 17	The content of the impact assessment study is prescribed by the minister in more detail, but certain parts are always implied: data on the project holder; description of the location where the project is planned; project description; presentation of the main alternatives considered by the project holder; presentation of the state of the environment at the location and the immediate surroundings (micro and macro location); description of possible significant impacts of the project on the environment; environmental impact assessment in the event of an accident; a description of the measures envisaged in order to prevent, reduce and, where possible, eliminate any significant adverse impact on the environment.	EIA content
Decree on determining the List of projects for which an EIA is mandatory and the List of projects for which an EIA can be requested (Official Gazette of RS, No. 114/08)	Article 1 Article 2 Article 3 Article 4	These articles refer to List 1 and List 2. List 1 prescribes projects requiring development of Environmental Impact Assessment, while List 2 prescribes projects that may require an Environmental Impact Assessment.	EIA Lists

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Name/Date/Number	**Section**	**Description**	
Regulation on the contents of requests for the necessity of Impact Assessment and on the contents of requests for specification of scope and contents of the EIA (Official Gazette of RS, No. 69/05)	Article 1	Determines content of the request for deciding on the need for an impact assessment and the content of the request for determining the scope and content of the environmental impact assessment study.	Introduction
	Article 2	The contain of Application for the need of EIA is prescribed inside Annex 1 of this Regulation.	Application content
	Article 3	The contain of Application for determining of scope and content of the EIA is prescribed inside Annex 2 of this Regulation.	Application content
Regulation on the procedure of public inspection, presentation and public consultation about the EIA (Official Gazette of RS, No. 69/05)	Article 1	Prescribes procedure for public inspection, presentation and public discussion on the environmental impact assessment study.	Introduction
Law on Strategic Environmental Impact Assessment (Official Gazette of RS, No. 135/04, 88/10)	Article 9 Article 10 Article 11	Preparation stage means that the competent planning authority, in accordance with the previously obtained opinion of the competent environmental protection authority and other authorities and organizations concerned, shall make the decision on the strategic assessment elaboration.	Preparatory phase
	Article 12 Article 13 Article 14 Article 15 Article16 Article 17	The strategic assessment report is the document that describes, evaluates and assesses the potential significant impact on the environment, which could result from implementation of, plans and programmes. It shall also define measures for reduction of adverse effects on the environment.	Content

National Law			VEC
Name/Date/Number	**Section**	**Description**	
	Article 18 Article 19 Article 20 Article 21 Article 22 Article 23 Article 24	Decision making procedure includes participation of authorities and organizations as well as public participation. Authorities and organizations should submit their opinions; also, public should be included to the strategic assessment report to express public opinions. After that, the report on participation of authorities, organizations and the public should be compiled. Then, the strategic assessment report should be submitted to the competent environmental protection authority so as to evaluate and then, if the application for the strategic assessment report takes approval, grant will be supplied. The Ministry responsible for environmental protection shall conduct the exchange of information on trans boundary impact of plans and programmes on the environment. The strategic assessment report and results of participation of the authorities and organizations and public concerns and other states in cases of trans boundary impact shall make integral parts of the documentation of plans and programmes.	Decision-making process
Law on Nature Protection (Official Gazette of RS, No. 36/09, 88/10, 91/10 -Corr., 14/16, 95/18 - other law, 71/21)	Article 1	This Law governs protection and conservation of nature and biological, geological and landscape diversity as part of the environment.	Introduction
	Article 3	This Law protects human life, health or property under any threat.	Usage
	Article 4	Expressions such as activity in the nature, biological diversity, a gene pool, registered natural good, ecological corridor, ecosystems are identified.	Definitions
	Article 5	It mentions nature protection principles. For example, everyone should be aware of his/her duty and responsibilities to protect the nature. Moreover, it states applications of national laws.	Nature Protection Principles
	Article 7	Nature protection is carried by establishing and evaluating the state, phenomena and processes in the nature and the landscape; also implementing the measures for protection of nature and landscapes etc.	Nature Protection Measures
	Article 8	Planning, regulation and use of space, natural resources, protected areas and ecological network shall be implemented on the basis of spatial and urban development plans planning and design documentation, bases and programmes for the management and use of natural resources and goods in mining, energy, transport, water management, agriculture, forestry, hunting, fisheries, tourism and other activities affecting the nature, in compliance with measures and conditions of nature protection.	Environment
	Article 9	In the development of plans, bases, programmes, projects, works and activities referred to in Article 8 of this Law, nature protection conditions, issued by the competent institute for nature conservation, shall be obtained.	Conditions for Nature Protection

National Law			VEC
Name/Date/Number	**Section**	**Description**	
	Article 12	In order to reduce harmful consequences to nature, compensatory measures should be implemented in compliance with the decision issued by the Ministry at the Institute's proposal.	Mitigation of harmful effects
	Article 14	The protection of biological diversity shall be accomplished by carrying out measures for protection and improvement of species, their populations, natural habitats and ecosystems.	Biological Diversity
	Article 15 Article 16 Article 17	In order to conserve small biotopes and habitats, measures shall be undertaken which will include creation of protected areas, maintenance and management of habitats within protected areas, recovery of destroyed biotopes and creation of new biotopes. A habitat map is used thanks to basis of GIS. Conservation of habitat types is succeeded through implementation of measures and activities.	Ecology - Protection
	Article 18 Article 19	Conservation of biological diversity of forest ecosystems should be carried out with purpose of strengthening the generally beneficial functions of forests, in accordance with the law. Biological and biotechnical agents can be used in protected areas with purpose of conserving biological diversity.	Ecology - Protection
	Article 26	According to their natural and created characteristics, landscapes shall be divided into landscape types which express the diversity of natural and cultural heritage.	Landscape protection
	Article 27 Article 28 Article 29 Article 30 Article 31 Article 32 Article 33 Article 34 Article 35 Article 36 Article 37	Protected areas should be migratory species and places which have landscape diversity. Strict natural reserves are the area in which unchanged natural characteristics with representative natural ecosystems. Protected habitats include one or more types of natural habitats that are significant for the conservation of one or more populations of wild species and their communities. There are three protection regimes, which is 1st degree, 2nd degree and 3rd degree, for protection regimes. 1st degree is strict protection and usage of natural sources are prohibited. 2nd degree protection is active protection and can include management interventions in order to restore, revitalize and generally improve the protected area. 3rd degree protection regime – proactive protection, shall be implemented in the protected area or part thereof with partially changed and/or changed ecosystems, landscape and geo heritage objects of scientific and practical importance. Ecological areas should be determined and protected.	Protected natural areas

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Name/Date/Number	**Section**	**Description**	
	Article 38 Article 39 Article 40		
	Article 80	Public roads and other traffic routes, telecommunication and electric systems, waterworks and other buildings whose construction cuts off usual corridors for daily and seasonal migration of wild animals, causes habitat fragmentation or in some other way disturbs their normal life cycle, shall be constructed so as to reduce negative impacts with the application of special construction and technical solutions on the buildings and around them, during the periods of both construction and exploitation.	Measures for Protection of Migratory Species
Decree on Ecological Network (Official Gazette of RS, No. 102/10)	Article 1 Article 3 Article 4	This law aims to protect the natural plants and animals (i.e species). Protecting species can be imported or exported, provided that relevant licenses and certificates are gotten.	Introduction
	Annex 1 Annex 2	This Regulation regulates the ecological network as well as a detailed method of management and funding of the ecological network with a view to conservation of biological and landscape diversity. Annex 1 represents ecologically important areas in the republic of Serbia, whereas Annex 2 represents internationally important ecological corridors in the Republic of Serbia.	Lists
Regulation on the Criteria for Separation of Habitat Types, about Habitat Types, Sensitive, Vulnerable, Rare, and for the Protection of Priority Habitat Types and Protection Measures for Their Preservation (Official Gazette of RS, No. 35/10)	Article 1	This Regulation prescribes criteria for distinguishing habitat types, habitat types, sensitive, endangered, rare and priority habitat types for protection as well as protection measures for the preservation of habitat types.	Introduction
Law on Waters (Official Gazette of RS, No. 30/10, 93/12, 101/16, 95/18, 95/18 - other law)	Article 18	Water facilities for water use are facilities that are for the supply of drinking water and sanitary and hygienic needs, water intakes, drinking water treatment plants, main pipelines and reservoirs with their associated equipment, for irrigation, for the production of hydroelectric energy, for fish farming etc.	Water

National Law			VEC
Name/Date/Number	Section	Description	
	Article 19	Water facilities for collecting, draining and treating wastewater and water protection are: main collectors, waste water treatment plants, waste sludge treatment plants, wastewater treatment plants for solid waste landfills, discharges from plants to the receiver (recipient) and others associated devices as well as dams with reservoirs to improve water quality.	Wastewater
	Article 67 Article 70 Article 71 Article 72	General use of water means the use of water without prior treatment, and without the use of special devices like pumps or construction of water bodies for drinking, firefighting etc. Upon the expiration of the right to the exclusive use of water, it shall be obliged to remove this facility at its own expense within one year. If the right holder fails to remove the facility within the period referred to in paragraph 1 of this Article, its removal shall be performed by the public water management company, at the expense of the person referred to in paragraph 1 of this Article. If the facility referred to in paragraph 1 of this Article used for protection of water against harmful effects, protection of water quality or for conservation of ecosystems, it shall become public property. The use of water includes the use of surface and groundwater for the supply of drinking water, for sanitary and hygiene purposes, for industrial and other purposes, and for irrigation purpose etc. Qualified groundwater for drinking and public source is used for supplying water to the population for sanitary and hygiene needs, for the needs of industry requiring high quality water.	Water Use
	Article 73	The areas where the water bodies referred to in paragraph 1 of this Article are located must be protected from intentional or accidental pollution and other influences that may adversely affect the abundance of the spring and the health of the water.	Water Protection
	Article 74 Article 75	A public company or other legal entity carrying out water supply operations should take measures to ensure the quality of drinking water. Drinking water must meet health requirements. Bathing water must meet the requirements for safety and quality.	Health and Water Quality
	Article 77	For the purpose of sanitary protection zones, the areas used as sources for drinking water supply are designated by three sanitary protection zones, namely: a wider protection zone, a narrower protection zone and an immediate protection zone.	Sanitary Protection

National Law			VEC
Name/Date/Number	**Section**	**Description**	
	Article 92 Article 93 Article 94	Water protection is a set of measures to protect to surface and ground water quality and promote the protection in order to preserve the life and health of people and to reduce pollution by preventing further deterioration of water status etc. Moreover, the physicochemical parameters and limit values of pollutant emissions are determined. Water protection is implemented in accordance with the water protection plan against pollution.	Water protection
	Article 97	Determines prohibitions to protect water quality: 1) entering of waste water containing hazardous and polluting substances into surface waters; 1a) entering of all hazardous substances into groundwater; 1b) entering of other polluting substances into groundwater to the extent that they cause deterioration of groundwater; 2) discharge of waste water into stagnant water; 3) discharge from vessels or from the coast of polluting substances that directly or indirectly reach the waters; 4) discharge of excessively thermally polluted water; 4a) disposal of sludge, treated or untreated, from municipal wastewater treatment plants; 5) use of fertilizers or plant protection products in the coastal zone up to 5 m; 6) discharge into the public sewage system of waste water containing hazardous substances; 7) use of abandoned wells as septic tanks; 8) leaving materials that can pollute water in the large water trough of natural and artificial watercourses and lakes, as well as on other land; 9) washing of vehicles, machines, equipment and devices in surface water and on watery land.	Water Quality
	Article 98 Article 99	A legal entity, entrepreneur, or natural person who discharges or disposes of substances that can contaminate water , other than a natural person who uses drinking water for his or her own and sanitary purposes, is obliged before discharging into the public sewer system or recipient, completely dispose of wastewater in accordance with this Law. In order to ensure, a people referred to in paragraph 1, should provide funds and set deadlines for construction and operation of wastewater treatment plant. The sludge produced during wastewater treatment is treated used or disposed in a way that it doesn't endanger in environment and human health in accordance with this law.	Wastewater

National Law			VEC
Name/Date/Number	**Section**	**Description**	
		If wastewaters containing hazardous substances are generated in a particular plant or part of a plant, the person referred to in paragraph 1 should measure the quantities and examine the quality of the wastewater before connecting it to other wastewater streams.	
	Article 100	For collecting and treating wastewater is obliged to check correctness of facilities.	Control
	Article 101	In case of immediate danger of pollution, the legal entity, entrepreneur and natural person referred to in Article 98 must take measures to prevent, reduce and remediate water pollution. If mentioned persons, don't take measures, the measures must be taken by the public water management company.	Imminent water pollution prevention
	Article 103	The owner, i.e. user of oil pipelines and devices for receiving, is obliged to maintain them in such a way like collecting, and treating wastewater in order to prevent the leakage and leakage of oil into the water, in accordance with a special law.	Pollution Prevention
	Article 104	If pollution is detected in the water, it should be immediately reported to relevant authorities.	Report Pollution
	Article 105	Wastewater quality testing can be carried out by a legal entity authorized by the Ministry to perform these operations.	Wastewater Quality
	Article 106	In case of accidental water pollution, the administrative institution responsible for conducting state monitoring of water quality is obliged to inform the Ministry, the ministry competent for environmental affairs, the ministry competent for the environment, the ministry responsible for internal affairs, without delay.	Accident monitoring
	Article 110	Protected areas in the river basin district are zones for sanitary protection of springs, areas intended for the abstraction of water for human consumption etc.	Protection
	Article 111	In order to protect and improve the quality of surface waters, a classification of surface water bodies is made, depending on their ecological and chemical status. In order to protect and improve the quality of groundwater, a classification of groundwater bodies is carried out, depending on their quantitative and chemical status.	Classification
	Article 113	In order to ensure a unified water regime and to achieve water management and water acts are issued in accordance with the Strategy, water management plan and related technical documentation. Water acts are water conditions, water approval and water permit.	Water act

National Law			VEC
Name/Date/Number	**Section**	**Description**	
	Article 115	Water conditions are issued in the process of preparation of technical documentation for the construction of new structures or reconstruction of existing structures and for the upgrading of existing structures and performing other works that may permanently, occasionally or temporarily affect changes in the water regime, or endanger environmental objectives, as well as the preparation of planning documents for landscaping, management of fisheries and protected areas and forest management. Water conditions determine the technical and other requirements that must be fulfilled in the construction, upgrading and reconstruction of facilities, the preparation of planning documents and the execution of other works referred to in paragraph 1 of this Article, in order to comply with the provisions of this law and regulations adopted pursuant to it.	Issuance of water conditions
	Article 117	Water conditions are issued for the construction of new structures, reconstruction of existing structures, upgrading of existing structures, execution of other works and construction planning documents.	Issuance of water conditions
	Article 119	Water consent is obtained for buildings and works and planning documents for which the construction permit is issued by the ministry responsible for construction affairs in accordance with the law regulating planning and construction. The water consent establishes that the technical documentation for the facilities, works and planning documents has been completed in accordance with the issued water conditions.	Authorization
	Article 121	Water approval should be stopped being valid if, within two years from the date of receiving the water permit, construction, reconstruction or upgrading of the facility, execution of works, or preparation of planning documents does not start, and in the case of mining facilities, unless a request for a construction permit is submitted.	Termination of Water Permission
	Article 122	The water permit determines the manner, conditions and extent of water use, the manner, conditions and extent of wastewater discharge, storage and discharge of hazardous and other substances that may pollute the water, as well as the conditions for other works affecting the water regime. A water permit for the use of groundwater cannot be issued without a decision of the ministry responsible for geological research on the established and classified reserves of groundwater. The water permit is issued by the authority or public water utility responsible for issuing water conditions.	Water Permit
	Article 123	Issuing of a water permit without water conditions and water approval states that a water permit cannot be issued without obtaining water conditions and a water permit issued.	Issuing of a water permit

National Law			VEC
Name/Date/Number	**Section**	**Description**	
	Article 124	Water permit is not issued for discharge wastewater from households and legal entities that use the water used for drinking and sanitary purposes into the public sewer system, maintenance of the fairway etc.	Exemptions from the obligation to issue a water permit
	Article 126	The decision on determining the termination of the validity of a water permit should be issued by the authority and public water management company that is responsible for the water permit.	Termination of Water Permit
	Article 134	The owner or user of the real estate located in the sanitary protection zone is obliged to adjust the way of using the real estate to the conditions established for the use and maintenance of the sanitary protection zones.	Obligations
	Article 139	If a publicly owned water body is damaged by the actions of a legal or natural person, the cost of repairing the damage caused to the water body shall be paid by that person.	Compensation for damage
Regulation on the content and form of requests for the issuance of water acts, the content of opinions in the procedure for issuing water conditions and the content of reports in the procedure for issuing a water permit (Official Gazette of RS, No. 72/17, 44/18 - other law, 12/22)	Article 1	Prescribes content and form of requests for the issuance of water acts, the content of opinions issued by the republican organization responsible for hydrometeorological affairs, the administrative body responsible for the implementation of state monitoring of water quality and the public water company in the process of issuing water conditions, as well as the content of the report issued by the public water company in the process of issuing a water permit.	Introduction
Regulation on determining the cases in which it is necessary to obtain a water permit (Official Gazette of RS, No. 30/17)	Article 1	Prescribes cases in which it is necessary to obtain a water permit in the process of issuing water documents.	Introduction
Regulation on the method and conditions for measuring the quantity and testing the quality of wastewater and the content of the report on the measurements (Official Gazette of RS, No. 33/16)	Article 1	Prescribes method and conditions for measuring the quantity and testing the quality of wastewater and the content of the report on the performed measurements.	Introduction
	Article 4	An entrepreneur who discharges wastewater into a receiver and/or public sewer, monitors wastewater in accordance with Annex 1 - Technical conditions for monitoring, through a legal entity authorized to test wastewater or independently if it meets the conditions for this in accordance with the law, they regulate the waters. If in the production process in a certain facility or part of the facility, wastewater containing hazardous substances is generated, the entrepreneur monitors the internal flows of these wastewaters before they merge with other wastewater flows.	Monitoring

National Law			VEC
Name/Date/Number	**Section**	**Description**	
		The frequency of measuring the quantity and testing the quality of wastewater is carried out in accordance with the dynamics of the generation of wastewater and the applied methods for its purification or pre-treatment, in accordance with Annex 2 - Sampling of wastewater.	
	Article 7	The quantity is measured for municipal, technological and cooling wastewater, continuously or discontinuously. Continuous measurement is carried out in the case of constant generation and discharge of wastewater, using a device, a flow meter. Discontinuous measurement is performed in the case of seasonal/occasional activities when the generation and discharge of wastewater is intermittent.	Measurement of wastewater quantity
	Annex 2	Determines: place of wastewater sampling, composite sample, minimum number of samplings for periodic measurements.	Wastewater sampling
Law on protection against noise in the environment (Official Gazette of RS, No. 96/21)	Article 1	Regulates subjects of environmental protection against noise; measures and conditions of noise protection in the environment; measurement of noise in the environment; access to noise information; supervision and other issues of importance for environmental protection and human health. The provisions of this law refer to noise in the environment to which people are exposed, especially in built-up areas, public parks or other quiet zones in agglomerations, in quiet zones outside settlements, near schools, hospitals and other facilities, noise-sensitive zones, which originates from the operation of noise sources in the sense of this law.	Introduction
Decree on noise indicators, limit values, methods for evaluating noise indicators, disturbance and harmful effects of noise in the environment (Official Gazette of RS, No. 75/10)	Article 1	Regulates noise indicators in the environment, limit values, methods for evaluating noise indicators, disturbance and harmful effects of noise on human health.	Introduction
Law on Disaster Risk Reduction and Emergency Management (Official Gazette of RS, No. 87/18)	Article 1	Prescribes reduction of the risk of disasters, prevention and strengthening of resilience and readiness of individuals and communities to respond to the consequences of disasters, protection and rescue of people, material, cultural and other assets, rights and obligations of citizens, associations, legal entities, bodies of local self-government units, autonomous provinces and of the Republic of Serbia, management of emergency situations, functioning of civil protection, early warning, notification and warning, international cooperation, inspection supervision and other issues of importance for the organization and functioning of the disaster risk reduction and emergency management system.	Introduction

National Law			VEC
Name/Date/Number	**Section**	**Description**	
Law on Waste Management (Official Gazette of RS, No. 36/09, 88/10, 14/16 and 95/18-other law)	Article 1 Article 2	This law regulates about waste and relevant about waste such as waste management, waste planning and entities. This law aims to protect environment and human health; also, includes rehabilitation for unregulated waste disposal site.	Environment
	Article 3	The purpose is to minimize the risk by reducing pollution of water, air and soil, dangers to plants and animals, risk of accidents, explosions or fire, negative effects to landscape and natural resources of special value, level of noise and odours.	Waste Management
	Article 6	It defines principles. Waste shall be treated or disposed of as near as possible to its place of origin, and/or in the region in which it was generated, in order to avoid unwanted environmental impacts of its transportation. For the selection of the location of treatment plant to treat waste depends on type and volume of waste and manner of transportation and economic conditions etc. The waste management hierarchy is in order of prevention, preparing for re-use, recycling, other recovery operations (recovery for energy production, etc.) and disposal. According to polluter pays principle, a polluter accepts all costs of the consequences of their activities.	Principles
	Article 8	A waste catalogue which is given is a comprehensive list of non-hazardous and hazardous waste classified by its origin and composition.	Classification of Waste
	Article 35	It explains the regulations concerning the transport of hazardous cargo that shall apply to the transport of hazardous waste and/or mode of transportation, conditions that refer to hazardous waste packaging, and to the vehicle and employees involved in handling and transport of hazardous waste.	Waste Transportation
Regulation on medical waste management (Official Gazette of RS, No. 48/19)	Article 1	Regulates manner and procedure of medical waste management, as well as the content of the medical waste management plan from institutions where human health care is provided.	Introduction
	Article 3	The medical waste management plan contain is described through Article 3, and it covers topics such as identification of company, waste management, responsibilities, procedures, classification, collection, segregation, disposal, treatment, holding of records, measures, conditions, trainings, etc.	Medical Waste Management Plan
	Article 5	Collection and sorting of medical waste at the place of origin - medical waste is collected and sorted at the place of origin and packed in suitable packaging adapted to its properties, quantity, method of temporary storage, transport and treatment.	Collection and segregation
	Article 6	Packaging of medical waste - sorted medical waste is packed in accordance with the regulation governing the storage, packaging and marking of hazardous waste. Certain	Packaging of medical waste

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		types of medical waste are also packaged in the following way: communal (household) waste - in black bags; sharp objects - in yellow containers; pathoanatomical waste - in brown bags; infectious waste - in yellow bags or containers; waste contaminated with blood and body fluids - in double bags or yellow containers.	
	Article 7	On the packaging in which sorted medical waste is packed, stickers in written form about the danger of medical waste with a dimension of at least 50 mm x 75 mm are placed, which contain the following: symbol for marking waste; date of generation of waste; index number and name of the type of waste according to the Waste Catalogue; place of waste generation (name of medical waste producer); amount of waste (at the time of collection); the name of the person who fills in the stickers.	Labelling
	Article 8	The transport of medical waste within institutions where people's health care is provided is carried out with waste transport equipment that is used exclusively for that purpose, which is: easy to load and unload; easy to clean and maintain; without sharp edges, with smooth, impermeable and impermeable surfaces.	Transportation
	Article 9	Before transport, treatment or collection of all types of medical waste by the operator, the waste can be temporarily stored at the location of the waste producer, i.e. at the place of origin. That location consists of a fenced and separated space, room or facility intended only for that purpose. The place for temporary storage of infectious waste at the location of the waste producer, i.e. at the place of its origin, is disinfected at least once a week, and more often if necessary. Waste producers who produce less than 0.5 kg of medical waste on a daily basis, and do not have a separate and fenced space for temporary waste storage, are obliged to provide a secondary container.	Temporary storage
	Article 10	Medical waste, in a facility where waste storage and/or treatment is carried out, is stored in the manner prescribed by this Regulation, the regulation governing the storage, packaging and marking of hazardous waste and the law governing waste management.	Storage
	Article 11	Infectious medical waste, at the location of the waste producer, as well as in the facility where waste storage and/or treatment is carried out, is stored at the following temperatures: up to +8 °C for a maximum of seven days; from +8 °C to +15 °C for a maximum of five days; above +15 °C for a maximum of 72 hours. Producer of infectious medical waste that produces less than 0.5 kg of waste on a daily basis, stores said waste temporarily outside the work area within which it provides health care services and other activities in which medical waste is generated, within the same facility, for a maximum of 15 days from the day of its creation, at a temperature of up to +15 °C.	Storing conditions

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	Article 12	Pathoanatomical waste at the location of the waste producer, as well as in the facility where waste storage and/or treatment is carried out, is stored in refrigeration chambers at standard freezing temperatures.	Storing conditions
	Article 13	Transport of medical waste, sorted, packaged and marked in accordance with this Regulation, from the producer of medical waste who does not treat his own waste, to the operator of the facility for storage and/or treatment of waste, is carried out by vehicles intended for the transport of medical waste, in accordance with regulations governing waste management and regulations governing the transport of dangerous goods. Medical waste is handed over to a person who has a license to collect and transport medical waste, if the producer of medical waste does not have his own vehicle for transporting medical waste.	Transportation
	Article 14	Treatment of medical waste is carried out by the waste producer independently or through an operator, in accordance with the permit issued by the competent authority, according to the law regulating waste management and other regulations. Hazardous medical waste, for the treatment of which there are no technical facilities or facilities in the Republic of Serbia, is exported for treatment, in accordance with the regulations governing waste management and cross-border movement of waste.	Treatment
	Article 16	The operator who performs the treatment of infectious waste with the disinfection/sterilization process, has the obligation to test the waste after the treatment, in order to determine that the waste has become non-hazardous through the treatment. Control of the effectiveness of infectious waste treatment is carried out during each treatment with physico-chemical indicators. Microbiological control of treatment efficiency is performed with test organisms.	Treatment
	Article 17	Infectious waste and sharp objects are treated with disinfection/sterilization methods in autoclaves, i.e. sterilizers, grinding, i.e. crushing in crushers and other recognized methods that achieve removal of hazardous properties, volume reduction and unrecognizability of waste.	Treatment
	Article 18	Waste contaminated with blood and body fluids is treated by incineration in facilities intended for thermal treatment of municipal waste or in other facilities for thermal treatment of waste.	Treatment
	Article 19	The treatment of patho-anatomical waste is carried out in facilities intended for the thermal treatment of patho-anatomical waste, that is, by cremation or burial in cemeteries. Bags with blood, blood derivatives and body fluids are treated by incineration	Treatment

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		and co-incineration, and/or disinfection/sterilization. Blood and blood derivatives that are mixed with chemicals during diagnostic tests are classified as chemical waste.	
	Article 20	Chemical waste from facilities where health care is provided, which is left over from treatment and health care procedures, is treated by physico-chemical procedures or incineration in facilities that have a permit for the treatment of hazardous waste.	Treatment
	Annex	Marking and labelling of medical waste - sticker layout for cytotoxic waste, pharmaceutical waste, chemical waste, sharp objects, infectious waste, anatomical waste.	Labelling
Law on Occupational Health and Safety (Official Gazette of RS, No. 101/05, 91/15, 113/17 - other law)	Article 9	The employer is obliged to provide the employee with work at the workplace and in the working environment in which occupational H&S measures have been implemented. The employer is obliged to ensure that the work process is adapted to the physical and psychological capabilities of the employee, and that the working environment, means of work and means and equipment for personal protection at work are arranged, i.e. manufactured and provided.	Operator obligations
	Article 10	The employer is obliged to ensure that the implementation of safety and health measures at work does not cause financial obligations for the employee and employee representatives and does not affect their material and social position acquired at work and in connection with work.	Operator obligations
	Article 11	The employer is obliged, when organizing the work and the work process, to provide preventive measures to protect the life and health of employees, as well as to provide the necessary financial resources for their implementation.	Operator obligations
	Article 13	The employer is obliged to issue Study on risk assessment in written form for all workplaces in the working environment and to determine the method and measures for eliminating possible types of hazards and harm.	Operator obligations
	Article 14	The employer is obliged to determine the rights, obligations and responsibilities in the field of safety and health at work by means of a general act, that is, a collective agreement. If there are up to ten employees, this can be regulated by an employment contract.	Operator obligations
	Article 15	The employer is obliged to: 1) appoint a person for H&S at work by means of an act in written form; 2) appoint the employee to perform tasks at the workplace where occupational H&S measures have been implemented; 3) informs employees and their representatives about the introduction of new technologies and means of work, as well as about the dangers of injury and damage to	Operator obligations

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		health arising from their introduction, that is, in such cases, to issue appropriate instructions for safe work; 4) trains employees for H&S work; 5) provide employees with the use of means and equipment for personal protection at work; 6) ensure maintenance of means of work and means and equipment for personal protection at work in proper condition; 7) engages a legal entity with a license to conduct preventive and periodic inspections and checks of work equipment, as well as preventive and periodic tests of working environment conditions; 8) ensure, on the basis of the act on risk assessment and assessment of the occupational medicine service, prescribed medical examinations of employees in accordance with this law; 9) ensure the provision of first aid, as well as to train the appropriate number of employees for the provision of first aid, rescue and evacuation in case of danger; 10) stop any type of work that poses an immediate danger to the life or health of employees; 11) ensure fire protection measures, rescue and evacuation in accordance with a special law.	
	Article 16	The employer is obliged to determine the special health conditions that must be met by employees at the workplace with an increased risk, based on the evaluation of the occupational medicine service, by means of a risk assessment act.	Operator obligations
	Article 17	The employer is obliged to provide the employee with means and/or equipment for personal protection at work, in accordance with the Study on risk assessment.	Operator obligations
	Article 18	The employer is obliged to report, at least eight days before the start of work, to the competent labour inspection on: 1) the beginning of his work; 2) operation of a separate unit; 3) any change in the technological procedure, if these changes change the working conditions.	Special obligations
	Article 23	The employer is obliged to provide employees with means of work, i.e. means and equipment for personal protection at work, on which the prescribed measures for H&S at	PPE

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		work have been applied, and to ensure control of their use in accordance with the purpose.	
	Article 24	The employer can provide employees with work equipment and means and equipment for personal protection at work, only if they comply with the prescribed technical requirements, if their compliance is assessed according to the prescribed procedure, if they are labeled in accordance with the regulations and if they are followed by the prescribed compliance documents and other prescribed documentation.	PPE and equipment
	Article 24a	The employer may allow employees to use hazardous chemical substances and other chemical substances for which the obligation to prepare and deliver a safety data sheet is prescribed only if he has made the safety data sheet available to him along with the chemical substance, in accordance with the regulations governing chemicals, as well as if he has provided all measures resulting from the content of the safety data sheet.	SDSs
	Article 27	The employer is obliged to train the employee for safe and healthy work when establishing an employment relationship, i.e. other employment, transfer to other jobs, when introducing new technology or new tools for work or changing work equipment, as well as when changing the work process that may cause a change in measures for safe and healthy work.	HS Training
	Article 28	The training of employees for H&S work is carried out theoretically and practically by the employer, in accordance with the training program for H&S work brought by the employer. Periodical testing of the competence for H&S work of an employee working in a workplace with increased risk are carried out within one year from the date of the previous check, and in other workplaces no later than four years from the date of the previous check.	HS Training
	Article 29	An employer with whom, on the basis of a contract, agreement or on any other basis, the employees of another employer perform work, is obliged to train those employees for H&S work, in accordance with this law.	HS Training
	Article 30	When the technological work process requires additional training of the employee for safe and healthy work, the employer is obliged to inform the employee about performing the work process in a safe way, through notifications, instructions or instructions in written form. The employer is obliged to ensure that pregnant women and employees who are breastfeeding, employees under the age of 18, persons with disabilities and occupationally ill persons, in addition to being trained for safe and healthy work, are	HS Training

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		informed in writing of the results of the risk assessment at workplace and measures to eliminate risks in order to increase H&S at work.	
	Article 31	The employer is obliged as soon as possible to warn every person, who is in the working environment for any reason, of dangerous places or health hazards that occur in the technological process, i.e. of the safety measures he must apply, and to point to safe movement zones. The employer is obliged to ensure that access to the workplace in the working environment, where there is an immediate danger of injury or health damage (poisoning, suffocation, etc.), has access only to persons who are qualified for safe and healthy work, who have received instructions to stop working and/or immediately leave the workplace and go to a safe place, special instructions for working in such a place and which are provided with appropriate means and equipment for personal protection at work.	HS Training
	Article 37	The employer is obliged to organize tasks for H&S at work. H&S at work can be performed by a person who has passed a professional exam. The employer can designate one or more of its employees or hire a legal entity, i.e. a licensed entrepreneur, to carry out H&S at work tasks. The employer can carry out occupational H&S tasks by himself without taking a professional exam, if he has up to 20 employees.	HS Management
	Article 38	The employer is obliged to enable the person responsible for occupational safety and health to independently and independently perform tasks in accordance with this law and access all necessary data in the field of occupational safety and health. The employer is obliged to ensure the improvement of knowledge in the field of safety and health at work to the employee whom he appoints to perform these tasks.	HS Management
	Article 39	An employer who hires a legal entity or an entrepreneur to carry out occupational H&S tasks is obliged to familiarize them with the technological process, risks in the work process and measures to eliminate risks.	HS Management
	Article 40	H&S Officer performs tasks in accordance with this law, and in particular: 1) conducts the risk assessment procedure; 2) controls and gives advice to the employer in the planning, selection, use and maintenance of work equipment, hazardous materials and equipment for personal protection at work; 3) participates in equipping and arranging the workplace; 4) organizes preventive and periodic examinations of working environment conditions; 5) organizes preventive and periodic inspections and checks of work equipment;	HS Management

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		6) proposes measures to improve working conditions; 7) daily monitors and controls the implementation of H&S measures at the employer; 8) monitors the state of work-related injuries and occupational diseases, as well as work-related diseases; 9) prepares and implements the training of employees for safe and healthy work; 10) prepares instructions for safe work and controls their implementation; 11) forbids work at the workplace or the use of work equipment, in the event that it determines an immediate danger to the life or health of the employee; 12) cooperates and coordinates work with the occupational medicine service on all issues in the field of H&S at work; 13) keeps records in the field of H&S at work with the employer.	
	Article 41	The employer engages the occupational health service to perform the health protection of employees at work.	HS Management
	Article 43	The employer is obliged to provide the employee at the workplace with an increased risk before starting work with a previous medical examination, as well as a periodic medical examination during work. If, during the periodical medical examination, it is determined that the employee does not meet the special health conditions for performing tasks at the workplace with increased risk, the employer is obliged to transfer him to another workplace that corresponds to his health capabilities.	HS Management
	Article 49	The employer is obliged to keep and keep records of: 1) workplaces with increased risk; 2) employees assigned to workplaces with increased risk and medical examinations of employees assigned to those workplaces; 3) injuries at work, occupational diseases and illnesses related to work; 4) employees trained for safe and healthy work; 5) dangerous substances used during work; 6) performed tests of working environment conditions; 7) performed inspections and checks of work equipment; 8) reports of serious injuries and deaths; 9) issued means and equipment for personal protection at work;	Records

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		10) performed medical examinations of employees.	
	Article 54	In order to perform occupational health and safety tasks and the tasks of a responsible person, an appropriate professional exam is taken. The professional exam is taken before the appropriate committee formed by the minister responsible for work.	HS Management
Decree on health and safety at work on temporary or mobile construction sites (Official Gazette of RS, No. 14/09, 95/10, 98/18)	Article 15	The employer is obliged to: 1) provide the employee with work at the workplace and in a working environment where occupational safety and health measures have been applied, and especially when applying preventive measures, implement the measures for safe and healthy work determined in the Overview of measures for safe and healthy work on temporary and mobile construction sites (Annex 4); 2) when carrying out works on the construction site, he takes into account the instructions and instructions he receives from the project development coordinator and the work execution coordinator, as well as to cooperate with other employers and persons in the implementation of safety and health measures at work. All employers on the construction site are obliged to familiarize themselves with the Plan of preventive measures for safety and health at work (Annex 5), i.e. its amendments and additions, which they report to the investor, i.e. the investor's representative, in writing.	HS at construction sites
Regulation on preventive measures for safe and healthy work to prevent the occurrence and spread of infectious disease epidemics (Official Gazette of RS, No. 94/20)	Article 1	Prescribes preventive measures that the employer is obliged to implement in order to prevent the occurrence and spread of an infectious disease and to eliminate risks for the safe and healthy work of employees, as well as persons who find themselves in the work environment, when the competent authority declares an epidemic of an infectious disease.	Introduction
	Article 3	The employer is obliged to adopt, for all workplaces in the working environment, a plan for the implementation of measures to prevent the occurrence and spread of an infectious disease epidemic, which is an integral part of the act on risk assessment that is adopted in accordance with the law and regulations in the field of occupational safety and health.	Action Plan
	Article 4	The plan for the implementation of measures must contain: 1) preventive measures and activities to prevent the outbreak of an infectious disease epidemic; 2) responsibility for the implementation and control of the implementation of preventive measures and activities;	Action Plan

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		3) measures and activities for action in the event of an outbreak of an infectious disease.	
	Article 5	The employer is obliged to ensure the application of preventive measures at every workplace in the working environment: 1) before starting work, provide written instructions and instructions on measures and procedures to prevent the occurrence of an epidemic of an infectious disease, which contain information on the symptoms of an infectious disease; 2) in accordance with possibilities, if shift work is not organized, redistribute working hours by introducing a second or third shift with a smaller number of employees; 3) implements enhanced hygiene and disinfection of working and auxiliary premises, which includes regular disinfection of premises and frequent ventilation of the working space; 4) provide employees with sufficient amounts of soap, towels, running water and alcohol-based disinfectants for washing hands; 5) ensure regular cleaning of all surfaces that are frequently touched at the workplace, especially rooms and equipment such as toilets, door handles, fixed telephones, computer equipment and other work equipment; 6) regulate the way of keeping records on the disinfection of working and auxiliary premises, which it organizes and implements; 7) ensure the development of instructions for safe and healthy work with contractors, suppliers, distributors and external collaborators; 8) organize and ensure the regular removal of waste and garbage (garbage bins lined with plastic bags) from the premises so that they can be emptied without contact with the contents. The employer is obliged to ensure the application of preventive measures in the event of an infectious disease among his employees: 1) the space where the infected employee stayed is regularly physically and chemically disinfected and ventilated; 2) the procedures for entering and exiting the employer's premises are followed, prescribed means and equipment for personal protection at work and other protection measures are used during the work process; 3) the directions of movement of employees through work and auxiliary rooms are precisely defined;	Measures

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		4) strict control of the movement of employees from the organizational unit where the infected employee worked is organized; 5) contacts of employees from the organizational unit where the infected employee stayed with other employees are limited to the necessary with prescribed protection measures; 6) apply all other measures recommended by the epidemiologist.	
	Article 6	The employer is obliged to arrange the obligations and responsibilities related to the monitoring and control of the implementation of occupational safety and health measures in the implementation plan. The verification of the efficiency of the implementation of safety and health measures of the employees at work at the employer is carried out by the H&S Officer.	Obligation
	Article 7	H&S Officer, in cooperation with the employer, plans, implements and encourages the application of preventive measures.	Measures
	Article 8	Employee is obliged to: 1) implements all preventive measures of safety and health at work in order to preserve his health, as well as the health of other employees; 2) purposefully uses prescribed means and equipment for personal protection at work and handles them carefully, so as not to endanger his own safety and health as well as the safety and health of other persons; 3) takes extra care of his hygiene by regularly and properly washing his hands; 4) keeps personal clothing separate from means and equipment for personal protection at work and work clothes; 5) must inform the employer if he suspects symptoms of an infectious disease in himself, other employees or members of his family; 6) before starting work, inspect his workplace, including the tools he uses, as well as the tools and equipment for personal protection at work, and report any deficiencies to the employer or other authorized person; 7) before leaving the workplace, to leave the workplace and means of work in such a condition that they do not endanger other employees; 8) in accordance with his knowledge, immediately inform the employer about irregularities, harm, dangers or other phenomena that could threaten his safety and health or the safety and health of other employees at the workplace;	Obligations

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		9) cooperates with the employer and the person for safety and health at work, in order to implement additional necessary measures for safety and health at work.	
Regulation on records in the field of occupational health and safety (Official Gazette of RS, No. 62/07, 102/15)	Article 1	Prescribes way of keeping records in the field of safety and health at work, which the employer is obliged to keep and keep: 1) workplaces with increased risk; 2) employees assigned to workplaces with increased risk and medical examinations of employees assigned to those workplaces; 3) injuries at work, occupational diseases and illnesses related to work; 4) employees trained for safe and healthy work; 5) dangerous substances used during work; 6) performed tests of working environment conditions; 7) performed inspections and checks of work equipment; 8) reports of fatal, collective and serious injuries at work, injuries at work due to which the employee is unable to work for more than three consecutive working days, occupational diseases and dangerous occurrences that could threaten the safety and health of employees; 9) issued means and equipment for personal protection at work; 10) performed medical examinations of employees in accordance with regulations on safety and health at work.	Introduction
Regulation on preventive measures for safe and healthy work when using means and equipment for personal protection at work (Official Gazette of RS, No. 92/08, 101/18)	Article 1	Prescribes minimum requirements that the employer is obliged to fulfil in ensuring the application of preventive measures when using means and equipment for personal protection at work.	Introduction
Regulation on the provision of labels for health and/or safety at work (Official Gazette of RS, No. 95/10, 108/17)	Article 1	Prescribes minimum requirements that the employer is obliged to fulfil when providing signs for health and/or safety at work.	Introduction
	Article 5	The employer is obliged to, taking into account the risk assessment, provide and highlight signs for health and/or safety at work where the risk, i.e. dangers and harms could not be eliminated or reduced by the application of health and safety measures at work. The employer is obliged, in addition to the signs from Annex 5 of this Regulation, to place appropriate signs determined by regulations in the field of road, rail, river, sea or air traffic.	Obligations

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Name/Date/Number	**Section**	**Description**	
Regulation on the method and procedure of risk assessment at the workplace and in the working environment (Official Gazette of RS, No. 72/06, 84/06 - correction, 30/10, 102/15)	Article 3	Risk assessment is based on the systematic recording and assessment of all factors in the work process - possible types of hazards and harm in the workplace and in the working environment that can cause injury at work, damage to health or illness of the employee. Risk assessment looks at the organization of work, work processes, means of work, raw materials and materials used in technological and work processes, means and equipment for personal protection at work, as well as other elements that can cause a risk of injuries at work, damage employee's health or illness.	Scope of Risk Assessment
	Article 11	Based on the assessed risks at the workplace and in the working environment, the employer determines the way and measures for their prevention, elimination or reduction to the smallest possible extent. The employer takes care of the implementation of measures to eliminate, reduce or prevent risks directly or through a person appointed for health and safety at work or another person appointed by the Study on risk assessment.	Measures
	Article 12	Measures to prevent, eliminate or reduce risk are determined by the employer based on the assessed risk, established priority and respecting the principles of prevention, in accordance with regulations on health and safety at work, technical regulations, standards or generally recognized measures.	Measures
	Article 18	With the decision to initiate the risk assessment procedure, the employer designates one or more persons responsible for the implementation of the risk assessment procedure. A professional can be an employer, an employee of an employer or an employee of a legal entity or an entrepreneur with a license to perform health and safety at work, if he has passed the professional exam on practical ability to perform health and safety at work.	Responsibility
	Article 19	An expert draws up a plan for the implementation of the risk assessment procedure approved by the employer. If the employer engages a legal entity, that is, an entrepreneur to perform risk assessment activities, the engaged legal entity, that is, an entrepreneur, shall attach a photocopy of the license for the performance of occupational safety and health activities along with the plan for the implementation of the risk assessment procedure.	Implementing Risk Assessment
Regulation on preventive measures for safe and healthy work at the workplace (Official Gazette of RS, No. 21/09, 1/19)	Article 4	The employer is obliged to provide the employee with work at a workplace where the measures for healthy and safe work established in the Overview of measures for healthy and safe work at the workplace, which is an integral part of this regulation, have been implemented.	Obligations
	Article 5	The employer is obliged to provide:	Obligations

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		1) that the traffic areas intended for the movement of vehicles and people towards the exits for evacuation in case of danger, as well as the exits themselves, should always be free; 2) to carry out technical maintenance of the workplace and work equipment on a regular basis, and remove all observed defects that may affect safety and health at work immediately; 3) that the workplace and work equipment are regularly cleaned and maintained at a satisfactory level of hygiene; 4) to regularly maintain and check the correctness of equipment and devices intended for the prevention or elimination of danger and/or harm.	
	Article 4	Inspections and testing of work equipment are carried out by a legal entity with a license to carry out inspections and checks of work equipment, which has appropriate instruments and devices for carrying out inspections and checks, listed with technical characteristics in the accepted methodology.	Inspection and testing
	Article 5	An expert report on the performed inspection and testing of the work equipment is issued to the user of the work equipment, no later than within 30 days from the day of the performed inspection and check of the work equipment.	Report
	Article 7	Preventive inspections and testing of work equipment are performed before the start of use, i.e. before giving it to employees, after overhaul, reconstruction or breakdown, as well as before starting work at a new place of work if the stationary equipment has been moved from one place to another, after removing defects established by a legal entity with a license, after a fatal or serious injury at work to an employee while using work equipment, after a measure ordered by the labour inspector, as well as if there are any changes to the work equipment that affect the safe and healthy work of employees.	Deadlines
	Article 8	Periodic inspections and testing of work equipment are performed within the period established by technical regulations and standards or determined by the manufacturer's instructions, and no later than within 3 years from the date of the previous inspection and testing, except for periodic inspections and testing of temporary electrical installations with devices, equipment and accessories, which are performed within 6 months from the date of the preliminary inspection and testing and periodic inspections and testing of work equipment.	Deadlines
	Article 9	Preventive and periodic examinations of the conditions of the working environment check and determine whether occupational safety and health measures established by regulations in the field of occupational safety and health, technical regulations and	Workplace conditions

National Law			VEC
Name/Date/Number	**Section**	**Description**	
		standards have been applied at the workplace and in the working environment. Preventive and periodic tests are carried out according to the Plan and program for monitoring working environment conditions, which necessarily contain measuring points, parameters for monitoring and periodic tests.	
	Article 10	Inspections are performed by analysing all elements of the working environment conditions so that a unique assessment of the performed inspections is given. Inspections are, as a rule, carried out in conditions when all technological capacities are working (work equipment, installations for air conditioning, ventilation, etc.), which is specifically stated in the expert report.	Workplace conditions
	Article 16	Examination of the conditions of the working environment, except for the examination of biological hazards, is carried out by a legal entity with a license to perform the work of examination of the conditions of the working environment, which has the appropriate equipment for examination of the conditions of the working environment. Examination of the conditions of the working environment - biological hazards is carried out by a legal entity with a license to perform the work of testing the conditions of the working environment - biological hazards, which has the appropriate instruments, equipment, laboratories and devices for testing and analysing biological hazards.	Workplace conditions
	Article 17	An expert report on the performed examination of the conditions of the working environment is issued no later than 30 days from the day of the performed examination. The expert report is issued as a whole for all tests of working environment conditions, depending on the technological process. Exceptionally, a special expert report can be issued for testing biological hazards.	Reporting
	Article 20	Preventive tests of working environment conditions are carried out for a period of six months, from the beginning of the work, i.e. the technological process, the reconstruction of the building in which the work process is carried out (devices for heating, ventilation or air conditioning, etc.) or the replacement of technical capacities which working conditions change, whereby testing of working environment conditions must begin on the day the technological process begins and must be performed every three months, independently of testing planned by the Plan and program for monitoring working environment conditions.	Deadlines
	Article 21	Periodic examinations of working environment conditions are carried out at the workplace in the working environment in accordance with the Plan and program for monitoring working environment conditions no later than three years from the date of the previous examination, and for workplaces with increased risk no later than two years from the day of the previous examinations.	Deadlines

National Law			VEC
Name/Date/Number	**Section**	**Description**	
Regulation on general measures of protection at work against the dangerous effect of electric current in facilities intended for work, work rooms and at work sites (Official Gazette of RS, No. 21/89)	Article 1	Determines general measures of protection at work against the dangerous effect of electric current in facilities intended for work, work rooms and at work site, which are also applied when performing work on electrical installations, when using electrical devices and when using electrical installations with rated direct current voltages higher than 50 V and a frequency of 50 Hz, i.e. nominal DC voltages higher than 120 V without a non-alternating component.	Introduction
Regulation on preventive measures for safe and healthy work when exposed to vibrations (Official Gazette of RS, No. 93/11, 86/19)	Article 1	Prescribes minimum requirements that the employer is obliged to fulfil in ensuring the application of preventive measures in order to eliminate or reduce the risk of injuries or damage to the health of employees that occur or may occur when exposed to mechanical vibrations.	Introduction
Regulation on preventive measures for safe and healthy work during manual load transfer (Official Gazette of RS, No. 106/09)	Article 1	Prescribes minimum requirements that the employer is obliged to fulfil in ensuring the application of preventive measures during the manual transfer of loads where there is a particular risk of injury or disease of the spinal column.	Introduction
Regulation on preventive measures for healthy and safe work when exposed to carcinogens or mutagens (Official Gazette of RS, No. 96/11, 117/17)	Article 1	Prescribes minimum requirements that the employer is obliged to fulfil in ensuring the application of preventive measures to eliminate or reduce the risk of damage to the health of employees that occur or may occur when exposed to carcinogens or mutagens at the workplace and exposure limit values.	Introduction
Regulation on preventive measures for safe and healthy work when exposed to artificial optical radiation (Official Gazette of RS, No. 120/12, 29/13 - correction, 130/21)	Article 1	Prescribes requirements that the employer is obliged to fulfil in ensuring the application of preventive measures with the aim of eliminating or minimizing the risk of damage to the health of employees that occur or may occur during exposure to artificial optical radiation, especially the risk of damage to the eyes and skin.	Introduction
Regulation on preventive measures for safe and healthy work related to exposure to biological hazards (Official Gazette of RS, No. 96/10, 115/20)	Article 1	Minimum requirements that the employer is obliged to fulfil in ensuring the application of preventive measures are prescribed in order to eliminate or reduce the risk of injury or damage to the health of employees that occur or may occur when exposed to biological hazards at the workplace.	Introduction
	Article 2	It does not apply to workplaces where genetically modified organisms are present, except in the case where the provisions of this rulebook prescribe a higher level of safety and health at work.	Non applying
	Article 4 Article 6 Article 7	The employer is obliged to carry out an assessment of the risk of injury or damage to the health of employees for all workplaces in the working environment, where there is a possibility of exposure of employees to biological hazards, with the aim of determining the nature, degree and duration of exposure of employees and ways and measures to	Obligations

National Law			VEC
Name/Date/Number	**Section**	**Description**	
	Article 8 Article 9 Article 10 Article 11 Article 13 Article 14	eliminate or reduce these risks; to avoid performing tasks in which there is a possibility of exposure of employees to dangerous biological hazards, if the nature of the tasks allows it, by replacing and organizing the performance of tasks in which, according to current knowledge, exposure to biological hazards is not dangerous, that is, it is less dangerous to the health of employees; to prevent the exposure of employees to biological hazards; to inform the competent authorities that there is a risk to the H&S of employees; to provide the employee with certain hygiene, means and equipment for personal protection at work; to provide all information on the measures taken in order to achieve safe and healthy working conditions when exposed to biological hazards; at the workplace in the working environment, provide written instructions or instructions and, if necessary, highlight notices that contain procedures to be implemented in the event of an injury at work or a dangerous occurrence related to the handling of biological hazards; as well as the handling of biological hazards; to provide prescribed health monitoring for employees who work or should work at workplaces with biological hazards. Employer is obliged to inform the competent labour inspection and the competent institute for public health about the start of work that may involve exposure to biological hazards at least eight days before the start of work. The report must also be sent before the first use of each new harmfulness of group 4 and each new harmfulness of group 3, when the employer himself provisionally classifies that biological hazards.	
	Article 18	The classification of biological hazards of groups 2–4 is given in – Annex 3. When the biological damage to be assessed is not classified in one of the groups of this Regulation and cannot be clearly classified in one of those groups, the classification in the group with the highest level of risk must be carried out.	Classification
	Annex 1	Overview of jobs where there is a possibility of exposure to biological hazards	Areas
	Annex 3	Classification of biological hazards	Classification
Regulation on preventive measures for safe and healthy work when using work equipment (Official Gazette of RS, No. 23/09, 123/12, 102/15, 101/18, 130/21)	Article 1	Prescribes minimum health and safety requirements at work that the employer is obliged to fulfil in ensuring the application of preventive measures when using work equipment.	Introduction
Regulation on preventive measures for healthy and safe work when using screen equipment (Official Gazette of RS, No. 106/09, 93/13, 86/19)	Article 1	Prescribes minimum requirements that the employer is obliged to fulfil in ensuring the application of preventive measures when using the equipment for working with the screen.	Introduction

National Law			VEC
Name/Date/Number	**Section**	**Description**	
Regulation on previous and periodic medical examinations of employees at workplaces with increased risk (Official Gazette of RS, No. 120/07, 93/08, 53/17)	Article 1	Prescribes method, procedure and deadlines for performing a preliminary medical examination of a person who establishes an employment relationship, that is, a person hired by the employer to work at a workplace with increased risk and periodic medical examination of an employee who works at a workplace with increased risk. Previous and periodic medical examinations are carried out by the occupational medicine service.	Introduction
Regulation on the method of providing first aid, the type of means and equipment that must be provided at the workplace, the method and deadlines for training employees to provide first aid (Official Gazette of RS, No. 109/16)	Article 1	Prescribes method of providing first aid, the types of tools and equipment that must be provided at the workplace, the method and deadlines for training employees to provide first aid.	Introduction
Regulation on occupational safety during construction works (Official Gazette of RS, No. 53/97, 14/09 - other decree)	Article 1	Prescribes special measures and norms of occupational safety that are applied during construction works: construction of a new building, reconstruction, extension, repair or demolition of an existing building, then works on maintenance of the building with associated installations, equipment and devices, as well as preparatory works for the execution of works on building, finishing works on the arrangement of the area around the building and works on the liquidation of the construction site.	Introduction
Law on Radiation and Nuclear Safety and Security (Official Gazette of RS, No. 95/18, 10/19)	Article 1	Regulates radiation and nuclear safety and security measures, conditions for performing activities with radiation sources, actions in the situation of planned, existing and extraordinary exposure to ionizing radiation in order to ensure the protection of individuals, the population and the environment from the harmful effects of ionizing radiation, now and in the future. This law establishes the Directorate for Radiation and Nuclear Safety and Security of Serbia for the purpose of regulatory control of the activities governed by this law.	Introduction
Regulation on determining occupational diseases (Official Gazette of RS, No. 14/19)	Article 1	Determines occupational diseases, workplaces, i.e. jobs where these diseases appear and the conditions under which they are considered occupational diseases.	Introduction
Regulation on preventive measures for safe and healthy work when exposed to noise (Official Gazette of RS, No. 96/11, 78/15, 93/19)	Article 1	Prescribes minimum requirements that the employer is obliged to fulfil in ensuring the application of preventive measures with the aim of eliminating or reducing to the smallest possible extent the risk of injury or damage to the health of employees that occur or may occur when exposed to noise, and in particular the risk of hearing damage, requirements that legal entities with a license to carry out testing of working environment conditions in the procedure of preventive and periodic testing of working environment conditions, limit	Introduction

National Law			VEC
Name/Date/Number	**Section**	**Description**	
		values of noise exposure, action values of noise exposure and peak values of sound pressure and action value of noise exposure are obliged to fulfil.	
Regulation on preventive measures for safe and healthy work when exposed to chemical substances (Official Gazette of RS, No. 106/09, 117/17, 107/21)	Article 1	Prescribes minimum requirements for safety and health at work that the employer is obliged to fulfil in ensuring the application of preventive measures in order to eliminate or reduce the risk of injuries or damage to the health of employees that occur or may occur as a result of exposure to chemical substances at the workplace or as a result of any activity which includes chemical substances.	Introduction
Law on Transport of Dangerous Goods (Official Gazette of RS, No. 104/16, 83/18, 95/18 - other laws, 10/19 - other law)	Article 1	Determines conditions for carrying out internal and international transport of dangerous goods in road, rail and inland water traffic on the territory of the Republic of Serbia, requirements in relation to packaging, mobile equipment under pressure, i.e. a tank, i.e. means of transport intended for the transport of dangerous goods, conditions for appointing a body that inspect and control packaging, mobile equipment under pressure, i.e. tank, i.e. vehicle for the transport of dangerous goods, conditions for authorizing bodies that examine and control ships for the transport of dangerous goods, competences of state authorities and organizations in the transport of dangerous goods, conditions and obligations that should filled out by participants in the transport of dangerous goods, supervision, as well as other issues related to the transport of dangerous goods.	Introduction
Law on Strike (Official Gazette of RS, No. 29/96, 101/05 - other law, 103/12 - US)	Article 1	A strike is a work stoppage organized by employees to protect their professional and economic interests based on work. Employees freely decide on their participation in the strike.	Introduction
Law on Prevention of Harassment at the Workplace (Official Gazette of RS, No.36/10)	Article 1	Regulates prohibition of abuse at work and in connection with work; measures to prevent abuse and improve relations at work; the procedure for the protection of persons exposed to abuse at work and in connection with work and other issues of importance for the prevention and protection from abuse at work and in connection with work.	Introduction
Law on Peaceful Settlement of Labour Disputes (Official Gazette of RS, No. 125/04, 104/09, 50/18)	Article 1	The method and procedure for the peaceful resolution of collective and individual labour disputes, the selection, rights and obligations of conciliators and arbitrators and other issues of importance for the peaceful resolution of labour disputes are regulated by this law.	Introduction
Law on Gender Equality (Official Gazette of RS, No. 52/21)	Article 1	Regulates concept, meaning and measures of the policy for achieving and improving gender equality, types of planning acts in the field of gender equality and the way of reporting on their implementation, the institutional framework for achieving gender equality, the supervision of the implementation of the law. The law also regulates	Introduction

National Law			VEC
Name/Date/Number	**Section**	**Description**	
		measures to suppress and prevent all forms of gender-based violence, violence against women and violence in the family. The law regulates the obligations of public authorities, employers and other social partners to integrate a gender perspective in the area in which they operate.	
Law on the Prohibition of Discrimination (Official Gazette of RS, No. 22/09, 52/21)	Article 1	This law regulates the general prohibition of discrimination, forms and cases of discrimination, as well as procedures for protection against discrimination. This law establishes the Commissioner for the Protection of Equality (hereinafter: the Commissioner), as an independent state body, independent in performing the duties established by this law.	Introduction
Law on Protection of Whistle Blowers (Official Gazette of RS, No. 128/14)	Article 1	This law regulates whistle-blowing, whistle-blowing procedure, rights of whistle-blowers, obligations of state and other authorities and organizations and legal and natural persons in relation to whistle-blowing, as well as other issues of importance for whistle-blowing and protection of whistle-blowers.	Introduction
Regulation on Conduct of Employers and Employees in Relation to Prevention and Protection from Harassment at Work (Official Gazette of RS, No. 62/10)	Article 1	Regulates rules of behaviour of employers and employees, in connection with the prevention and protection against abuse at work and in connection with work, that is, against sexual harassment.	Introduction
	Article 2 Article 3 Article 4 Article 6	Obligations of the employer: to provide employees with working conditions in which they will not be exposed to abuse by the employer, i.e. the responsible person or the employer’s employees; to implement measures to inform and train employees and their representatives to recognize the causes, forms and consequences of abuse; before starting work, submit a notice on the prohibition of abuse and the rights, obligations and responsibilities of the employee and the employer in connection with the prohibition of abuse; to make data available on: the person to whom an employee who suspects that he is exposed to abuse can turn to for advice and support, to persons authorized to initiate proceedings for protection against abuse.	Obligations

APPENDIX D

CHANCE FIND PROCEDURE

INTRODUCTION

This document presents the Chance Find Procedure for 'Torlak Institute BSL-3 Subproject' and is prepared by 2U1K Muhendislik ve Danismanlik A.S.

This document is intended to avoid potential impacts of the Sub-project on any cultural heritage during land preparation works, including excavation. At the baseline studies, field survey and literature review were conducted for the Sub-project and its vicinity to identify potential archaeological and immovable cultural properties. No archaeological or immovable cultural property was encountered during the study.

This Procedure is a part of the general package as an annex to the Environmental and Social Impact Assessment (ESIA) developed for the Sub-project.

SCOPE

Types of Cultural Heritage Covered by This Procedure

Tangible Cultural Heritage

Tangible (physical) cultural heritage refers to movable or immovable objects, sites, structures, groups of structures, and natural features and landscapes that have archaeological, paleontological, historical, architectural, religious, aesthetic, or other cultural significance.

ROLES AND RESPONSIBILITIES

Roles	Responsibilities
Contractors	• Compliance with the Chance Find Procedure provided in contractor agreements • Provide appropriate training and information to the worksite personnel who work in the sub-project and who may disturb the cultural heritage so that they understand their responsibilities for cultural heritage
Project Owner	• Ensure compliance of the Sub-project with the Project Standards and other requirements given in this Plan • General responsibility for the scope and implementation of the Plan • Development, monitoring and revision of this Plan • Fulfilment of cultural heritage evaluation processes • Ensure that the operations do not disturb cultural properties and sites without the approval of the relevant authority • Investigation, reporting and monitoring of unauthorized damages to the worksite as well as of procedure violations • Management of amendments to laws or policies • Coordination with the organizations involved in the implementation and other stakeholders
All Workers	• Learn about the Chance Find Procedure through induction training and any other training provided

SUB-PROJECT STANDARDS

- Law on Cultural Property (1994) ,World Bank ESF (ESS 8: Cultural Heritage),
- Convention Concerning the Protection of the World Cultural and Natural Heritage (World Heritage Convention).

CHANCE FIND PROCEDURE

Initial Approach Adopted by the Contractor

- Action 1: Immediately stop all construction works in the vicinity of the chance find, in case of discovery of archaeological finds;
- Action 2: Immediately notify the project manager and/or environmental department;
- Action 3: Take photographs or make technical drawings;
- Action 4: Record the location of the location by keeping all remains in their position (without moving them);
- Action 5: Prevent damage to or loss of movable objects by encircling the area;
- Action 6: Contact an archaeologist from a local university for guidance;
- Action 7: Prepare the Chance Find Form (Annex 1).

Approach Adopted by the Archaeologist

Based on the description of the find, the archaeologist will make recommendations on actions to be taken by phone/e-mail or visit. The Sub-project team will take into account the following possible strategies, if the archaeologist(s) confirm(s) the presence of archaeological finds/remains/sites:

<u>Strategy 1: Avoidance by partial or full Sub-project redesign or relocation</u>

In case of any archaeological find or discovery, the Project Owner will provide the relevant information to authorities. This responsibility will apply even if the Sub-project is redesigned or relocated. In any case, the relevant governmental body will be informed of the archaeological find or discovery.

<u>Strategy 2: Implementation of worksite protection measures</u>

This option includes the implementation of site protection measures such as fencing or blockage.

<u>Strategy 3: Rescue or emergency excavation</u>

If the Project Owner fails to relocate or redesign the Project, this may require rescue or emergency excavation works. If notification is stipulated by the Law on Cultural Property, an application will be lodged to governmental bodies.

After the permit is obtained from the relevant authority, archaeological excavations will be performed with the attendance of scientific consultants from the archaeological departments of universities. Following the completion of archaeological excavations, the results will be submitted to relevant governmental bodies for the final decision to be taken for the progress of the Project.

Procedure for the Discovery of Potential Human Remains

Identification of human remains is very clear in terms of graves or burial sites. If a grave or burial site is found, relevant authority will be informed immediately.

KEY PERFORMANCE INDICATORS

The key performance indicators to be used during the implementation of this Procedure are set out below.

Table. Key Performance Indicators (KPIs)

No	KPIs	Target	Monitoring Measure
1	Non-conformities reported during the year with respect to key management controls identified in this Plan	Minimization of reported non-conformities, aiming at zero	Database Reporting Inspection Reports
2	Number of complaints lodged by local communities during the year regarding cultural heritages	Investigation of complaints about cultural heritage (disrespect, destruction, removal, sale of artefacts) and fulfilment of relevant actions. • Provision of prompt response to complaints from local communities regarding the misbehavior of personnel regarding cultural properties	Database Grievance Mechanism Records Reporting

ANNEX – 1 Sample Chance Find Form

Place:	Chance Find No:	Date:
Location Data: **Coordination:** **Elevation:** **Brief Area Description:**		
Chance Type:	[ ]Archaeological Items [ ]Metal Finds [ ]Terracotta Finds [ ]Pottery Shards [ ]Glass Finds	[ ]Sculpture etc. [ ]Human / Animal Bone [ ]Unidentified
Temporary Measures		
Photograph		
Discoverer's Name-Last Name:		
Signature:		

APPENDIX E

Responsibilities Laboratory Diagnostics Division

HEAD OF LABORATORY DIAGNOSTICS DIVISION

- manages the overall activities of the Laboratory Diagnostics Division (hereinafter: The Division): plans, develops and supervises the work of the Division by ensuring compliance with the applicable regulations and guidelines of Good Laboratory Practice
- defines, organizes and oversees the implementation of Standard Operating Procedures (SOPs)
- manages and coordinates the implementation of the provision of services of the Division in order to ensure the necessary quality of services as well as compliance with all applicable national and international regulations and guidelines of Good Laboratory Practice
- prepares a proposal for the work plan of the Division
- in cooperation with assistant heads in the Division, develops, revises and approves the proposal of the work plan of these organizational units
- supervises the execution of adopted work plans through reports submitted by assistant managers in the Division
- ensures that the work in the Division is carried out in accordance with written procedures, and that the documentation is regularly updated
- identifies non-conformities and inconsistencies in the Division
- monitors the implementation of recommended corrective measures
- reviews and revises standard operating procedures (SOPs) of the Division
- provides periodic review of documentation according to the guidelines of Good Laboratory Practice
- plans and oversees employee training programs
- prepares and submits periodic reports on the work of the Division to direct managers
- timely preparation of the needs of goods, services and works as well as their specifications that are necessary for the preparation of the Public Procurement Plan
- makes the plan of the needs of goods, services and works at the level of service and timely needs them
- assesses opportunities for improving the quality of services and products, efficiency and productivity, technological developments as well as cost reduction, makes suggestions for improving all of the above
- transfers knowledge and experience and works to achieve the autonomy of the associates
- maintains a good working atmosphere

- analyzes and proposes stimulations and disincentives based on work results and certain criteria
- achieves intensive communication and cooperation with the heads of other Divisions of the Institute
- follows the legal regulations and professional literature that enables him to successfully perform these tasks
- performs other tasks at the direction of a direct and/or senior manager
- responsible for his work to the Associate Director of the Institute at several levels of health care for diagnostics and scientific development and / or to a senior manager

ASSISTANT HEAD OF SERODIAGNOSTICS AND MOLECULAR DIAGNOSTICS DEPARTMENT

- plans and organizes the work in the organizational unit in accordance with the plans of the Laboratory Diagnostics Division and Torlak Institute
- monitors the implementation of procedures at the level of the Institute, legal regulations and is in charge of implementing standard operating procedures (SOPs) at the Institute
- plans and prepares laboratory documentation and its amendments, in accordance with the guidelines of good laboratory practice
- organizes the execution of the work order and is responsible for its implementation
- submits written reports on the consumption of goods in the process of realization of the work order
- is responsible for providing services and storage of goods and samples of biological material in accordance with good laboratory practice guidelines and applicable regulations
- independently sets up and performs laboratory tests according to SOPs
- independently performs experiments and works with highly infectious materials, while taking care of biosecurity
- reads and reports results, analyzes data obtained by performing immunological and virological tests
- writes and validates reports and forwards them to the Head of the Medical Division for Laboratory Diagnostics
- develops a regular annual plan and training program for employees in the organizational unit
- is responsible for the training of employees to work in the organizational unit
- supervises the work of employees after completing the training

- timely preparation of the needs of goods, services and works as well as their specifications that are necessary for the preparation of the Public Procurement Plan and forwards them to the Head of the Medical Division for Laboratory Diagnostics
- makes the plan of the needs of goods, services and works at the level of the organizational unit and timely needs them
- assesses opportunities for improving the quality of services and products, efficiency and productivity, technological developments as well as cost reduction, makes suggestions for improving all of the above
- transfers knowledge and experience and works to achieve the autonomy of the associates
- maintains a good working atmosphere
- suggests stimulations and disincentives based on the results of work and certain criteria
- achieves intensive communication and cooperation with the heads of other organizational units in the Institute
- follows the legal regulations and professional literature that enables him to successfully perform these tasks
- performs other tasks at the direction of a direct and/or senior manager
- he is responsible for his work to the Head of the Medical Laboratory Diagnostics Division and/or senior manager

DOCTOR OF MEDICINE, SPECIALIST IN MICROBIOLOGICAL DIAGNOSTICS IN SERODIAGNOSTICS AND MOLECULAR DIAGNOSTICS DEPARTMENT

- organizes the process of work in the organizational unit, in accordance with the work plan of the organizational unit
- independently conducts work orders according to the applicable procedures
- develops standard operating procedures, as well as their amendments, in accordance with the guidelines of good laboratory practice
- participates in the preparation of laboratory documentation, as well as its amendments in accordance with the guidelines of good laboratory practice
- manages and completes laboratory documentation from the scope of work of the organizational unit
- performs control of documentation on laboratory equipment, records of use and cleaning of laboratory equipment
- submits work reports to the direct manager

- participates in the development of the work plan of the organizational unit
- monitors the implementation of the procedures carried out in the organizational unit
- independently sets up and performs laboratory tests according to SOPs
- independently performs experiments and works with highly infectious materials, while taking care of biosecurity
- reads and reports results, analyzes data obtained by performing immunological and virological tests
- trains laboratory technicians and physical workers to work in the organizational unit
- proposes improvements in the quality of efficiency and productivity in the work of the organizational unit to the direct manager
- works within teams determined by the Director of the Institute at multiple levels of health care
- maintains a good working atmosphere
- follows the legal regulations and professional literature that enables him to successfully perform these tasks
- performs other tasks at the direction of a direct and/or senior manager
- for his work is responsible to the Assistant Head of Serodiagnostics and Molecular Diagnostics Department

APPENDIX F

BACKGROUND MEASUREMENT REPORTS

APPENDIX F-I

Air Quality Measurement Report

Anahem Laboratorija
Mocartova 10, 11160 Beograd, Srbija

Matični broj: 17615980; Šifra delatnosti: 7120
PIB: 103604091; Tekući račun: 205-81605-04
www.anahem.org; E-mail: vazduh@anahem.org
Tel.: 011 3422 800; Fax: 011 3422 900

ATC
01-261
ЛАБОРАТОРИЈА ЗА ИСПИТИВАЊЕ
ISO/IEC 17025

I Z V E Š T A J[1]

br. 82052401

O ISPITIVANJU KVALITETA VAZDUHA AMBIJENTA

Beograd, 28.12.2022. godine

[1] Izveštaj se ne sme umnožavati bez odobrenja ANAHEM Laboratorije. Kopija ovog izveštaja nije zvanični dokument. Izveštaj važi samo kao celina, sa originalom pečata;
Anahem doo Beograd je odgovoran za sve podatke iskazane u izveštaju o ispitivanju osim za one dobijene od korisnika ispitivanja.
Anahem doo Beograd se odriče odgovornosti na validnost rezultata za čije iskazivanje su korišćeni podaci dobijeni od korisnika.

Beograd, Mocartova 10 011/3422 800 011/3422 900 e-mail: vazduh@anahem.org

ATC 01-261
ЛАБОРАТОРИЈА ЗА ИСПИТИВАЊЕ ISO/IEC 17025

SADRŽAJ:

1 OPŠTI PODACI O OVLAŠĆENOM PRAVNOM LICU KOJE JE OBAVILO ISPITIVANJE

Naziv:	ANAHEM DOO
Adresa:	Beograd, ul. Mocartova br. 10
Telefon:	(011) 3422 800
Telefaks:	(011) 3422 900
E-mail:	vazduh@anahem.org
Lice za kontakt:	Latinka Slavković Beškoski, rukovodilac laboratorije za ispitivanje vazduha

2 OPŠTI PODACI O OPERATERU

Naziv:	ENACTA DOO BEOGRAD
Adresa:	ul. Svetog Save br. 25, 11000 Beograd (Vračar)
Telefon:	(060) 7010 655
Matični broj:	21381080
E-mail:	d.kovacevic@enacta.rs
Lice za kontakt:	Dragan Kovačević, direktor

3 OSNOV I PREDMET ISPITIVANJA

Prema zahtevu naručioca, laboratorija ANAHEM obavila je utvrđivanje nivoa zagađenosti vazduha ambijenta (određivanje masenih koncentracija suspendovanih čestica frakcije PM_{10} i suspendovanih čestica frakcije $PM_{2.5}$) na mernim mestima u okviru kruga Instituta za virusologiju, vakcine i serume TORLAK, definisanim od strane naručioca ispitivanja. Shodno zahtevu, obavljena su 24h ispitivanja, odnosno uzorkovanje po sedam 24-časovnih uzoraka navedenih parametara na dva merna mesta.

Merno mesto (MM)	*Zagađujuće materije*	*Period uzorkovanja*
Merno mesto br. 1: Prostor na obodu instituta Torlak, pored zgrade za naučno istraživacki rad	- Suspendovane čestice frakcije PM_{10} - Suspendovane čestice frakcije $PM_{2.5}$	07.12. - 14.12.2022. godine
Merno mesto br. 2: Prostor u dvorištu instituta Torlak, ka Farmacetskom fakultetu	- Suspendovane čestice frakcije PM_{10} - Suspendovane čestice frakcije $PM_{2.5}$	14.12. - 21.12.2022. godine

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4 MAKROLOKACIJA MERNOG MESTA

Institut za virusologiju, vakcine i serume TORLAK se nalazi u Beogradu, na adresi ul. Vojvode Stepe br. 458. U najbližem okruženju Instituta se nalaze Farmaceutski fakultet, individualni stambeni objekti i zelene površine.

Makrolokacioni prikaz:

5 MIKROLOKACIJA MERNOG MESTA

MERNO MESTO BR. 1:	Prostor na obodu instituta Torlak, pored zgrade za naučno istraživacki rad (objekat broj 4). Oprema za ispitivanje kvaliteta vazduha je postavljena zapadno od zgrade prema stambenim objektima. Nedaleko od mernog mesta, na otprilike 15 m severno, nalazi se zgrada kotlarnice.	
	GPS koordinate: N 44^0 44' 44,3"	E 20^0 29' 38,1"

Mikrolokacioni prikaz mernog mesta:

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Fotografija mernog mesta:	
Fotografija mernog mesta:	

IZVEŠTAJ O ISPITIVANJU br. 82052401

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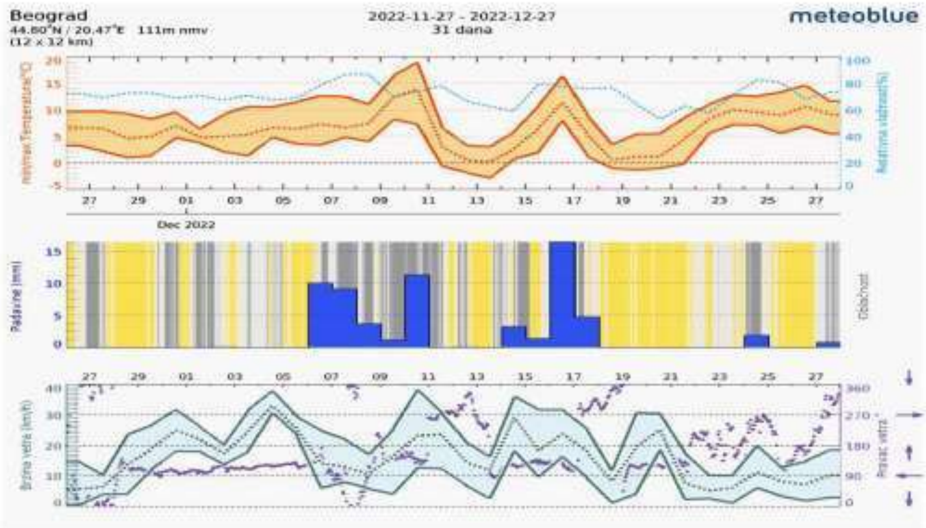
MERNO MESTO BR. 2:	Prostor u dvorištu instituta Torlak, ka Farmacetskom fakultetu. Merno mesto se nalazi na 20 m od zgrade Instituta, a udaljena je od Zavodske ulice 30 m.		
	GPS koordinate:	N 44^0 44' 46,4"	E 20^0 29' 43"
Mikrolokacioni prikaz mernog mesta:			
Fotografija mernog mesta:			

Beograd, Mocartova 10 011/3422 800 011/3422 900 e-mail: vazduh@anahem.org

Fotografija mernog mesta:

6 METEOROLOŠKI USLOVI U PERIODU UZORKOVANJA

Period uzorkovanja: 07.12.2022. - 21.12.2022. godine (izvor: *https://www.meteoblue.com*)



- Temperatura, uključujući relativnu vlažnost vazduha u vremenskim intervalima
- Oblačnost (siva pozadina) i vedro nebo (žuta pozadina). Što je pozadina tamnija, oblačnost je sve gušća
- Brzina vetra i pravac (u stepenima 0° = Sever, 90° = Istok, 180° = Jug i 270° = Zapad). U istorijskoj arhivi meteograma, ljubičaste tačke predstavljaju pravac vetra, kao što je predstavljeno na desnoj osi.

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7 MERNI UREĐAJI

Uređaj za uzorkovanje suspendovanih čestica frakcije PM_{10}

Proizvođač:	SVEN LECKEL Nemačka	Karakteristike
Model:	LVS3	• Protok: 1,0 - 2,3 m^3/h • Prečnik filtera za uzorkovanje: 47 - 50 mm
Serijski broj:	18724	
Inventarski broj:	2021002	

Uređaj za uzorkovanje čestica frakcije $PM_{10}/PM_{2.5}$

Proizvođač:	SVEN LECKEL Nemačka	Karakteristike
Model:	LVS6	• Protok: 1,0 - 2,3 m^3/h • Prečnik filtera za uzorkovanje: 47 – 50 mm
Serijski broj:	19/0086	
Inventarski broj:	9123153	

Mikro vaga

Proizvođač:	RADWAG Poljska	Karakteristike
Model:	MYA 5/3Y	Merni opseg: 0 - 5 g
Serijski broj:	395172/13	
Inventarski broj:	2062501	

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8 PRIMENJENA ZAKONSKA REGULATIVA I METODE ISPITIVANJA

8.1 Zakonska regulativa

- Zakon o zaštiti vazduha ("Sl. glasnik RS" br. 36/2009 i 10/2013);
- Uredba o uslovima za monitoring i zahtevima za kvalitet vazduha („Sl. glasnik RS“, br. 11/2010, 75/2010 i 63/2013).

8.2 Standardi

Parametar ispitivanja	Metoda ispitivanja
Određivanje masene koncentracije suspendovanih čestica frakcija PM_{10} i $PM_{2.5}$	**SRPS EN 12341:2015** - Vazduh ambijenta - Standardna gravimetrijska metoda merenja za određivanje PM_{10} ili $PM_{2,5}$ masene koncentracije suspendovanih čestica

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9 REZULTATI ISPITIVANJA

Datum terenskih merenja/uzorkovanja: 07.12. - 21.12.2022. godine.
Datum prijema uzorka u laboratoriju: 08.12. - 21.12.2022. godine.
Datum početka/završetka analize: 26.12. - 27.12.2022. godine.

9.1 Rezultati ispitivanja kvaliteta vazduha ambijenta na mernom mestu br. 1

PARAMETAR	GV*	OZNAKE UZORAKA/DATUMI UZORKOVANJA						
		8205240102 (07.12. - 08.12. 2022. godine)	8205240104 (08.12. - 09.12. 2022. godine)	8205240106 (09.12. - 10.12. 2022. godine)	8205240108 (10.12. - 11.12. 2022. godine)	8205240110 (11.12. - 12.12. 2022. godine)	8205240112 (12.12. - 13.12. 2022. godine)	8205240114 (13.12. - 14.12. 2022. godine)
SUSPENDOVANE ČESTICE FRAKCIJE PM_{10} ($\mu g/m^3$)	50[1]	29,6 ± 17%	33,9 ± 17%	39,2 ± 17%	29,1 ± 17%	30,4 ± 17%	49,2 ± 17%	38 ± 17%
PARAMETAR	GV*	OZNAKE UZORAKA/DATUMI UZORKOVANJA						
		8205240101 (07.12. - 08.12. 2022. godine)	8205240103 (08.12. - 09.12. 2022. godine)	8205240105 (09.12. - 10.12. 2022. godine)	8205240107 (10.12. - 11.12. 2022. godine)	8205240109 (11.12. - 12.12. 2022. godine)	8205240111 (12.12. - 13.12. 2022. godine)	8205240113 (13.12. - 14.12. 2022. godine)
SUSPENDOVANE ČESTICE FRAKCIJE $PM_{2.5}$ ($\mu g/m^3$)	25[2]	34,6 ± 17%	33,7 ± 17%	23 ± 17%	22,4 ± 17%	30,7 ± 17%	47,6 ± 17%	31,4 ± 17%

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9.2 Rezultati ispitivanja kvaliteta vazduha ambijenta na mernom mestu br. 2

PARAMETAR	GV*	OZNAKE UZORAKA/DATUMI UZORKOVANJA						
		820524016 (14.12. - 15.12. 2022. godine)	8205240118 (15.12. - 16.12. 2022. godine)	8205240120 (16.12. - 17.12. 2022. godine)	8205240122 (17.12. - 18.12. 2022. godine)	8205240124 (18.12. - 19.12. 2022. godine)	8205240126 (19.12. - 20.12. 2022. godine)	8205240128 (20.12. - 21.12. 2022. godine)
SUSPENDOVANE ČESTICE FRAKCIJE PM_{10} ($\mu g/m^3$)	50[1]	23,5 ± 17%	36,1 ± 17%	40,8 ± 17%	96 ± 17%	72 ± 17%	30 ± 17%	47,5 ± 17%
PARAMETAR	GV*	OZNAKE UZORAKA/DATUMI UZORKOVANJA						
		8205240115 (14.12. - 15.12. 2022. godine)	8205240117 (15.12. - 16.12. 2022. godine)	8205240119 (16.12. - 17.12. 2022. godine)	8205240121 (17.12. - 18.12. 2022. godine)	8205240123 (18.12. - 19.12. 2022. godine)	8205240125 (19.12. - 20.12. 2022. godine)	8205240127 (20.12. - 21.12. 2022. godine)
SUSPENDOVANE ČESTICE FRAKCIJE $PM_{2.5}$ ($\mu g/m^3$)	25[2]	24,4 ± 17%	18,1 ± 17%	18,6 ± 17%	31,6 ± 17%	51,7 ± 17%	38 ± 17%	65,7 ± 17%

*GV- granična vrednost;
[1] *GV za 24-časovni uzorak, koja se odnosi na period usrednjavanja jedan dan (24h);*
[2] *GV koja se odnosi na period usrednjavanja kalendarska godina.*

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Iskazane merne nesigurnosti (±) predstavljaju ukupne merne nesigurnosti i date su sa faktorom pokrivanja k = 2, što odgovara nivou poverenja od približno 95%.

Terenska uzorkovanja obavili:	Analize uzoraka obavio:	Izveštaj izradio:
Mihailo Habenšus,dipl.inž.tehn. Miloš Stevanović, dipl.fiz.hem.	Damjan Gavrilović, master hemičar	Aleksandar Jeremić, dipl.hem.

Datum izdavanja izveštaja: 28.12.2022. godine

Kontrolisao i odobrio:

Rukovodilac Laboratorije za ispitivanje vazduha

(mp)

Latinka Slavković Beškoski, dipl.fiz.hem.

10 ANALIZA REZULTATA - IZJAVA O USAGLAŠENOSTI [4]

Upoređujući rezultate određivanja masenih koncentracija zagađujućih materija u ambijentalnom vazduhu na navedenim mernim mestima sa graničnim vrednostima definisanim u Prilogu X, Odeljak B **Uredbe o uslovima za monitoring i zahtevima za kvalitet vazduha ("Sl. Glasnik RS", br, 11/2010, 75/2010 i 63/2013)*, može se zaključiti sledeće:

➢ <u>*Merno mesto br. 1*</u>

- Izmerene vrednosti masenih koncentracija suspendovanih čestica frakcije PM_{10} ***NE PRELAZE*** graničnu vrednost (GV) definisanu navedenom **Uredbom* za period usrednjavanja 24 h.
- Za parametar suspendovane čestice frakcije $PM_{2.5}$ nije definisana granična vrednost (GV) za period usrednjavanja 24 h. Izmerene vrednosti masenih koncentracija suspendovanih čestica frakcije $PM_{2.5}$ u 4 od 7 uzoraka ***PRELAZE*** graničnu vrednost (GV) definisanu navedenom **Uredbom* za period usrednjavanja kalendarska godina.

➢ <u>*Merno mesto br. 2*</u>

- Izmerene vrednosti masenih koncentracija suspendovanih čestica frakcije PM_{10} u 2 od 7 uzoraka ***PRELAZE*** graničnu vrednost (GV) definisanu navedenom **Uredbom* za period usrednjavanja 24 h.
- Za parametar suspendovane čestice frakcije $PM_{2.5}$ nije definisana granična vrednost (GV) za period usrednjavanja 24 h. Izmerene vrednosti masenih koncentracija suspendovanih čestica frakcije $PM_{2.5}$ u 4 od 7 uzoraka ***PRELAZE*** graničnu vrednost (GV) definisanu navedenom **Uredbom* za period usrednjavanja kalendarska godina.

Izradio:		Kontrolisao i odobrio: Zamenik direktora ANAHEM Laboratorije
	m.p.	
Aleksandar Jeremić, dipl.hem.		dr Žaklina Todorović, dipl.fiz.hem.

[4] *Ω Primenjena pravila odlučivanja: binarni sistem jednostavnog odlučivanja, odnosno "podeljen rizik" definisano na web stranici anahem.org.*

11 Prilozi

11.1 Izvod iz obima akreditacije Anahem laboratorije

ATC

Акредитациони број/ *Accreditation No.* **01-261**
Важи од/*Valid from:* 29.11.2022.
Замењује Обим од / *Replaces Scope dated:* 25.03.2021.

Место испитивања: на терену*, на терену и у лабораторији (Београд, Моцартова 10) **Физичка и хемијска испитивања** ваздух (амбијентални ваздух и ваздух у радној околини)				
Р.Б.	**Предмет испитивања материјал / производ**	**Врста испитивања/или карактеристика која се мери (техника испитивања)**	**Опсег мерења/ лимит детекције/ лимит квантификације** *(где је применљиво)*	**Референтни документ**
3.	**Ваздух** *наставак* Амбијентални ваздух (аутоматска континуална мерења)	Одређивање садржаја сумпордиоксида (ултраљубичаста флуоресценција) (аутоматски анализатор)*	(5 - 10000) µg/m³	SRPS EN 14212:2013 SRPS EN 14212:2013/AC: 2015
		Одређивање садржаја азот моноксида (NO) и азот диоксида (NO_2) (хемилуминисценција) (аутоматски анализатор)*	(5 - 1200) µg/m³	SRPS EN 14211:2013
		Одређивање садржаја озона (ултраљубичаста фотометрија) (аутоматски анализатор)*	(5 - 1000) µg/m³	SRPS EN 14625:2013
		Одређивање метеоролошких параметара (температура, брзина ветра, правац ветра, релативна влажност, барометарски притисак, падавине) (метеоролошка станица)*	RH: (20 - 90) % T: (-40 - 60) °C Ваzд. притисак: (750 - 1,100) hpa Брзина ветра: (0,1 - 50) m/s Смер ветра: 360° Количина падавина: (0 - 9,999) mm	DML 3.15:2019
		Одређивање барометарског притиска*	(750 - 1200) hPa	DML 2.16:2019
		Мерење концентрације угљен-моноксида (CO) (NDIR)*	(0,06 - 100) mg/m³	SRPS EN 14626:2013
	Амбијентални ваздух	Одређивање масене концентрације честица PM10 или PM2,5 (гравиметрија)	PM10: (1 - 150) µg/m³ PM2,5: (1 - 120) µg/m³	SRPS EN 12341:2015
		Одређивање масене концентрације метала (Pb, Cd, As, Ni) у честицама фракције PM10	Pb: (1 - 4000) ng/m³ Cd: (0,1 - 50) ng/m³ As: (0,5 - 350) ng/m³ Ni: (2 - 100) ng/m³	SRPS EN 14902:2008 SRPS EN 14902:2008/AC: 2013

АТС-ПР15-О02 Издање/Измена: 4/0 Датум: 15.06.2022. Страна: 47/107

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Место испитивања: на терену*, на терену и у лабораторији (Београд, Моцартова 10)
Физичка и хемијска испитивања ваздух (амбијентални ваздух и ваздух у радној околини)

Р.Б.	**Предмет испитивања материјал / производ**	**Врста испитивања/или карактеристика која се мери (техника испитивања)**	**Опсег мерења/ лимит детекције/ лимит квантификације** *(где је примењиво)*	**Референтни документ**
3.	**Ваздух** Амбијентални ваздух *наставак*	Одређивање масене концентрације сумпор диоксида (спектрофотометрија)	(20 - 500) μg/m³	DML 3.3:2013
		Одређивање масене концентрације азотних оксида (спектрофотометрија)	(1 - 2000) μg/m³	DML 3.13:2017
		Одређивање укупних суспендованих честица (гравиметрија)	> 10 μg/m³	EPA METHOD IO-2.1:1999
		Одређивање таложних материја (гравиметрија)	(5 - 2000) mg/m²/dan	DML 3.4:2012
		Одређивање чађи (рефлектометрија)	(4 - 3000) μg/m³	DML 3.5:2011
		Одређивање садржаја бензена (термална десорпција/ GC FID)	(2 - 100) μm/m3	SRPS EN 14662-1:2008
		Одређивање масене концентрације полицикличних ароматичних угљоводоника (Naftalen, Acenaften, Acenaftilen, Fluoren, Fenantren, Antracen, Fluoranten, Piren, Krizen, Benzo[a]antracen, Benzo [b]fluoranten, Benzo [k]fluoranten, Benzo [a]piren, Indeno[1,2,3-cd]piren, Dibenzo[a,h]antracen, Benzo[ghi]perilen) (GC/MS)	(0,05 - 1) ng/m3	SRPS ISO 12884:2010
	Ваздух у радној околини	Одређивање садржаја угљенмоноксида (CO) (електрохемија)*	(0 - 1000) ppm	DML 3.6:2015
		Одређивање садржаја лакоиспарљивих органских једињења (VOC) (PID детекција)*	(0 - 2000) ppm	DML 3.6:2015
		Одређивање садржаја укупне прашине (гравиметрија)	(0,1 - 100) mg/m³	DML 3.12:2016

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11.2 Dozvola za merenje kvaliteta vazduha

Република Србија
МИНИСТАРСТВО ЕНЕРГЕТИКЕ,
РАЗВОЈА И ЗАШТИТЕ ЖИВОТНЕ СРЕДИНЕ
Број: 353-01-00247/2013-08
Датум: 15.03.2013.
Београд

На основу члана 60. став 1. Закона о заштити ваздуха („Службени гласник РС", бр. 36/09 и 10/13), чл. 2, 3, 4. и 5. Правилника о условима за издавање дозволе за мерење квалитета ваздуха и дозволе за мерење емисије из стационарних извора загађивања („Службени гласник РС", број 1/12) и члана 192. Закона о општем управном поступку („Службени лист СРЈ", бр. 33/97 и 31/01 и „Службени гласник РС", број 30/10), решавајући по захтеву правног лица „АНАХЕМ" д.о.о. Предузеће за производњу, промет и услуге, улица Моцартова 10, Београд, Министарство енергетике, развоја и заштите животне средине, Министар на основу члана 23. став 2. Закона о државној управи („Службени гласник РС", бр. 79/05, 101/07 и 95/10), издаје

ДОЗВОЛУ
- за мерење квалитета ваздуха -

1. УТВРЂУЈЕ СЕ да правно лице „АНАХЕМ" д.о.о. Предузеће за производњу, промет и услуге, улица Моцартова 10, Београд, испуњава услове прописане чланом 60. став 1. Закона о заштити ваздуха („Службени гласник РС", бр. 36/09 и 10/13) и чл. 2, 3, 4. и 5. Правилника о условима за издавање дозволе за мерење квалитета ваздуха и дозволе за мерење емисије из стационарних извора загађивања („Службени гласник РС", број 1/12) у погледу кадра, опреме и простора, као и да је стручно и технички оспособљено према захтевима стандарда SRPS ISO/IEC 17025 да врши мерење квалитета ваздуха – **мерење нивоа загађујућих материја** у ваздуху и то загађујућих материја из прилога 1. који је одштампан уз ово решење и чини његов саставни део.

2. УТВРЂУЈЕ СЕ да за обављање послова из тачке 1. ове дозволе правно лице „АНАХЕМ" д.о.о. Предузеће за производњу, промет и услуге, улица Моцартова 10, Београд, поседује опрему из прилога 2. који је одштампан уз ово решење и чини његов саставни део.

3. ОВЛАШЋУЈУ СЕ запослени у правном лицу „АНАХЕМ" д.о.о. Предузеће за производњу, промет и услуге, улица Моцартова 10, Београд, да обављају послове из тачке 1. ове дозволе, наведени у прилогу 3. који је одштампан уз ово решење и чини његов саставни део.

4. ОБАВЕЗУЈЕ СЕ правно лице „АНАХЕМ" д.о.о. Предузеће за производњу, промет и услуге, улица Моцартова 10, Београд, да ће мерења из прилога 1. обављати на начин прописан Уредбом о условима за мониторинг и захтевима квалитета ваздуха („Службени гласник РС", бр. 11/10 и 75/10).

Образложење

Захтевом број 353-01-00247/2013-08 од дана 22.02.2013. године, правно лице „АНАХЕМ" д.о.о. Предузеће за производњу, промет и услуге, улица Моцартова 10, Београд, обратило се Министарству енергетике, развоја и заштите животне средине за добијање дозволе за мерење квалитета ваздуха – мерење нивоа загађујућих материја у ваздуху. По захтеву Министарства од 25.02., 27.02. и 28.02.2013. године документација је допуњена 26.02., 27.02. и 28.02.2013. године.

Чланом 60. став 1. Закона о заштити ваздуха („Службени гласник РС", бр. 36/09 и 10/13) прописано је да правна лица која врше послове мерења емисије загађујућих материја из стационарних извора загађивања и нивоа загађујућих материја у ваздуху могу да врше наведена мерења по добијању дозволе Министарства, уколико испуњавају услове у погледу кадра, опреме и простора, као и ако су стручно и технички оспособљена према захтевима стандарда SRPS ISO 17025.

Наведени услови у погледу кадра, опреме и простора које мора да испуњава правно лице које врши мерење квалитета ваздуха прописани су чл. 2, 3, 4. и 5. Правилника о условима за издавање дозволе за мерење квалитета ваздуха и дозволе за мерење емисије из стационарних извора загађивања („Службени гласник РС", број 1/12). На основу документације достављене уз захтев број 353-01-00247/2013-08 од дана 22.02.2013. године и допуне документације од дана 26.02., 27.02. и 28.02.2013. године утврђено је да правно лице „АНАХЕМ" д.о.о. Предузеће за производњу, промет и услуге, улица Моцартова 10, Београд, поседује решење о утврђивању обима акредитације број 01-261 од 26.11.2012. године, чиме испуњава услов дефинисан у члану 60. став 1. Закона о заштити ваздуха („Службени гласник РС", бр. 36/09 и 10/13) да је стручно и технички оспособљено према захтевима стандарда SRPS ISO/IEC 17025 да врши контролу квалитета ваздуха – мерење нивоа загађујућих материја у ваздуху као и услове у погледу кадра, опреме и простора из чл. 2, 3, 4. и 5. Правилника о условима за издавање дозволе за мерење квалитета ваздуха и дозволе за мерење емисије из стационарних извора загађивања („Службени гласник РС", број 1/12). Имајући у виду наведено, а сагласно члану 192. Закона о општем управном поступку („Службени лист СРЈ", бр. 33/97 и 31/01 и „Службени гласник РС", број 30/10) којим је прописано да орган надлежан за решавање доноси решење о управној ствари која је предмет поступка, као и члану 23. став 2. Закона о државној управи („Службени гласник РС", бр. 79/05, 101/07 и 95/10) по коме Министар доноси решења у управним и другим појединачним стварима, донето је решење као у диспозитиву.

ПОУКА О ПРАВНОМ ЛЕКУ:
Ово решење је коначно у управном поступку.
Против истог се може покренути управни спор тужбом код Управног суда Србије у року од 30 дана од пријема решења.

Доставити:
1. „АНАХЕМ"-у д.о.о. Предузећу за производњу, промет и услуге, улица Моцартова 10, Београд
2. Сектору за контролу и надзор, Министарство енергетике, развоја и заштите животне средине, Др Ивана Рибара 91, Нови Београд
3. Архиви

МИНИСТАР

проф. др Зорана Михајловић

APPENDIX F-II

Background Noise Measurement Report

Anahem Laboratorija
Mocartova 10, 11160 Beograd, Srbija
Matični broj: 17615980; Šifra delatnosti: 7120
PIB: 103604091; Tekući račun: 205-81605-04
www.anahem.org; E-mail: buka@anahem.org
Tel.: 011 3422 800; Fax: 011 3422 900

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ANP-27-12

ENACTA DOO BEOGRAD
Svetog Save 25
11000 BEOGRAD

Beograd, 30.12.2022

Br. Izveštaja: 92052402

IZVEŠTAJ O MERENJU BUKE U ŽIVOTNOJ SREDINI

LOKACIJA ISPITIVANJA: **Institut za virosologiju, vakcine i serume TORLAK**
Datum merenja: **08.-10.12.2022**

Ovaj Izveštaj se može reprodukovati isključivo u celosti

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Sadržaj **Strana**

Beograd, Mocartova 10 011/3422 800 011/3422 900 e-mail: buka@anahem.org

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1. OPŠTI DEO

1.1 PODACI O ORGANIZACIJI ZA MERENJE BUKE

Naziv: „ANAHEM" d.o.o.

Pravna forma: Društvo sa ograničenom odgovornošću

Sedište: Beograd

Puno poslovno ime: Preduzeće za proizvodnju, promet i usluge„ANAHEM" d.o.o.

Adresa: Mocartova 10, Beograd, Srbija

Matični broj: 17615980

PIB: 103604091

Datum registracije: 27.12.2005. godine

Broj registracije: BD 50388

Telefon: (011) 3422-800

Fax: (011) 3422-900

E-mail: office@anahem.org

Lice odgovorno za potpisivanje Izveštaja o merenju buke: Vojislav Popović, dipl. inž. elek.

1.2 PODACI O MERNOJ OPREMI

R.br.	Naziv / Proizvođač	Tip	Klasa	Serijski broj	Datum etaloniranja
1.	Fonometar Bruel&Kjaer	BK 2250	1	2551226	10.06.2022
2.	Kondenzatorski mikrofon Bruel&Kjaer	BK 4189	1	2550210	10.06.2022
3.	Akustički kalibrator Bruel&Kjaer	BK 4231	1	2147255	10.06.2022
4.	Termohigroanemometar TESTO	TESTO 435	/	02489196	20.06.2019
5.	Barometar TESTO	TESTO 511	/	39108883/403	18.08.2019

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1.3 PODACI O NARUČIOCU MERENJA
Naziv: ENACTA DOO BEOGRA-VRAČAR
Adresa: Svetog Save 25, 11000 Beograd
Telefon: -

2. ZADATAK MERENJA

2.1 PREDMET MERENJA

Merenje nivoa buke u životnoj sredini pri radu izvora buke Instituta za virusologiju, vakcine i serume Torlak, Svetog Save 25 u Beogradu, u dnevnom, večernjem i noćnom periodu, u zoni uticaja izvora buke, prema Pravilniku o metodama merenja buke, sadržini i obimu izveštaja o merenju buke („Službeni glasnik RS", број 72/10) i Uredbi o indikatorima buke, graničnim vrednostima, metodama za ocenjivanje indikatora buke, uznemiravanja i štetnih efekata buke u životnoj sredini (Sl. glasnik RS br. 75/10)

2.2 OSNOV MERENJA

Zahtev naručioca merenja: e-mailom od 24.05.2022
Rešenje inspektora za zaštitu životne sredine:.

2.3 NORMATIVNA DOKUMENTA

- Zakon o zaštiti od buke („Sl. Glasnik RS", broj 96/21)
- Pravilnik o metodama merenja buke, sadržini i obimu izveštaja o merenju buke („Sl. Glasnik RS", broj 72/10)
- Uredba o indikatorima buke, graničnim vrednostima, metodama za ocenjivanje indikatora buke, uznemiravanja i štetnih efekata buke u životnoj sredini („Sl. Glasnik RS", broj 75/10)
- SRPS ISO 1996-1:2019 Akustika – Opisivanje, merenje i ocenjivanje buke u životnoj sredini – Deo 1: Osnovne veličine i procedure ocenjivanja
- SRPS ISO 1996-2:2019 Akustika – Opisivanje, merenje i ocenjivanje buke u životnoj sredini – Deo 2: Određivanje nivoa zvučnog pritiska

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3. USLOVI I REZULTATI MERENJA

3.1 OPIS LOKACIJE

Lokacija ispitivanja pripada urbanoj zoni grada Beograda, sa sadržajem tipičnim za gradska područja – prometne saobraćajnice, poslovni, komercijalni i stambeni kompleksi sa parking prostorima i zelenim površinama.
Merne tačke se nalaze u krugu Instituta za virusologiju, vakcine i serume "Torlak" i odredjene su zahtevom naručioca.

3.2 AKUSTIČKA ZONA

Merna tačka 1 (MT1): Granične vrednosti indikatora buke na otvorenom prostoru: Zona 3 (tabela 1) – Čisto stambena područja, za dnevni, večernji i noćni period, u smislu Uredbe o indikatorima buke, graničnim vrednostima, metodama za ocenjivanje indikatora buke, uznemiravanja i štetnih efekata buke u životnoj sredini („Sl. Glasnik RS", broj 75/10).

Granične vrednosti indikatora buke za zonu 3:
Na otvorenom prostoru: **dan/veče: 55 dB; noć: 45 dB**

NAPOMENA: Akustička zona na otvorenom prostoru u skladu je sa „Odlukom o određivanju akustičkih zona na teritoriji grada Beograda" (Sl.list 2/22).

Merna tačka 2 (MT2) ne pripada ni jednoj zoni definisanoj Uredbom o indikatorima buke, graničnim vredno-stima, metodama za ocenjivanje indikatora buke, uznemiravanja i štetnih efekata buke u životnoj sredini („Sl. Glasnik RS", broj 75/10)

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3.3 METEOROLOŠKI USLOVI
08.-10.12.2022: malo oblačno, bez padavina; temperatura 5^0-12^0; vlažnost vazduha do 56%; brzina vetra do 1.5m/s; pritisak 1008hPa..

3.4 DATUM I VREME MERENJA
Datum:08.- 10.12.2022.; **Vreme merenja**: u dnevnom, večernjem i noćnom periodu

3.5 PODACI O IZVORIMA BUKE

3.5.1 ISPITIVANI IZVORI BUKE

Opis i položaj:

U OKOLINI MT1

- Trafo stanica na udaljenosti od oko 4m od merne tačke
- Parking prostor – uticaj kretanja vozila

U OKOLINI MT2.

- Gasni odušak iz podruma zgrade – dominantan izvor buke
- Dva ventilaciona izvoda – čujan rad ventilatora
- Rashladni čiler, na udaljenosti od oko 20m od merne tačke
- Saobraćaj u ulici Vojvode Stepe – slab uticaj



Režim rada:

Merenje buke u životnoj sredini obavljeno je pri istovremenom i neprekidnom radu svih navedenoh izvora buke

Karakteristike buke:

- Prema vremenskom toku: Promenljiva
- Prema frekvencijskom sadržaju: Širokopojasna

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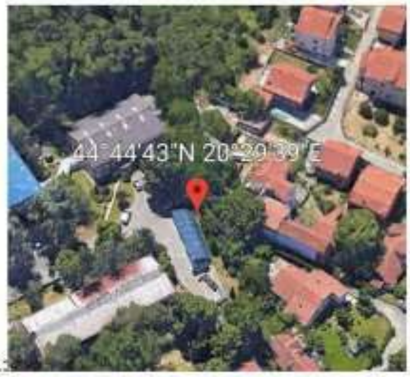
3.6 PODACI O MERNIM MESTIMA

MT 1: 

 MT2

3.7 METODA MERENJA
SRPS ISO 1996-1:2019 Akustika – Opisivanje, merenje i ocenjivanje buke u životnoj sredini – Deo 1: Osnovne veličine i procedure ocenjivanja
SRPS ISO 1996-2:2019 Akustika – Opisivanje, merenje i ocenjivanje buke u životnoj sredini – Deo 2: Određivanje nivoa zvučnog pritiska

3.8 MERNA OPREMA

R.br.	Naziv / Proizvođač	Tip	Klasa	Serijski broj	Datum etaloniranja
1.	Fonometar Bruel&Kjaer	BK 2250	1	2551226	10.06.2022
2.	Kondenzatorski mikrofon Bruel&Kjaer	BK 4189	1	2550210	10.06.2022
3.	Akustički kalibrator Bruel&Kjaer	BK 4231	1	2147255	10.06.2022

3.9 PODACI O KALIBRACIJI RUČNIM KALIBRATOROM

R.br.	Kalibracija	Vreme	Nivo/Frekvencija [dB(A)] / Hz	Odstupanje od prethodne [dB(A)]
1.	Pre merenja	08.12.2022 21:50	94 / 1000	0,00
2.	Posle merenja	10.12.2022 22:10	94 / 1000	0,00

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Merna nesigurnost:

- Merna nesigurnost ispitne metode izražava se kao ukupna merna nesigurnost koja je dobijena množenjem kombinovane nesigurnosti i faktora k = 2 koji za normalnu raspodelu odgovara nivou poverenja od približno 95%. Procenjena proširena merna nesigurnost iznosi 2,8dB(A)
- Kod merenja buke u životnoj sredini, pravilo odlučivanja definiše se tako da se merodavna vrednost ukupne buke upoređuje sa sa graničnim vrednostima buke u životnoj sredini, ne uzimajući u obzir mernu nesigurnost. Ispitivani izvori buke usaglašeni su sa istim ako je merodavni nivo Leq ≤ GVE

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3.6. REZULTATI MERENJA*

MERNO MESTO 1 (MT1) – KONTINUALNO MERENJE

MERNO MESTO 1: Na zapadnoj strani poseda, prema stambenom naselju						
Merna tačka: Na udaljenosti 2m od ograde poseda, na visini 1,5 m od tla.				GPS:	N 44° 44' 43,55" E 20° 29' 39,14"	
REZULTATI MERENJA NA MERNOM MESTU 1						
Ref. vremenski interval	**Dan** 06^{00}-18^{00}		**Veče** 18^{00}-22^{00}		**Noć** 22^{00}-06^{00}	
Datum merenja	09.12	10.12	09.12	10.12	09.12	10.12
Ekvivalentni nivo L_{Aeq} *[dB(A)]*	48,5	47,2	44,5	48,8	41,8	44,3
Merodavni nivo L_{Req} *[dB(A)]*	**49**	**47**	**45**	**49**	**42**	**44**
L_{min} (1) *[dB(A)]*	40,4	39,1	40,5	40,8	39,8	38,9
L_{max} (2) *[dB(A)]*	70,4	71,8	63,3	64,3	54,7	65,7
L_1 (3) *[dB(A)]*	60,2	57,1	49,6	58,4	46,7	54,8
L_{10} (3) *[dB(A)]*	49,6	47,5	45,5	51,3	42,3	43,9
L_{50} (3) *[dB(A)]*	43,9	42,7	43,1	43,9	41,1	41,4
L_{90} (3) *[dB(A)]*	42,4	41,1	41,6	42,1	40,5	40,0
L_{99} (3) *[dB(A)]*	41,1	39,9	41,1	41,4	40,1	39,3

(1) Minimalni nivo buke u posmatranom vremenskom intervalu
(2) Maksimalni nivo buke u posmatranom vremenskom intervalu
(3) N % nivo buke L_N (N=1, 10, 50, 90 i 99) u posmatranom vremenskom intervalu (nivo buke koji je premašen u N % mernog intervala)

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MERNO MESTO 2 (MT2) – KONTINUALNO MERENJE

MERNO MESTO 2: Na severnoj strani poseda, prema farmaceutskom fakultetu

Merna tačka: Na udaljenosti 20m od ograde poseda, na visini 1,5 m od tla — GPS: N 44^0 44' 46,54" E 20^0 29' 43,67"

REZULTATI MERENJA NA MERNOM MESTU 1

Ref. vremenski interval	Dan 06^{00}-18^{00}		Veče 18^{00}-22^{00}		Noć 22^{00}-06^{00}	
Datum merenja	09.12	10.12	09.12	10.12	09.12	10.12
Ekvivalentni nivo L_{Aeq} *[dB(A)]*	56,6	55,7	56,9	56,4	55,3	54,7
Merodavni nivo L_{Req} *[dB(A)]*	**57**	**56**	**57**	**56**	**55**	**55**
$L_{min}^{(1)}$ *[dB(A)]*	53,7	52,5	53,3	52,6	53,9	52,6
$L_{max}^{(2)}$ *[dB(A)]*	74,3	71,5	76,8	64,6	61,1	64,0
$L_1^{(3)}$ *[dB(A)]*	62,6	59,9	57,3	61,4	58,6	57,9
$L_{10}^{(3)}$ *[dB(A)]*	57,6	56,7	56,2	58,3	56,8	56,0
$L_{50}^{(3)}$ *[dB(A)]*	55,7	55,0	54,9	55,7	55,0	54,2
$L_{90}^{(3)}$ *[dB(A)]*	54,5	53,4	54,0	54,0	54,3	53,3
$L_{99}^{(3)}$ *[dB(A)]*	53,9	52,8	53,4	53,1	54,0	53,1

(1) Minimalni nivo buke u posmatranom vremenskom intervalu
(2) Maksimalni nivo buke u posmatranom vremenskom intervalu
(3) N % nivo buke L_N (N=1, 10, 50, 90 i 99) u posmatranom vremenskom intervalu (nivo buke koji je premašen u N % mernog intervala)

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4. ZAKLJUČAK

Na osnovu merenja nivoa buke pri radu izvora buke Instituta za virusologiju, vakcine i serume Torlak, Svetog Save 25 u Beogradu, prema Pravilniku o metodama merenja buke, sadržini i obimu izveštaja o merenju buke („Službeni glasnik RS", 6poj 72/10) i *Uredbi o indikatorima buke, graničnim vrednostima, metodama za ocenjivanje indikatora buke, uznemiravanja i štetnih efekata buke u životnoj sredini (Sl. glasnik RS br. 75/10), može se zaključiti da:

- Merodavni nivoi ukupne buke na mernoj tački 1 (MT1) **NE PRELAZE** najveće dozvoljene vrednosti za **dnevni, večernji i noćni period** u ispitivanom režimu rada.
- Merodavni nivoi ukupne buke na mernoj tački 2 (MT2) **zadovoljavaju** granične vrednosti zona 3, 4 i 5, definisanih Uredbom o indikatorima buke, graničnim vrednostima, metodama za ocenjivanje indikatora buke, uznemiravanja i štetnih efekata buke u životnoj sredini (Sl. glasnik RS br. 75/10)

Merenja i izradu izveštaja izvršili: Vojislav Popović, dipl. inž. elek;

Odgovorno lice

M.P.

Vojislav Popović, dipl. inž. elek.

Kraj Izveštaja o merenju buke

Beograd, Mocartova 10 011/3422 800 011/3422 900 e-mail: buka@anahem.org

5. PRILOG
5.1 KOPIJA REŠENJA O AKREDITACIJI I OVLAŠĆENJU ZA MERENJE BUKE 5.2 KOPIJA UVERENJA O ISPRAVNOSTI MERILA

Beograd, Mocartova 10 011/3422 800 011/3422 900 e-mail: buka@anahem.org

5.1 KOPIJA REŠENJA O AKREDITACIJI I OVLAŠĆENJU ZA MERENJE BUKE

ATC

Акредитациони број/ Accreditation No 01-261
Важи од/ *Valid from*: 25.03.2021.
Замењује Обим од / *Replaces Scope dated*: 30.03.2020.

Место испитивања: на терену*, на терену и у лабораторији (Београд, Моцартова 10)
Физичка и хемијска испитивања ваздух (амбијентални ваздух и ваздух у радној околини)

Р.Б.	Предмет испитивања материјал / производ	Врста испитивања/или карактеристика која се мери (техника испитивања)	Опсег мерења (где је примењиво)	Референтни документ
4.	**Ваздух** Ваздух у радној околини *наставак*	Одређивање садржаја метала и металоидних честица (Cu, Zn, Cd, Cr, Sn,Ni, Pb, Mn, Fe) (ICP)	Cu:(10-5000) mg/m³ Zn:(10-1000) mg/m³ Cd:(10-2000) mg/m³ Cr:(40-10000) mg/m³ Sn:(10-40000) mg/m³ Ni: (100-5000) mg/m³ Pb: (50-20000) mg/m³ Mn:(10-3000) mg/m³ Fe: (30-5000) mg/m³	OSHA METHOD ID-125G
		*Мерење температуре ваздуха	(-20 – +70) °C	DML 3.8:2015
		*Мерење релативне влажности ваздуха	(0 – 100) %	DML 3.8:2015
		*Мерење брзине струјања ваздуха	(0 – 5) m/s	DML 3.8:2015

Место испитивања: терен
Физичка испитивања: бука и осветљеност

Р.Б.	Предмет испитивања материјал / производ	Врста испитивања/или карактеристика која се мери (техника испитивања)	Опсег мерења (где је примењиво)	Референтни документ
5.	**Животна средина**	Мерење буке у животној средини	(20-130) dB	SRPS ISO 1996–1:2019 SRPS ISO 1996–2:2019
	Радна околина	Одређивање изложености буци у радној околини	(20-140) dB	SRPS EN ISO 9612:2016, осим т.11
6.	**Осветљеност у радној околини**	Мерење дневног и електричног осветљења	(0-1000) lx	SRPS U.C9.100:1962 - *повучен*

Beograd, Mocartova 10 011/3422 800 011/3422 900 e-mail: buka@anahem.org

Република Србија
МИНИСТАРСТВО
ЗАШТИТЕ ЖИВОТНЕ СРЕДИНЕ
Број: 353-01-00105/2022-03
Датум: 07.02.2022. године
Београд

На основу чл. 25. Закона о заштити од буке у животној средини ("Сл. гласник РС", бр. 96/2021), чл. 136. и 141. став 2. Закона о општем управном поступку („Службени гласник РС", бр. 18/16 и 95/18-аутентично тумачење), чл. 6. став 1. и 39. став 1. тачка 4) Закона о министарствима („Службени гласник РС", број 128/20), као и чл. 23. став 2. и 24. став 3. Закона о државној управи („Службени гласник РС", бр. 79/05, 101/07, 95/10, 99/14, 30/18 - др. закон и 47/18), решавајући по захтеву Анахем д.о.о, Моцартова 10, 11160 Београд, Министарство заштите животне средине, државни секретар Александар Дујановић по овлашћењу број: бр. 021-01-13/1/2021-09 од 22.07.2021. године, доноси:

Р Е Ш Е Њ Е

1. **УТВРЂУЈЕ СЕ** да Анахем д.о.о, Моцартова 10, 11160 Београд, **испуњава прописане услове да врши мерење буке у животној средини.**

2. **ОВЛАШЋУЈУ СЕ:**
   1. Војислав Поповић, дипл. инжењер електротехнике,
   2. Немања Бојковић, мастер инжењер заштите животне средине,
   3. Владимир Марковић, дипл. инжењер технологије,

   запослени у Анахем д.о.о, Моцартова 10, 11160 Београд, да врше мерења из тачке 1. диспозитива решења.

3. Ово решење важи четири године.

4. Овим решењем ставља се ван снаге решење Министарства заштите животне средине број 353-01-00989/2020-03 од 27.05.2020. године.

О б р а з л о ж е њ е

Анахем д.о.о, Моцартова 10, 11160 Београд, поднео је захтев Министарству заштите животне средине за овлашћивање организације за мерење буке у животној средини.

На основу захтева, приложене документације (Уверење о исправности мерила, документација о лицима за која се тражи овлашћење за мерење буке у животној средини, Извештај о мерењу буке у животној средини бр. 51102003, Сертификат о акредитацији број 01-261 од 25.03.2021. год. и Записник од 21.01.2022. године), утврђено је да Анахем д.о.о, Моцартова 10, 11160 Београд, испуњава услове да врши мерење буке у животној средини, а на основу члана 5. Правилника о условима које мора да испуњава стручна организација за мерење буке, као и о документацији која се подноси уз захтев за добијање овлашћења за мерење буке ("Службени гласник РС", бр. 72/2010), како је решено у диспозитиву.

У складу са чланом 25. став 7. Закона о заштити од буке у животној средини утврђено је да решење важи четири године. Овим решењем ставља се ван снаге решење Министарства заштите животне средине број 353-01-00989/2020-03 од 27.05.2020. године.

Поука о правном леку:

Ово решење је коначно у управном поступку и против њега се може покренути управни спор пред Управним судом у Београду у року од 30 дана од дана достављања решења.

ДРЖАВНИ СЕКРЕТАР

Александар Дујановић

5.2 KOPIJA UVERENJA O ISPRAVNOSTI MERILA

ИМС IMS INSTITUT IMS AD BEOGRAD

ATC 02-016 ЛАБОРАТОРИЈА ЗА ЕТАЛОНИРАЊЕ ISO/IEC 17025

ilac-MRA

Institut za ispitivanje materijala ad
Centar za materijale
Beograd, Bulevar vojvode Mišića 43
Metrološka laboratorija za akustiku i vibracije
Beograd, Viktora Igoa 7
tel: (011) 369-15-59
fax: (011) 369-27-72, 369-27-82
e-mail: office@institutims.rs
www.institutims.rs

UVERENJE O ETALONIRANJU

br. 7037/22

Naziv merila:	Fonometar
Proizvođač:	Bruel & Kjaer, Danska
Tip:	2250
Serijski broj:	2551226
Imalac merila:	ANAHEM D.O.O., Mocartova 10, Beograd
Broj zahteva:	41-6684 od 2. 6. 2022
Datum etaloniranja:	10. 6. 2022
Sadržaj:	Ukupno 6 strana
Napomena:	*Sastavni deo fonometra je mikrofon tip 4189, proizvođača Bruel & Kjaer, Danska, s.br. 2550210*

U Beogradu, 13. 6. 2022.

Metrološka laboratorija za akustiku i vibracije,
Rukovodilac,

mr Aleksandar Milenković, dipl.inž.

Strana 4 od 7

ИМС IMS INSTITUT IMS AD BEOGRAD

ATC 02-016 ЛАБОРАТОРИЈА ЗА ЕТАЛОНИРАЊЕ ISO/IEC 17025

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Institut za ispitivanje materijala ad
Centar za materijale
Beograd, Bulevar vojvode Mišića 43
Metrološka laboratorija za akustiku i vibracije
Beograd, Viktora Igoa 7
tel: (011) 369-15-59
fax: (011) 369-27-72, 369-27-82
e-mail: office@institutims.rs
www.institutims.rs

UVERENJE O ETALONIRANJU

br. 7039/22

Naziv merila:	Merni mikrofon 1/2"
Proizvođač:	Bruel & Kjaer, Danska
Tip:	4189
Serijski broj:	2550210
Naručilac / Imalac merila:	ANAHEM D.O.O., Mocartova 10, Beograd
Broj zahteva:	41-6684 od 2. 6. 2022.
Datum etaloniranja:	10. 6. 2022.
Sadržaj:	Ukupno 3 strane.

U Beogradu, 13. 6. 2022.

Metrološka laboratorija za akustiku i vibracije,
Rukovodilac,
mr Aleksandar Milenković, dipl.inž.

ИНСТИТУТ ИМС АД БЕОГРАД

Strana 5 od 7

Beograd, Mocartova 10 011/3422 800 011/3422 900 e-mail: buka@anahem.org

ИМС IMS INSTITUT IMS AD BEOGRAD

АТС 02-018 ЛАБОРАТОРИЈА ЗА ЕТАЛОНИРАЊЕ ISO/IEC 17025

ilac-MRA

Institut za ispitivanje materijala ad
Centar za materijale
Beograd, Bulevar vojvode Mišića 43
Metrološka laboratorija za akustiku i vibracije
Beograd, Viktora Igoa 7
tel: (011) 369-15-59
fax: (011) 369-27-72, 369-27-62
e-mail: office@institutims.rs
www.institutims.rs

UVERENJE O ETALONIRANJU

br. 7038/22

Naziv merila:	Oktavni (1/1) i tercni (1/3) filter
Proizvođač:	Bruel & Kjaer, Danska
Tip:	2250: ANALIZATOR FREKVENCIJA Napr. (0)
Serijski broj:	2551226
Naručilac / Imalac merila:	ANAHEM D.O.O., Mocartova 10, Beograd
Broj zahteva:	41-6684 od 2. 6. 2022.
Datum etaloniranja:	10. 6. 2022.
Sadržaj:	Ukupno 6 strana
Napomena:	*Filteri su sastavni deo fonometra tip 2250, proizvođača Bruel & Kjaer, Danska, s.br. 2551226*

U Beogradu, 13. 6. 2022.

Metrološka laboratorija za akustiku i vibracije,
Rukovodilac,
mr Aleksandar Milenković, dipl.inž.

ИНСТИТУТ ИМС А.Д. 1 БЕОГРАД

ИМС IMS INSTITUT IMS AD BEOGRAD

ATC 02-016 ЛАБОРАТОРИЈА ЗА ЕТАЛОНИРАЊЕ

ilac-MRA

Institut za ispitivanje materijala ad
Centar za materijale
Beograd, Bulevar vojvode Mišića 43
Metrološka laboratorija za akustiku i vibracije
Beograd, Viktora Igoa 7
tel: (011) 369-15-59
fax: (011) 369-27-72, 369-27-82
e-mail: office@institutims.rs
www.institutims.rs

UVERENJE O ETALONIRANJU

br. 7040/22

Naziv merila:	Kalibrator zvuka
Proizvođač:	Bruel & Kjaer, Danska
Tip:	4231
Serijski broj:	2147255
Naručilac / Imalac merila:	ANAHEM D.O.O., Mocartova 10, Beograd
Broj zahteva:	41-6684 od 2. 6. 2022.
Datum etaloniranja:	10. 6. 2022.
Sadržaj:	Ukupno 3 strane.

U Beogradu, 13. 6. 2022.

Metrološka laboratorija za akustiku i vibracije,
Rukovodilac,

mr Aleksandar Milenković, dipl.inž.

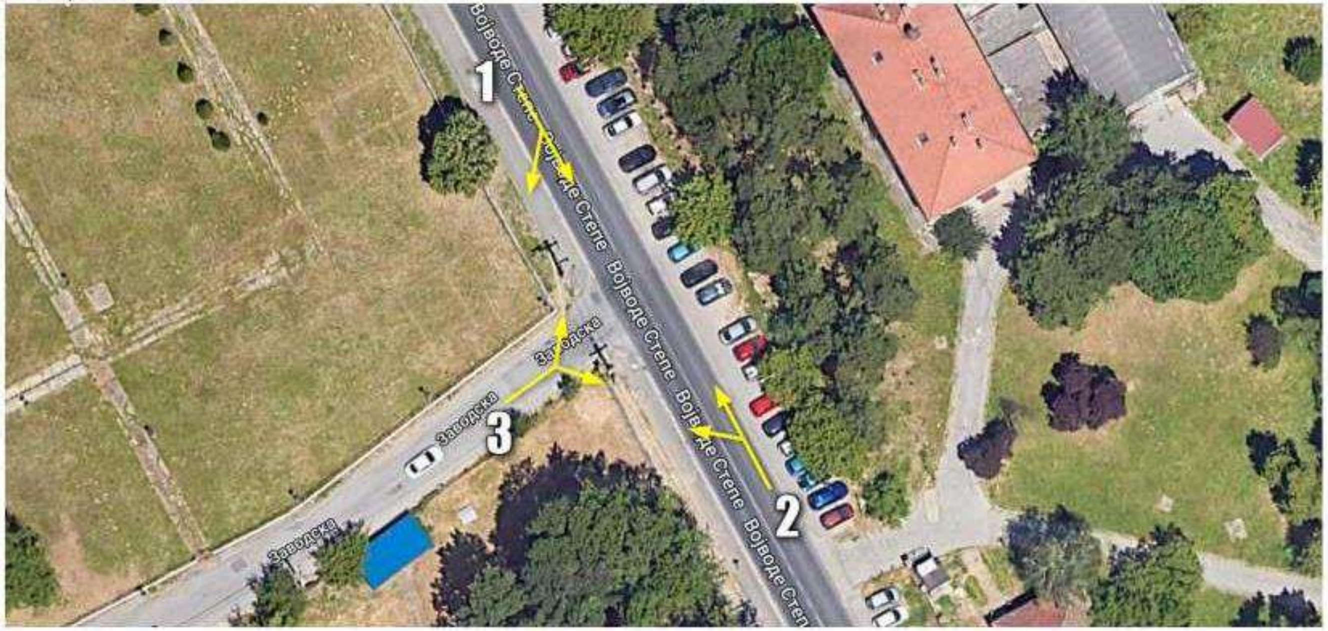
APPENDIX F-III

Report on Traffic Counting

Наручилац: ENACTA LTD BELGRADE	РУЧНО БРОЈАЊЕ ДИНАМИЧКОГ САОБРАЋАЈА	БРОЈ: 04 - 204
	САТНА ДИСТРИБУЦИЈА ВОЗИЛА	ДАТУМ: 28.12.2022.

Ознака пута	ID деоница	ЛОКАЦИЈА	Први дан бројања	Други дан бројања	Број налога	Обрада
-	-	Раскрсница / Војводе Степе - Заводска	22.12.2022.	24.12.2022.	01 / 2022	inženjering

ЛОКАЦИЈА БРОЈАЊА



Наручилац: ENACTA LTD BELGRADE	РУЧНО БРОЈАЊЕ ДИНАМИЧКОГ САОБРАЋАЈА	БРОЈ: 04 - 204
	САТНА ДИСТРИБУЦИЈА ВОЗИЛА	ДАТУМ: 28.12.2022.

Ознака пута	ID деоница	ЛОКАЦИЈА	Први дан бројања	Други дан бројања	Број налога	Обрада
-	-	Раскрсница / Војводе Степе - Заводска	22.12.2022.	24.12.2022.	01 / 2022	tm inženjering

ПРВИ ДАН БРОЈАЊА – РАДНИ ДАН | ЧЕТВРТАК 22.12.2022.

САТНА ДИСТРИБУЦИЈА ВОЗИЛА

Дан	Сат	1 - 2	1 - 3	2 - 1	2 - 3	3 - 1	3 - 2	УКУПНО	инт.слеђ. (s)
		Бр. возила	Бр. возила	Бр. возила	Бр. возила	Бр. возила	Бр. возила		
22.12.2022.	[06:00-07:00]	100	15	398	15	27	8	**563**	6,39
22.12.2022.	[07:00-08:00]	136	24	441	24	70	24	**719**	5,01
22.12.2022.	[08:00-09:00]	160	20	333	31	35	12	**591**	6,09
22.12.2022.	[09:00-10:00]	222	39	319	80	92	31	**783**	4,60
22.12.2022.	[10:00-11:00]	247	21	308	33	45	12	**666**	5,41
22.12.2022.	[11:00-12:00]	182	16	275	75	68	26	**642**	5,61
22.12.2022.	[12:00-13:00]	200	14	293	34	49	9	**599**	6,01
22.12.2022.	[13:00-14:00]	195	30	254	56	52	13	**600**	6,00
22.12.2022.	[14:00-15:00]	251	21	337	69	63	18	**759**	4,74
22.12.2022.	[15:00-16:00]	424	33	437	38	31	13	**976**	3,69
22.12.2022.	[16:00-17:00]	404	60	333	16	32	43	**888**	4,05
22.12.2022.	[17:00-18:00]	370	61	363	55	58	24	**931**	3,87
22.12.2022.	[18:00-19:00]	318	17	364	33	21	13	**766**	4,70
22.12.2022.	[19:00-20:00]	312	17	262	13	32	9	**645**	5,58
22.12.2022.	**[06:00-20:00]**	**3.521**	**388**	**4.717**	**572**	**675**	**255**	**10.128**	**4,98**

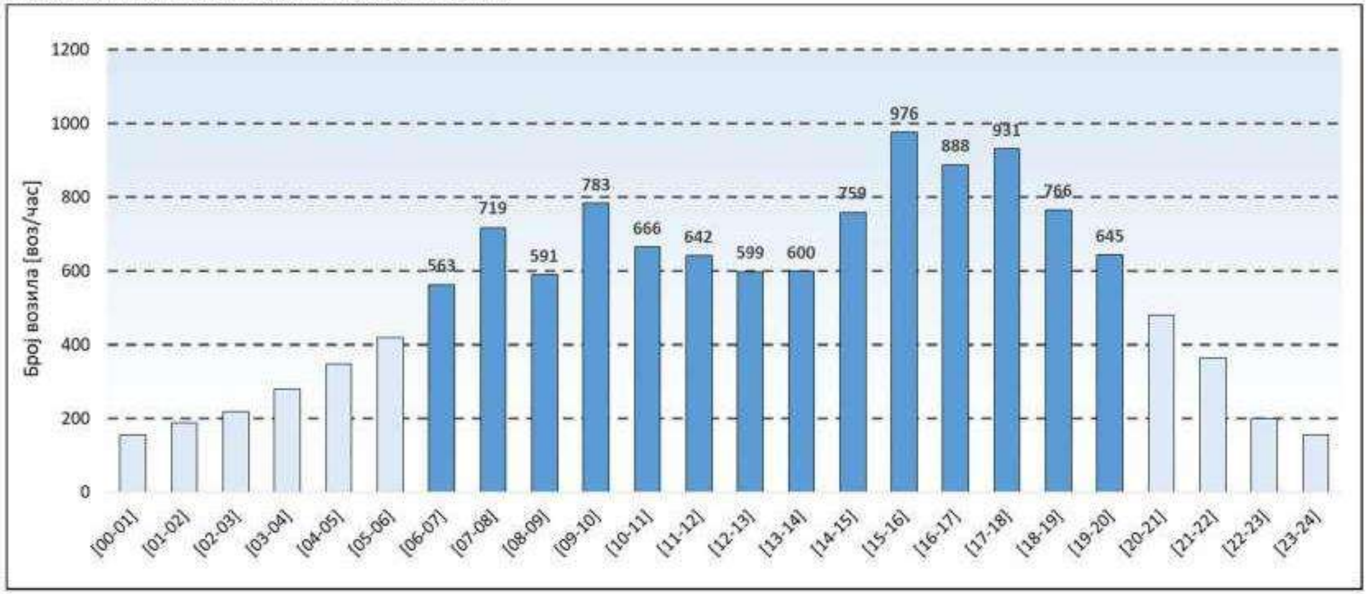
Напомена:
Табела се односи на укупан број возила по свим категоријама.
Ознаке 1 – 2, 1 – 3, и остале, представљају смерове кретања возила, нпр. број возила из крака 1 у крак 2 и тако редом.
Интервал слеђења представља просечан временски период између наиласка два узастопна возила на раскрсници, изражен у секундама

Наручилац:	РУЧНО БРОЈАЊЕ ДИНАМИЧКОГ САОБРАЋАЈА	БРОЈ: 04 - 204
enACTA ENACTA LTD BELGRADE	САТНА ДИСТРИБУЦИЈА ВОЗИЛА	ДАТУМ: 28.12.2022.

Ознака пута	ID деоница	ЛОКАЦИЈА	Први дан бројања	Други дан бројања	Број налога	Обрада
-	-	Раскрсница / Војводе Степе - Заводска	22.12.2022.	24.12.2022.	01 / 2022	tm inženjering

ПРВИ ДАН БРОЈАЊА – РАДНИ ДАН | ЧЕТВРТАК 22.12.2022.

ГРАФИЧКИ ПРИКАЗ САТНЕ ДИСТРИБУЦИЈЕ ВОЗИЛА

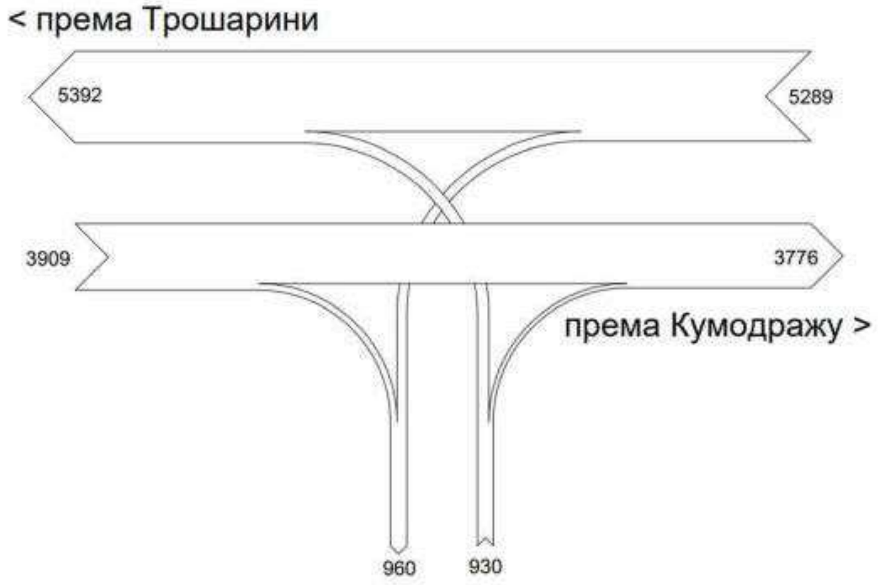


Наручилац:		РУЧНО БРОЈАЊЕ ДИНАМИЧКОГ САОБРАЋАЈА	БРОЈ: 04 - 204
enACTA	ENACTA LTD BELGRADE	САТНА ДИСТРИБУЦИЈА ВОЗИЛА	ДАТУМ: 28.12.2022.

Ознака пута	ID деоница	ЛОКАЦИЈА	Први дан бројања	Други дан бројања	Број налога	Обрада
-	-	Раскрсница / Војводе Степе - Заводска	22.12.2022.	24.12.2022.	01 / 2022	tm inženjering

ПРВИ ДАН БРОЈАЊА – РАДНИ ДАН | ЧЕТВРТАК 22.12.2022.

САОБРАЋАЈНА СЛИКА

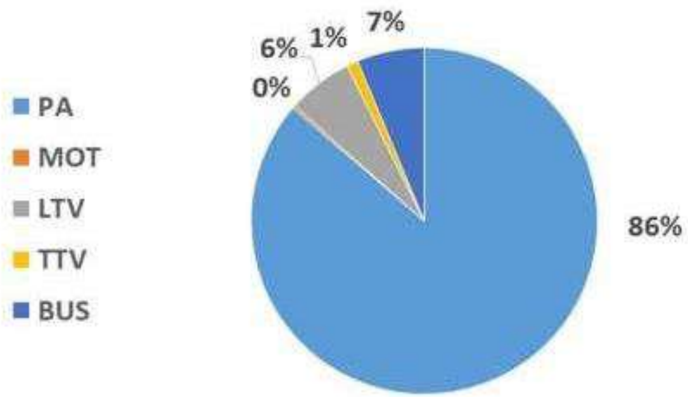


Наручилац: ENACTA LTD BELGRADE	РУЧНО БРОЈАЊЕ ДИНАМИЧКОГ САОБРАЋАЈА	БРОЈ: 04 - 204
	САТНА ДИСТРИБУЦИЈА ВОЗИЛА	ДАТУМ: 28.12.2022.

Ознака пута	ID деоница	ЛОКАЦИЈА	Први дан бројања	Други дан бројања	Број налога	Обрада
-	-	Раскрсница / Војводе Степе - Заводска	22.12.2022.	24.12.2022.	01 / 2022	tm inženjering

ПРВИ ДАН БРОЈАЊА – РАДНИ ДАН | ЧЕТВРТАК 22.12.2022.

СТРУКТУРА САОБРАЋАЈНОГ ТОКА



PUTNIČKI AUTOMOBIL	MOTOCIKL	LTV - LAKO TERETNO VOZILO	TTV - TEŠKO TERETNO VOZILO	BUS - AUTOBUS

Наручилац:		РУЧНО БРОЈАЊЕ ДИНАМИЧКОГ САОБРАЋАЈА	БРОЈ: 04 - 204
enACTA	ENACTA LTD BELGRADE	САТНА ДИСТРИБУЦИЈА ВОЗИЛА	ДАТУМ: 28.12.2022.

Ознака пута	ID деоница	ЛОКАЦИЈА	Први дан бројања	Други дан бројања	Број налога	Обрада
-	-	Раскрсница / Војводе Степе - Заводска	22.12.2022.	24.12.2022.	01 / 2022	inženjering

ДРУГИ ДАН БРОЈАЊА – НЕРАДНИ ДАН | СУБОТА 24.12.2022.

САТНА ДИСТРИБУЦИЈА ВОЗИЛА

Дан	Сат	1 - 2	1 - 3	2 - 1	2 - 3	3 - 1	3 - 2	УКУПНО	инт.слеђ. (s)
		Бр. возила	Бр. возила	Бр. возила	Бр. возила	Бр. возила	Бр. возила		
24.12.2022.	[06:00-07:00]	150	13	155	14	4	4	**340**	10,59
24.12.2022.	[07:00-08:00]	62	15	139	32	13	9	**270**	13,33
24.12.2022.	[08:00-09:00]	110	51	135	17	15	18	**346**	10,40
24.12.2022.	[09:00-10:00]	176	8	216	13	5	1	**419**	8,59
24.12.2022.	[10:00-11:00]	85	2	166	10	0	4	**267**	13,48
24.12.2022.	[11:00-12:00]	62	6	160	1	5	5	**239**	15,06
24.12.2022.	[12:00-13:00]	107	12	208	10	9	1	**347**	10,37
24.12.2022.	[13:00-14:00]	135	14	166	2	12	15	**344**	10,47
24.12.2022.	[14:00-15:00]	138	20	192	11	3	15	**379**	9,50
24.12.2022.	[15:00-16:00]	175	5	219	7	2	14	**422**	8,53
24.12.2022.	[16:00-17:00]	112	10	215	9	6	5	**357**	10,08
24.12.2022.	[17:00-18:00]	151	15	224	8	0	16	**414**	8,70
24.12.2022.	[18:00-19:00]	96	15	151	8	2	4	**276**	13,04
24.12.2022.	[19:00-20:00]	137	7	140	2	3	9	**298**	12,08
24.12.2022.	**[06:00-20:00]**	**1.696**	**193**	**2.486**	**144**	**79**	**120**	**4.718**	**10,68**

Напомена:
Табела се односи на укупан број возила по свим категоријама.
Ознаке 1 – 2, 1 – 3, и остале, представљају смерове кретања возила, нпр. број возила из крака 1 у крак 2 и тако редом.
Интервал слеђења представља просечан временски период између наиласка два узастопна возила на раскрсници, изражен у секундама

Наручилац:		РУЧНО БРОЈАЊЕ ДИНАМИЧКОГ САОБРАЋАЈА	БРОЈ: 04 - 204
enACTA	ENACTA LTD BELGRADE	САТНА ДИСТРИБУЦИЈА ВОЗИЛА	ДАТУМ: 28.12.2022.

Ознака пута	ID деоница	ЛОКАЦИЈА	Први дан бројања	Други дан бројања	Број налога	Обрада
-	-	Раскрсница / Војводе Степе - Заводска	22.12.2022.	24.12.2022.	01 / 2022	tm inženjering

ДРУГИ ДАН БРОЈАЊА – НЕРАДНИ ДАН | СУБОТА 24.12.2022.

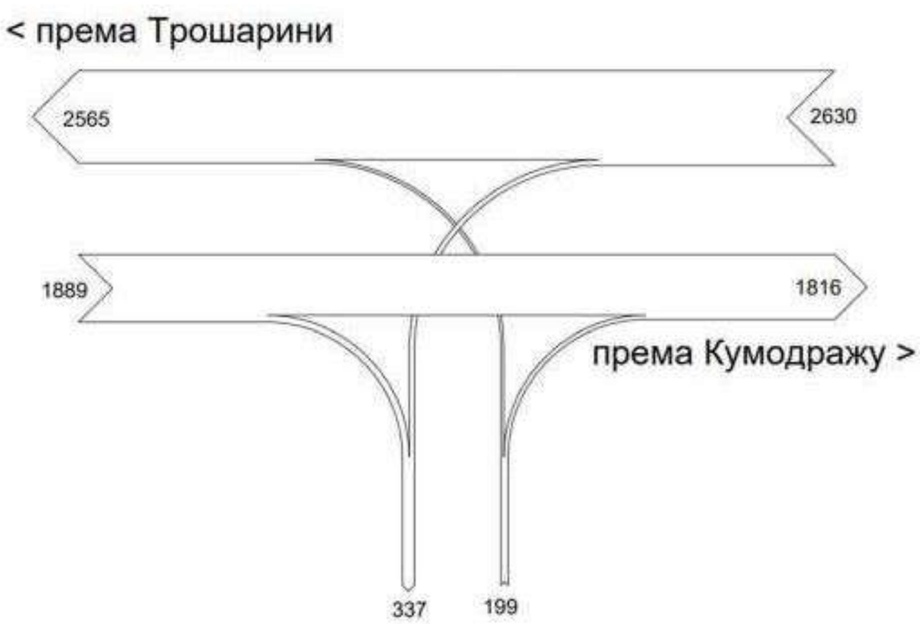
ГРАФИЧКИ ПРИКАЗ САТНЕ ДИСТРИБУЦИЈЕ ВОЗИЛА

Наручилац: ENACTA LTD BELGRADE	РУЧНО БРОЈАЊЕ ДИНАМИЧКОГ САОБРАЋАЈА	БРОЈ: 04 - 204
	САТНА ДИСТРИБУЦИЈА ВОЗИЛА	ДАТУМ: 28.12.2022.

Ознака пута	ID деоница	ЛОКАЦИЈА	Први дан бројања	Други дан бројања	Број налога	Обрада
-	-	Раскрсница / Војводе Степе - Заводска	22.12.2022.	24.12.2022.	01 / 2022	tm inženjering

ДРУГИ ДАН БРОЈАЊА – НЕРАДНИ ДАН | СУБОТА 24.12.2022.

САОБРАЋАЈНА СЛИКА

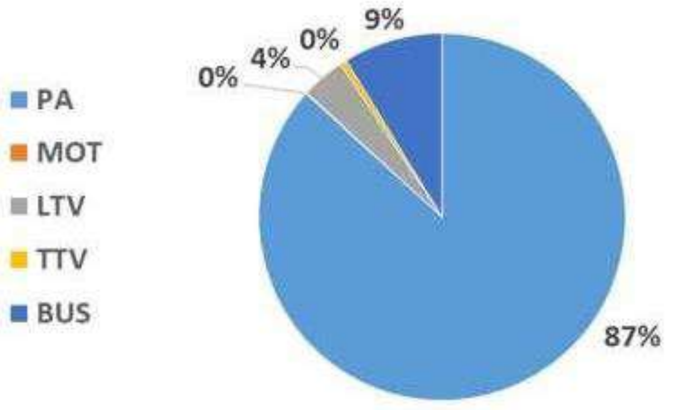


Наручилац: ENACTA LTD BELGRADE	РУЧНО БРОЈАЊЕ ДИНАМИЧКОГ САОБРАЋАЈА	БРОЈ: 04 - 204
	САТНА ДИСТРИБУЦИЈА ВОЗИЛА	ДАТУМ: 28.12.2022.

Ознака пута	ID деоница	ЛОКАЦИЈА	Први дан бројања	Други дан бројања	Број налога	Обрада
-	-	Раскрсница / Војводе Степе - Заводска	22.12.2022.	24.12.2022.	01 / 2022	tm inženjering

ДРУГИ ДАН БРОЈАЊА – НЕРАДНИ ДАН | СУБОТА 24.12.2022.

СТРУКТУРА САОБРАЋАЈНОГ ТОКА



PUTNIČKI AUTOMOBIL	MOTOCIKL	LTV - LAKO TERETNO VOZILO	TTV - TEŠKO TERETNO VOZILO	BUS - AUTOBUS

APPENDIX G

Decontamination with Hydrogen Peroxide

DECONTAMINATION WITH VAPORIZED HYDROGEN PEROXIDE

Gaseous Decontamination

Gaseous decontamination is typically utilized in high containment zones under specific conditions (e.g., after a spill or accidental release of infectious material or toxins, prior to the removal of large equipment, prior to maintenance work on contaminated systems, and prior to retesting HVAC control systems). Gaseous decontamination of rooms typically necessitates hazardous chemicals (such as formaldehyde, vaporized hydrogen peroxide (VHP), chlorine dioxide (ClO_2), and ethylene oxide). Therefore, it is essential that gaseous decontamination be performed by personnel who have been trained in the procedure and the use of appropriate PPE, such as respiratory protection. The two-person rule (also known as a "buddy system"), which requires the constant presence of two authorized and trained individuals, pertains to this procedure. Prior to gaseous decontamination, it is recommended that the room or laboratory be tested for leakage with a tracer gas, such as mint, in order to identify and mitigate leaks.

VHP is an oxidizing agent effective against a variety of pathogens, including bacterial organisms. This method of decontamination does not produce hazardous byproducts, as VHP is decomposed into non-toxic oxygen and water. VHP is compatible with a wide variety of materials and coatings; however, it has been demonstrated that it is incompatible with natural rubbers, certain plastics, and paints. Recent advancements in VHP technology have enabled the decontamination of ever-larger spaces, from tiny pass-through chambers to 280 m^3 (10 000 cubic feet) and beyond.

In the case of VHP fumigation, the required parameters are autonomously generated by commercially available gas generators such as PEA-Geschko, STERIS VHP 1000ED, and Bioquell Clarus Z-2. The generators may be either mobile or integrated into the laboratory. A further advantage of utilizing VHP gas generators is that this method is eco-friendly because its technical requirements are simple to meet, even at room temperature. H2O2 is injected at the duct blower outflow using the VHP fumigation cycle (24 total hours), which was programmed to include three operational phases: conditioning, decontamination, and aeration (refer to STERIS VHP 1000ED). Hydrogen peroxide can traditionally be vaporized and used to decontaminate glove cases and laboratory room areas. At concentrations ranging from 0.5 mg/L to 10 mg/L, vapor phase hydrogen peroxide has been proven to be an effective sporicide. The optimal concentration of this agent is approximately 2.4 mg/L with at least one hour of contact time. This system is capable of decontaminating glove cases, walk-in incubators, and small spaces. An advantage of this system is that the end products (i.e., water) are not toxic. Low relative humidity can be used[36,37,38,39].

Preparation of the laboratory

Prior to decontaminating the BSL-3 facility, a technical expert evaluates and validates the VHP decontamination protocol with regards to the HVAC project and the laboratory equipment.

Prior to executing gaseous decontamination, all surfaces must be cleaned to remove superficial organic matter and dirt so that the gas can effectively contact all surfaces. VHP decontamination in particular requires a spotless surface due to the lack of penetrating power of these particles. Placing biological indicators in various locations, such as those that are difficult for gas to reach or penetrate (e.g., corners, drawers, fissures), allows for the evaluation of the efficacy of the gaseous decontamination procedure. Chemical indicators can be used in conjunction with biological indicators to immediately affirm that the gas has spread to all targeted areas, but the area is not considered decontaminated until the results of the biological indicators are known. The VHP decontamination system is evaluated using biological indicators (BIs) with endospore surrogates (Geobacillus stearothermophilus, Bacillus atrophaeus, and Bacillus thuringiensis) in a BSL-3 laboratory and a material airlock[40,41,42,43].

Prior to decontamination with hydrogen peroxide, freezers and the emergency door are hermetically sealed with tape; computers and microscopes are disinfected by hand and wrapped in plastic bags; and Biological Safety Cabinets (BSCs) are turned on with the front shield exposed. In addition, incubator and centrifuge doors are left apart, power plug lids, drawers, cabinets, and inner laboratory doors are unsealed, and negative pressure and ventilation are turned off in the BSL-3 laboratory.

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[36] Johnson JW, Arnold JF, Nail SL, Renzi E. (1992). Vaporized hydrogen peroxide sterilization of freeze dryers. J Parenter Sci Technol. 46(6):215-25

[37] Krause J, McDonnell G, Riedesek H. (2001). Biodecontamination of animal rooms and heat-sensitive equipment with vaporized hydrogen peroxide. Contemp Top Lab Anim Sci. 40(6):18-21.

[38] Graham GS, Rickloff JR. (1992). Development of VHP sterilization technology. J Healthc Mater Manage. 10(8)54, 56-8.

[39] Czarneski MA. (2009). Microbial decontamination of a 65-room new pharmaceutical research facility. Applied Biosafety. 14(2):81-88

[40] National Standards Foundation (NSF). (2014). NSF/ANSI 49-2014 Annex K – Protocol for the Validation of Alternate Biosafety Cabinet Decontamination Methods and Agents. Ann Arbour, MI, USA: National Sanitation Foundation / American National Standards Institute.

[41] Lewis, C., Batdorf, N., Klinedinst, K. Dabisch, P., & Pitt, L. (2011). Efficacy of Vaporous Hydrogen Peroxide Against Bacillus atrophaeus and Bacillus anthracis Spores. Fort Detrick, MD, USA: Center for Aerobiological Sciences, United States Army Medical Research Institute of Infectious Diseases.

[42] Luftman, H. S., & Regits, M. A. (2008). *B. Atrophaeus and G. Stearothermophilus* Biological Indicators for Chlorine Dioxide Gas Decontamination. *Applied Biosafety*. 13(3):143-157

[43] Falaise, C., Bouvattier, C., Larigauderie, G., Lafontaine, V., Berchebru, L., Marangon, A., Vaude-Lauthier, V., Raynaud, F. and Taysse, T. (2022). Hydrogen Peroxide Vapor Decontamination of Hazard Group 3 Bacteria and Viruses in a Biosafety Level 3 Laboratory Applied Biosafety 27, 15-22.

In accordance with the validated protocol, gas hoses are set out inside the laboratory rooms, and an even distribution of the hydrogen peroxide vapour is achieved by placing rotating fans in the open doors. As few hoses as possible contacted the ground to prevent hydrogen peroxide condensation on the floor, which is several degrees cooler than the room air (see. Figure-1).

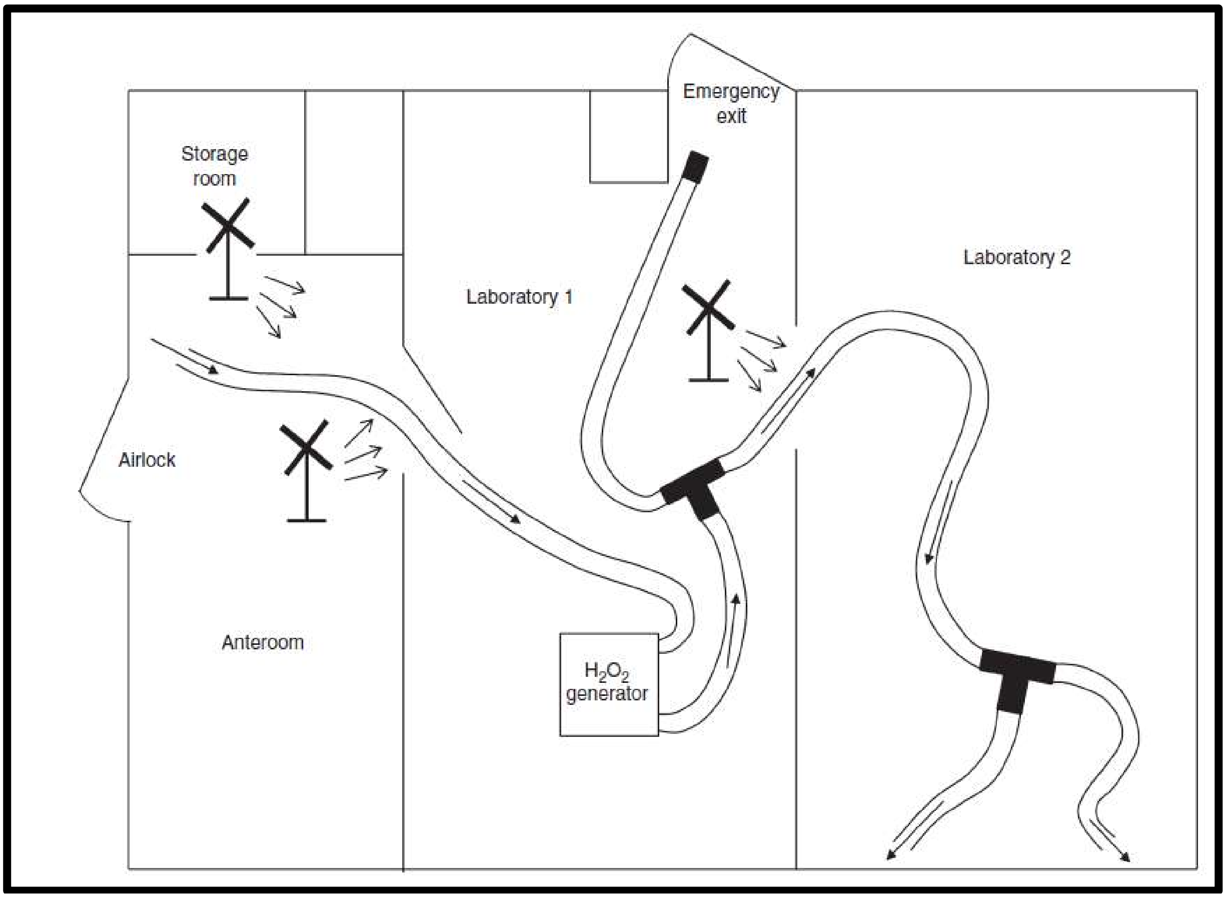

Figure-1. Schematic of BSL3 laboratory rooms with preparations for VHP decontamination[44]

The gas generator is installed in Laboratory 1, and hoses are arranged as described in the figure. The arrows indicate the direction of the gas flow, which indicates that hydrogen peroxide vapours were expelled into Laboratory 2 and evenly dispersed by three revolving fans installed in the open doorways. The generator is recirculated room air via a pipe in the foyer. The short piece of hose ending in front of the emergency exit is plugged, as it is not used in this validation.

[44] O. Kaspari, K. Lemmer, S. Howaldt, H. Natterman and R. Grunow. (2014). Decontamination of a BSL3 laboratory by hydrogen peroxide fumigation using three different surrogates for Bacillus anthracis spores. Journal of Applied Microbiology. 117, 1095-1103.

APPENDIX H

Report on Public Consultations (provided as a separate document)