

TERMS OF REFERENCE

for

CONSULTING SERVICES FOR TECHNICAL CONTROL OF DESIGN DOCUMENTATION FOR CONSTRUCTION OF NEW DIAGNOSTIC BUILDING INCLUDING BSL-3 LABORATORY AT THE “TORLAK” INSTITUTE OF VIROLOGY, VACCINES AND SERA, BELGRADE

1. BACKGROUND

The Republic of Serbia has received a loan from the World Bank in the amount of EUR 92 million equivalent for the implementation of *Serbia Emergency COVID-19 Response Project*. The objectives of the Project 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.

Part of the loan proceeds will be applied to payments for goods, works, related services and consultancy services to be procured under this project.

The SECRP consists of the following components:

Component 1: Emergency COVID-19 Response

Component 2: Implementation Management and Monitoring and Evaluation

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.

Establishing a BSL-3 laboratory: The capacity at the “Torlak” Institute of Virology, Vaccines and Sera will be strengthened by establishing a laboratory which fulfils requirements for handling pathogens such as SARS-Cov2, since there is currently no facility in Serbia that can handle pathogens requiring a BSL-3 or higher. Having appropriate laboratory would enable widening the research related to detection of viral presence in air, wastewater, soil and elsewhere. Most importantly, such a laboratory would enable handling of many other pathogens that require such a level of biosafety, like yellow fever virus, West Nile virus, eastern equine encephalitis virus, SARS-CoV-1 and MERS-CoV but also different bacterial, fungal and rickettsia pathogens, thus greatly strengthening Serbia’s national laboratory system.

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

Assistance will 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, ultrasound devices, X-ray devices, computed tomography (CT) scanners and (e) X-ray devices to be installed in community health canterers.

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

The Republic of Serbia intends to apply a portion of the loan for the provision of consultancy services for technical control of the design documentation for diagnostic building including BSL-3 laboratory at the “Torlak” Institute of Virology, Vaccines and Sera, Belgrade.

2. OBJECTIVE OF THE ASSIGNMENT

The objective of the assignment is to provide technical control services of design documentation for construction permit and other documentation, as defined below.

Designs for construction permit will include: architectural design, structural design, electrical high and low voltage designs, mechanical installation design (HVAC, medical gasses), plumbing and sewage design, energy efficiency elaborate and firefighting elaborate, project of technology i.e. laboratory and medical equipment and any other documentation that may be required by the law.

The Technical control will be conducted in line with the national legislation of the Republic of Serbia and international norms and standards pertaining to laboratory facilities.

Due to specific requests regarding building construction, building services etc., technical control will also include the control of studies, elaborates, technical specifications and the bill of quantities, regardless of the fact that there is no specific requirement for technical control of that kind of documents in the applicable Serbian laws.

3. SCOPE OF WORK AND DESCRIPTIONS OF LOCATIONS

3.1 General information on locations

The “Torlak” Institute of Virology, Vaccines and Sera is a national manufacturer of high-quality, safe and effective vaccines, sera and other immunobiological products.

The Institute is one of the oldest institutions of this kind in the world, with **95** years of experience and tradition.

The Institute was founded by the Serbian Government.

- “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.
- “Torlak” Institute, as a national vaccine producer, 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
- “Torlak” Institute performs trade, i.e. the import and export of medicines, medical devices, food supplements and raw materials for the production of medicines and other devices.

A new building for diagnostic including BSL-3 level laboratory will be financed by MoH and constructed within the complex of “Torlak” institute. Capacity at the “Torlak” Institute of Virology, Vaccines and Sera will be strengthened to enable one of its laboratories to meet requirements for handling pathogens requiring BSL-3, like SARS-CoV-2, since there is currently no facility in Serbia that can handle pathogens requiring a BSL-3 or higher.

The total gross area of the new building for diagnostic including BSL-3 will be approximately 3500m². From that area, approximately 150m² will in accordance with BSL-3 requirements. Technical control shall include complete building (around 3500m²) and dedicated building services including and BSL-3 part.

BSL-3 laboratory will be used to study infectious agents or toxins that may be transmitted through the air and cause potentially lethal infections. Researchers perform all experiments in a biosafety cabinet.

BSL-3 laboratory will be designed to be easily decontaminated. As an additional safety measure, this laboratory must use controlled or “directional” air flow to ensure that air flow from non-laboratory areas (such as the hallway) into laboratory areas. Other engineered safety features include a requirement for entry through two self-closing, interlocked doors, sealed windows, floors and walls, and filtered ventilation systems. BSL-3 labs must also be equipped for decontamination of laboratory waste using an incinerator, an autoclave, and/or another method of decontamination, depending on the biological risk assessment.

In general, BSL-3 laboratories have the following containment requirements:

Laboratory practices

- Access to the laboratory is restricted when work is underway
- An Occupational Health Program exists for medical surveillance of laboratory staff. Laboratory staff are under medical surveillance and may be offered immunizations against infectious agents or toxins they work with, if available.
- Access to the laboratory is restricted and controlled at all times.

Safety equipment

- Appropriate PPE is worn, including lab coats and gloves, eye protection and face shields.
- All procedures that can cause infection from aerosols or splashes are performed within a biological safety cabinet (BSC).
- Autoclaving or alternative method of decontamination is available.
- Appropriate PPE must be worn, and respirators might be required.
- All work with infectious agents or toxins must be performed within appropriate biosafety cabinet.

Facility construction

- A hands-free sink and eyewash are available near the exit.
- The laboratory has self-closing doors
- Exhaust air cannot recirculate; laboratory must have sustained directional airflow and air must flow into the
- laboratory from clean areas towards potentially contaminated areas.

3.2 Scope of work

The Consultant shall conduct technical control services of the detailed designs for new building for diagnostic including BSL-3 level laboratory verifying and accepting the detailed design documentation.

Technical control services will be performed prior, during and after the development of design documentation in order to make the verification process more efficient. It will include, but not be limited, to:

- a. Verification of design documentation for construction permits;
- b. Assessment of the adequate conditions for building foundations;
- c. Verification of correctness and accuracy of applied technical and technological solutions and construction means and methods;
- d. Stability and safety;
- e. Rationality of recommended materials;
- f. Compatibility with the national law and other international regulations, technical norms, standards and quality norms.

Technical control services will be performed simultaneously with the development of design documentation in order to make the verification process more efficient.

The scope of the technical control services for the subject location described above shall include, but will not be limited to:

3.2.1 Verification of design documentation for construction permits¹, including the following:

- Design documentation compliance with elaborates and studies which will be part of design documentation i.e. firefighting elaborate, energy efficiency elaborate, any other elaborate that may be required by the law;
- Design documentation compliance with all designing inputs (Terms of Reference, geotechnical researches, geodetic layouts etc.);
- Design documentation compliance with local and international norms and standards pertaining to laboratory facilities i.e. but not limited to Good Laboratory Practice (GLP); WHO Laboratory Bio-Safety Manual (LBM), fourth edition, 2020; WHO Bio risk Management: Laboratory Biosecurity Guidance, 2006, WHO/CDS/EPR/2006.6, ISO 35001: 2009 Bio-risk Management for Laboratories.
- Internal compliance of the designs within technical documentation;
- Compliance of technical documentation for the construction permit with recommended measures contained in the Studies, Elaborates or Projects (i.e. Environmental and Social Impact Assessment (ESIA) and its Environmental and Social Management Plan (ESMP), required by the relevant laws pertaining to construction of laboratory facilities.

3.2.3 Verification of firefighting elaborate and energy efficiency elaborate.

3.2.4 Verification of the bill of quantities and technical specifications:

³ According to the Law on Planning and Construction ("Official Gazette of RS" No. 72/09, 81/09, 64/10, 24/11, 121/12, 42/13, 53/13, 98/13, 132/14 and 145/14) and Rulebook on content, procedure and method of carrying out control of technical documentation by class and purpose of objects ("Official Gazette of RS" No. 23/15 and 77/15) and Official Gazette of RS" No. 73/2019

- Verification of the compliance between the design for construction permit and the bill of quantities;
- Verification of the compliance between the design for construction permit and technical specifications;
- Verification of the compliance between technical specifications and applicable laws, norms and standards;
- Verification of technical specifications and the bill of quantities' comprehensiveness, quality and sufficient level of details.
- Verification of materials planned to be used which should be up-to-date, hi-tech, and durable; choice of materials should be done in accordance with specific working environments in the new building laboratories including these in BSL-3 level: irradiation, toxic, caustic and chemically aggressive substances;

4. DELIVERABLES

- (i) Technical Control Reports (one report per location) - shall be prepared in line with the Rulebook on Content, Procedure and Method for Carrying out Control of Technical Documentation by Class and Purpose of Objects. Technical Control Report shall be prepared in line with the Law on Planning and Construction ("Official Gazette of RS" No. 72/09, 81/09, 64/10, 24/11, 121/12, 42/13, 53/13, 98/13, 132/14 and 145/14) and the Rulebook on Content, Procedure and Method for Carrying out Control of Technical Documentation by Class and Purpose of Objects ("Official Gazette of RS" No. 23/15 and 77/15) and shall be integral part of the project for building permit.
- (ii) Reports on elaborate verification;
- (iii) Reports on the bill of quantities and technical specifications verifications;
- (iv) Report on design compliance with the project of the Environmental and Social Impact Assessment (ESIA) and its Environmental and Social Management Plan (ESMP);
- (v) Any other report as required by the Client.

All reports shall be signed by responsible designers.

All documentation shall be presented in 3 (three) hard copies and 1 (one) electronic copy with non-editable files (in PDF format) and editable files, including an electronic (digital) version in common software (doc. files) application. With a view to obtaining the Client's approval, all reports must be presented to the Client in the Serbian language.

The Consultant shall be prepared for the new procedure set out in the new regulation on the electronic delivery of documentation to local authorities for the purpose of obtaining permits and approval

5. CONSULTANT CHARACTERISTICS AND REQUIRED QUALIFICATIONS

- 5.1 Prior to contract signing, the Consultant shall be registered in the Republic of Serbia as a company specialized in architectural/civil/mechanical engineering design;
- 5.2 The Consultant shall have experience in the development of Design for construction permit or technical control or construction supervision of at least: one (1) facility for

accommodation of BSL-3 laboratory, and (ii) three (3) buildings of at least 3500m², in the last ten (10) years.

- 5.3 The Consultant shall have at least one employed licensed architectural engineer and a licensed civil engineer (employed on a full-time or a part-time basis);
- 5.4 The Consultant shall have at least one employed engineer with experience in the development of design or technical control or construction of at least one BSL-3 laboratory in the last five years.
- 5.5 The Consultant shall engage licensed engineers for each part of the technical documentation, as required by the relevant law (i.e. mechanical, electrical (high and low voltage, including fire detection), plumbing, roads and fire protection). Engineers can be employed or subcontracted (contract with availability details is obligatory);
- 5.6 All engaged engineers shall have at least 5 years of experience in their field of expertise;
- 5.7 Prior to contract signing, all proposed engineers must be licensed by the Serbian Chamber of Engineers, in accordance with the Serbian Law on Planning and Construction.

6. TIMETABLE

The expected duration of the assignment is 6 weeks.

Technical control services will be performed simultaneously with the development of design documentation in order to make verification process more efficient. Technical services shall be finished (all reports delivered) one week after the design documentation submission to the Client (by previously selected designing company).