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LIST OF ABBREVIATIONS

DRG-s  Diagnostic Related Group System
EA  Environmental Assesment
e-HDF  e-Health Development Framework
EIA  Environmental Impact Assesment
EMFD  Environmental Management Framework Document
EMP  Environmental Management Plan
EU  European Union
HIF  Health Insurance Fund
HTA  Health Technology Assistant
LINAC  Linear Accelerator
OP  Operational Policy
PCF  Primary Care Facilities
RDNEIA  Request for Decision about Need for Environmental Impact Assessment
SH2P  Serbian Health 2 Project
T2DM  Type 2 Diabetes Mellitus
WB  The World Bank
WMP  Waste Management Plan
μSv  microsievert
EXECUTIVE SUMMARY

The Government of Serbia has requested a support from the World Bank in implementation of the Serbian Health 2 Project (SH2P). The main objectives of the Project are to strengthen the health financing systems by improving incentives for efficiency and quality in provider payments for primary and hospital care, and build management capacity to respond to these incentives. The other aims of the Project are to: improve efficiency of purchasing of health products by institutionalizing centralized procurement of pharmaceuticals, medical supplies, diagnostic reagents and medical devices; strengthening institutions and capacity to improve the quality of service delivery; strengthen facility accreditation, and enhancing quality monitoring and use of data for quality improvement; and to modernize cancer treatment at selected tertiary hospitals. The Project of the Ministry of Health Republic of Serbia will be implemented over five years, and will include the following five components: Component 1 – Health Financing; Component 2 – Efficient Purchasing of Health Products; Component 3 – Quality of Service Delivery; Component 4 – Modernizing Tertiary Cancer Treatment; and Component 5: Monitoring, Evaluation, and Project Management.
1. DESCRIPTION OF PROJECT COMPONENTS INCLUDING DESCRIPTION OF TYPE OF ACTIVITIES ELIGIBLE FOR FINANCING

1.1 Background

The current situation in the Health care system in Republic of Serbia is complicated considering the efficiency of primary and hospital care, and the situation with the purchase and installation of high-tech medical equipment, as well as hospital staff training. The prevention of most common diseases and the enhancement of the healthcare quality monitoring and use of data for healthcare quality improvement will be one of the goals to attain. By improving the efficiency and quality of the Health financing system most of the weaknesses of the health care system will be remedied.

1.2 Project description

Four components SH2P will be proposed by the Ministry of Health, with support of the World Bank, with the budget of 40 million of US dollars.

Component 1: Improving Health Financing (US$7.6 million)

This component will support reforms to improve the quality, efficiency, and transparency of HIF financing for primary care and hospitals. The component will finance technical assistance, training, goods and equipment to support the design and implementation of incentives and oversee results; finance initial piloting of a quality improvement grants scheme to DZs; and support upgrades of information technology capacity to improve financial reporting and performance monitoring at central, hospital, and primary levels.

Sub-component 1.1: Hospital Financing Reforms (US$3.7 million)

This sub-component will support reforms to strengthen transparency of and incentives for efficiency of HIF financing for public hospitals. The major focus will be supporting the phased implementation of a Diagnostic Related Group (DRG) payment system for acute care at hospitals.

Sub-component 1.2: Primary Health Care Financing (US$3.9 million)

Primary care financing activities will seek to improve the efficiency and quality of key preventive and other primary care services tailored to the burden of disease in Serbia and to the patient profiles registered with DZ providers. This component will support technical assistance to strengthen primary health care financing systems. The grants scheme will seek to develop criteria for risk-adjusted capitation as a basis for HIF payments and to incentivize facility-level quality improvements related to priority conditions.
Component 2: Efficient Purchasing of Pharmaceuticals and Medical Products (US$7.0 million)

Activities under this component will be organized around the following main areas: support for centralized procurement of drugs and supplies through framework contracts; strengthening of Health Technology Assessment (HTA); and improving systems for medical equipment maintenance. Activities in this area will support TA, training and equipment, including a piloting of a multi-vender medical equipment maintenance contact.

Sub-component 2.1: Centralized Procurement (US$2.3 million)

This sub-component will support introduction and implementation of framework agreements to centralize the procurement of pharmaceuticals, medical supplies, diagnostic reagents and medical devices, in order to increase efficiency of expenditures. Centralized procurement is expected to produce saving up to US$ 49 million that represents 14 percent reduction of current expenditure. Centralized procurement would be implemented by HIF through a competitive tendering process for multi-source drugs, and negotiation based on reference pricing for single source drugs, with framework agreements.

In addition, this sub-component will support the development and pilot testing of: (i) an e-Prescription system for primary health centers, hospitals, HIF, HMIS, pharmacies to provide accurate and timely information on use of drugs and medical supplies, (ii) e-procurement system to support centralized procurement and purchasing by facilities based on framework prices, (iii) the development of and training in a unified IT system that will enable the HIF to monitor the in-market availability and dispensing of pharmaceuticals.

Sub-component 2.2: Health Technology Assessment (US$2.7 million)

This sub-component will support the establishment of an independent unit for HTA, which is expected to be housed as a Department within the Agency for Accreditation of Health Care Institutions of Serbia (AZUS). The unit will make recommendations on drugs and equipment to be included in the HIF reimbursement list, and decisions will be taken by a central committee composed of representatives from MoF, HIF and IPH.

Sub-component 2.3: Medical Equipment Maintenance (US$2.0 million)

This sub-component will support the improvement of the MoH maintenance system by carrying out a preliminary assessment of the current (i) distribution of medical equipment; (ii) procedures for maintenance and repairs management; (iii) costs and allocation of funds for maintenance; and (iv) procurement of spare parts and services.
Component 3: Strengthening Quality of Service Delivery (US$22.4 million)

This component aims to improve standards of quality and efficiency of care in the Serbian health sector through two main approaches: (i) strengthening quality improvement systems; and (ii) modernizing cancer management at selected tertiary facilities. This component will strengthen cross-cutting systems of performance management and information technology that are pertinent across both sub-components, and will finance goods, civil works, technical assistance, training and equipment.

Sub-component 3.1: Quality Improvement Systems (US$3.9 million)

This sub-component will strengthen quality improvement systems along three main mechanisms:

- Clinical practice guidelines and pathways. National clinical practice guidelines will be developed under this subcomponent, aligned to international evidence but closely linked with the HIF budget envelope. Additional clinical pathways will be developed to ensure coverage of key conditions that represent the main burden of disease in Serbia.

- Quality improvement support. Activities under this subcomponent will fund training and TA to be coordinated through AZUS in order to provide targeted support to DZs to improve quality of care for priority conditions.

- Improved information management. Activities under this subcomponent will improve capacity for reporting and use of information on service quality and efficiency at key institutes involved in these functions, namely the MoH, HIF and IPH.

Sub-component 3.2: Improve Cancer Management (US$18.5 million)

This sub-component will support the purchase and installation of up to five linear accelerators, together with associated equipment and civil works, to increase the coverage and quality of radiation therapy cancer treatment at specialized tertiary oncology centers. Health facilities preliminary identified as beneficiaries of the new devices include the National Institute for Oncology and Radiology in Belgrade, and two tertiary hospitals in Kragujevac and Nis. The final locations of the linear accelerators will be agreed based on a detailed assessment by MOH of existing capacity and patient distribution. This will increase total accelerators in Serbia from 14 to 19. Technical assessment by the Bank confirmed that this additional treatment capacity is needed to cope with current and projected patient volumes, particularly if cancer screening programs were to scale up in the coming years. The accelerators will be procured together with extended warranties, to ensure four years of full-capacity operation and software updates. This component will also support training and technical assistance to improve monitoring of patient outcomes, including through strengthening the national cancer registry system. In addition, Project support to improve maintenance of medical equipment is expected to reduce “downtime” of existing accelerators, which will also allow more patients to receive radiotherapy treatment.
Component 5: Monitoring, Evaluation, and Project management (US$ 3 million). This component will finance day-to-day project management, operating costs, monitoring and evaluation, including inter-alia translation, interpretation, equipment, supervision costs, staffing costs of the PIU, M&E, studies and surveys, and incremental costs at the MoH. Study tours in countries where similar reforms could be envisaged.

### 1.2.1 Medical equipment for cancer treatment

Modern linear accelerators present standard equipment in radiotherapy centers worldwide. The application of the latest scientific and technical-technological achievements in the modern medical accelerator such as linear and/or cyclotron is necessary in clinical practice in the radiotherapy of carcinoma. The cyclotron represents a sophisticated technology for radio pharmaceuticals, as well as a valuable medical diagnostic device in radiotherapy of carcinoma. The main components of the LINAC are: base, rotating tripod with the accelerator head’s, a colorimeter, therapeutic table and laser system for the patient positioning.

Patient and medical stuff safety is very important and is assured in several ways. According to the national and international recommendations for protection against ionizing radiation that these devices produce during their use, LINAC must be placed in a specially constructed room – bunker, with concrete walls thick enough to adequately attenuate the primary radiation beam, as well as secondary photon scattering. Safety of the staff operating the linear accelerator is also important. The radiation therapist must turn on the accelerator from outside the treatment room. Because the accelerator only gives off radiation when it is actually turned on, the risk of accidental exposure is extremely low.

The linear accelerators providing therapeutic energy of 15 MeV produce also a very strong ionized radiation with photons with great penetrating power. For this reason the space in which a therapeutic accelerator is located must have excellent protection. The linear accelerator sits in a room with lead and concrete walls so that the high-energy x-rays are shielded. Primary care protection is placed in order to effectively attenuate the direct photon radiation, and secondary protection reduces the radiation that exists inside the therapy room. Radiation doses for cancer treatment are measured in a unit called Gray (Gy), which is a measure of the amount of radiation energy absorbed by 1 kilogram of human tissue. Different doses of radiation are needed to kill different types of cancer cells.

While ensuring safety, it is necessary to assess the likelihood of radiation exposure factors, and actual exposure. The fundamental and most effective principle of protection is projecting walls thick enough. In order to reduce risks, investigation of neutron exposure in the use of electronic medical
accelerator is made from the very transport of neutrons to protection accelerator equipment, treatment rooms with patients and medical staff. Quality control of the linear accelerator is also very important. There are several systems built into the accelerator so that it will not deliver a higher dose than the radiation oncologist has prescribed. However, an estimated radiation dose for the controlled area is 100 μSv and 20 μSv for surrounding public spaces on a weekly basis. Places where neutrons are produced or absorbed present potential sources of residual radioactivity. A well designed protection against high-energy photons and neutrons should be counted on. Neutron protection requires materials containing hydrogen, while the anti-H materials required large air mass and atomic number. The materials widely used for the protection are: ordinary and heavy (reinforced) concrete, lead, steel, or polyethylene wax, earth and wood.

1.3 Objectives of the Environmental Management Framework Document

This Environmental Management Framework Document (EMFD) suggests general policies, guidelines, codes of practice and procedures which will be implemented into the SH2P supported by WB. The document defines the steps, processes and procedures for screening, as well as alternative analysis, assessment, monitoring and management of the environmentally-related issues. In addition, the EMFD analyzes environmental policies and legal regime of Serbia and safeguard policies of the WB; presents the institutional and capacity assessment related to the environmental management; and describes the principles, objectives and approach to be followed while designing site-specific environmental mitigation measures. The EMFD should be used as a practical tool during program formulation, design, implementation, and monitoring in the SH2P.

1.4 Approach and Methodology

The Environmental Management Framework Document outlines the environmental policy, legal, and administrative framework for undertaking the project, presents the environmental baseline information and potential environmental impacts and includes the range of available mitigation measures that may be adopted, based on each particular situation. The EMFD describes how the potential environmental impacts of the project will be managed during preparation and implementation periods. The EMFD includes a blank EMP checklist (see Annex 1).
2. OPERATING REQUIREMENTS – DIAGNOSIS OF LEGAL AND INSTITUTIONAL FRAMEWORK AND APPLICABLE SAFEGUARDS

2.1 Foreword

The legal, legislative and institutional framework for the prevention health care system and the environmental protection in Republic of Serbia is founded on the Constitution of Serbia, which stipulates the right to a healthy environment and the duty of all, in line with the law, to protect and enhance the environment. Currently, the majority of these are harmonized with EU legislation. The list of currently valid environmentally-related legislation is presented in Chapter 2.4 and 2.5 in EMFD.

2.2 Relevant information

The Ministry of Energy, Development and Environmental Protection (Mo-EDEP) is the key institution in Republic of Serbia responsible for formulation and implementation of environmental policy matters. The other aspects of environmental management related to the environmental aspects of projects are dealt with several other institutions, among which are Serbian Radiation Protection and Nuclear Safety Agency (SRPNSA), Institute for Natural Protection (INP) and Ministry of Construction and Urban Planning (Mo-CUP). The Medicines and Medicals Devices Agency of Serbia (MMDAS) has an important role in the obtaining the necessary approval for putting on the market medical equipment.

2.3 EIA procedure in the Republic of Serbia

The Environmental Impact Assessment procedure (In the legal system of the Republic of Serbia) is regulated by the Law on Environmental Impact Assessment, which is completely in line with European EIA Directive 85/337/EEC. According to that Law, preparation of the Environmental Impact Assessment is not required for the projects unless they are placed within or in the vicinity of the nature or culture protected areas. In such cases the Project Proponent is obliged to submit so-called “Request for Decision about Need for Environmental Impact Assessment” (RDNEIA) to the Mo-EDEP. Depending on the Ministry’s assessment of significance of potential environmental impacts of the project, it is decided if there is a need (or not) to apply partial or full EIA procedure for the relevant section of project. Request for opinion regarding necessity of EIA procedure for each activity which will be undertaken adjacent or within the nature/cultural protected area will be submitted to Do-EIA together with other relevant project
documentation, which mandatory include preconditions of relevant institutions in charge of the environmental protection. Additionally, since SH2P will be funded by WB, the requirements related to Operational Policy OP 4.01 Environmental Assessment, will need to be observed. According to national Law on Environmental Protection, *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 (2009)*, preparation of the Environmental Impact Assessment is not required for the project related activities that are to be undertaken within the existing hospital compounds, except for those that are under specific regime of protection as a culture heritage or nature monument.

### 2.4 Other Relevant Government Policies, Act, Rules, Strategies and Guidelines

The relevant legislative in Republic of Serbia for environmental protection and Health project are:

- The Constitution of Serbia ("Official Gazette of RS", No. 98/06)
- Law on Medicines and Medical Devices ("Official Gazette of RS", No.30/10, 30/12)
- Law of Ionizing radiation and on Nuclear Safety (“Official Gazette of RS” No 36/09, 93/12),
- Law on Environmental Protection (“Official Gazette of RS” No. 135/04, 36/09, 72/09, 43/11),
- Law on Environmental Impact Assessment (“Official Gazette of RS” No. 135/04, 36/09),
- The Law on Waste Management (“Official Gazette of RS” No. 36/09),
- The Law on Occupational Safety and Health (“Official Gazette of RS” No. 101/05),
- Law on Planning and Construction (“Official Gazette of RS” No. 72/09, 81/09, 56/10, 24/11, 121/12, 42/13, 50/13),
- Law on Nature Protection, (“Official Gazette of RS” No. 36/09),
- Law on Strategic EIA (“Official Gazette of RS” No. 135/2004),

Regulations established on the basis of the Law on EIA include the following:

- 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 (“Official Gazette of RS” No.114/08)
• Rulebook 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 Study (“Official Gazette of RS” No. 69/05)
• Rulebook on the contents of the EIA Study (“Official Gazette of RS” No. 69/05)
• Rulebook on the procedure of public inspection, presentation and public consultation about the EIA Study (“Official Gazette of RS” No. 69/05)
• Rulebook on the work of the Technical Committee for the EIA Study (“Official Gazette of RS” No. 69/05)
• Law on confirmation of convention on information disclosure, public involvement in process of decision making and legal protection in the environmental area (“Official Gazette of RS”, 38/09)

The parts related to this project are briefly summarized in sections 2.5.1 to 2.5.7.

2.4.1  The Constitution of Serbia

Within the Serbia’s Constitution it is stated that everyone shall have the right to a healthy environment and the right to timely and full information about the state of the environment. Everyone, especially the Republic of Serbia and Autonomous Provinces, shall be accountable for the protection of the environment. Everyone shall be obliged to preserve and improve the environment.

2.4.2  Law on Health Care

Health care includes the implementation of measures for the preservation and improvement of public health, prevention, early prevention and detection of diseases, injuries and other health problems in timely and their effective treatment and rehabilitation. A citizen of the Republic of Serbia, as well as any other person who has permanent or temporary residence in the Republic has the right to health care, in accordance with the law, and the duty to protect and improve their health, health of other citizens, and environmental conditions and working environment.
2.4.3 Law on Medicines and Medical Devices

This Law regulates the conditions and procedures for issuing licenses for the marketing authorization, or entry of drugs into the registers maintained by the Agency for Medicines and Medical Devices Agency of Serbia, production and marketing of drugs and medical devices and monitoring in these areas, the Agency for Medicinal Products and Medical Devices Serbia and other issues relevant to the field of medicines and medical devices.

2.4.4 Law on Ionizing Radiation and on Nuclear Safety

This law prescribes measures to protect life, health and the environment from harmful effects of ionizing radiation and nuclear safety, measures in all proceedings related to nuclear activities and defines the conditions for conducting activities with ionizing radiation sources, nuclear materials and radioactive management. It is forbidden to carry out the activities with ionizing radiation sources and nuclear materials without prior approval by the Serbian Radiation Protection and Nuclear Safety Agency. The measuring of radiation level and ensuring safety and security is an integral part of the technical documentation for facilities that use or will use ionizing radiation sources, whose implementation ensures that such facilities meet the prescribed level of protection of exposed persons, and the environment from ionizing radiation. The Institute of Occupational Health of Serbia "Dr Dragomir Karajović" is accredited for measuring of ionized radiation.

2.4.5 Law on Environmental Protection


The main objectives of LEP are:

- Conservation and improvement of the environment; and
- Control and mitigation of pollution of the environment.

The main focuses of LEP are:

- Declaration of ecologically critical areas and restriction on the operations and processes, which can or cannot be carried out/ initiated in the ecologically critical areas;
- Regulations in respect of vehicles emitting smoke harmful for the environment;
• Environmental Approval;
• Regulation of industries and other development activities’ discharge permits;
• Promulgation of standards for quality of air, water, noise and soil for different areas for different purposes;
• Promulgation of a standard limit for discharging and emitting waste; and
• Formulation and declaration of environmental guidelines.

To implement the Law on Environmental Impact Assessment, a government Decree determines the list of projects for which an impact assessment is mandatory (2009) or may be required in accordance with the relevant EU directives 97/11/EC and 337/85/EEC. Public participation is also envisaged in all environmental impact assessment stages. All subsidiary regulations were adopted in 2005. Public information and public participation in decision-making have been introduced in line with EU Directive 2003/35/EC on public participation.

2.4.4 Law on Environmental Impact Assessment

The Law on EIA (LOEIA) provides categorization of industries and projects and identifies types of environmental assessment required against respective categories of industries or projects. The Law covers, among others:

• Declaration of ecologically critical areas;
• Classification of industries and projects into 2 categories;
• Procedures for issuing the Final Environmental Approval (FEA); and
• Determination of environmental standards.

LOEIA also contains the procedures for obtaining FEA from the Department of EIA for different types of proposed industries or projects.

2.4.5 The Law on Waste Management

The Law on Waste Management, which is harmonized with all relevant EU directives, has been adopted in 2009 and contains provisions that relate to electric and electronic waste.
2.4.6 The Law on Occupational Safety and Health

This Law regulates the occupational safety and health system in Serbia. By harmonizing this law with the ratified International Labor Organization conventions and EU Framework Directive 89/391/EEC, as well as special directives derived from the Framework Directive, all guidelines originating from them have been accepted in a form adjusted to national conditions. Apart from this Law, the regulatory framework of the occupational safety and health system is integrated by several sub-acts.

2.4.7 The Law on Planning and Construction

This law is regulated with the terms and manner of spatial development and use construction land and construction of buildings; supervision over implementation of this legislation and inspection, the second issue of importance for the development of space, editing and use of land for construction.

2.5 World Bank’s Environmental Safeguard Policy

Following is the short summary of several relevant Banks’ Safeguards Policies. The full texts could be found at the WB web site.

2.5.1 OP/BP 4.01 Environmental Assessment

The Bank requires Environmental Assessment (EA) of projects proposed for Bank support to ensure that they do not have, or mitigate potential negative environmental impacts. The EA is a process whose breadth, depth, and type of analysis depend on the nature, scale, and potential environmental impact of the proposed project. The EA evaluates a project’s potential environmental risks and impacts in its area of influence; examines project alternatives; identifies ways of improving project selection, siting, planning, design, and implementation by preventing, minimizing, mitigating, or compensating for adverse environmental impacts and enhancing positive impacts; and includes the process of mitigating and managing adverse environmental impacts throughout project implementation. The EA takes into account the natural environment (air, water and land); human health and safety; social aspects; and trans-boundary and global environmental aspects. The Borrower is responsible for carrying out the EA and the Bank advises the Borrower on the Bank’s EA requirements.

The Bank classifies the proposed projects into three major categories, depending on the type, location, sensitivity, scale of the project and the nature and magnitude of its potential environmental impacts:
• Category A: The proposed project is likely to have significant adverse environmental impacts that are sensitive, diverse, or unprecedented. These impacts may affect an area broader than the sites or facilities subject to physical works.

• Category B: The proposed project's potential adverse environmental impacts on human population or environmentally important areas—including wetlands, forests, grasslands, or other natural habitats—are less adverse than those of Category A projects. These impacts are site specific; few if any of them are irreversible; and in most cases migratory measures can be designed more readily than Category A projects.

• Category C: The proposed project is likely to have minimal or no adverse environmental impact

According to the World Bank standards, SH2P is categorized as a project belonging to environmental category B, due to activities that are to be undertaken under Project Component 4.

2.5.2 OP/BP 4.04 Natural Habitats

The policy deals with activities to be executed near or within protected natural habitats. Bank supports the protection, maintenance, and rehabilitation of natural habitats and their functions in its economic and sector work, project financing, and policy dialogue. The full text of the policy is available at the WB web site.

2.5.3 OP/BP 4.11 Physical Cultural Resources

The policy deals with the protection of physical cultural heritage. Physical cultural resources are defined as 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. Physical cultural resources are important as sources of valuable scientific and historical information, as assets for economic and social development, and as integral parts of a people's cultural identity and practices. The full text of the policy is available at the WB web site.

2.5.4 OP/BP 4.36 Forestry

The policy envisages the protection of forests through consideration of forest-related impact of all investment operations, ensuring restrictions for operations affecting critical forest conservation areas, and improving commercial forest practice through the use of modern certification systems. In the process of forest conservation interventions, especially the local people, the private sector and other pertinent stakeholders should be consulted.
In general, the Policy aims at reducing deforestation and enhancing the environmental and social contribution of forested areas. The full text of the policy is available at the WB web site.

2.5.5 OP/BP 4.12 Involuntary Resettlement

This policy is aiming on assisting the displaced persons in their efforts to improve or at least restore their standards of living, which may be adversely affected by the project related activities. The full text of the policy is available at the WB web site.

2.5.6 IFC Environmental, Health and Safety Guidelines

The Environmental, Health and Safety (EHS) Guidelines of the International Finance Corporation (IFC), 2008 are the safeguard guidelines for environment, health and safety for the development of the industrial and other projects. They contain performance levels and measures that are considered to be achievable in new facilities at reasonable costs using existing technologies. The full text of the policy is available at the WB web site.
3. POTENTIAL ENVIRONMENTAL IMPACTS

During the implementation of Project Component 4 the following activities should be undertaken:

- Assessment of the current network of accelerators compared to current and anticipated patient load, and optimal organization of cancer care and treatment based on current international the best practices,
- Evaluation of necessary equipment, type and quantity,
- Selection of location of specialized tertiary hospitals, where the purchased equipment will be situated and installation of the new equipment,
- Selection of the old equipment that will be replaced,
- Preparation, planning and construction of new objects,
- Construction of new objects where equipment will be located, or rehabilitation/upgrade of the existing facilities,
- Procurement, transport of the equipment, obtaining the necessary approval and technical documents (by the Medicines and Medicals Devices Agency of Serbia, Serbian Radiation Protection and Nuclear Safety Agency and Ministry of Construction and Urban Planning, Ministry of Energy, Development and Environmental Protection),
- Replacing the old equipment with the new one,
- The storage of old equipment, the utilization of equipment, primary disposal and the storage.

The Project is rated environmental category B. Most of the Project Components are environmentally neutral; however Component 4 will include installation of the medical equipment into already existing, purpose-built facilities (bunkers) that will be modified, to suit specifications of the new equipment. Environmental Management Framework (EMF) is being prepared for the Project. The related civil works activities will be undertaken within existing hospitals and medical centers throughout Serbia, and are not expected to have any significant negative environmental impact. The issues related to this type of activities include noise, dust, vibrations, and management of construction waste during civil engineering activities - which could be successfully managed and mitigated by application of good engineering practices. Specific issues that will also be taken care of relate to management of the site (as hospitals must continue operating during the execution of works), and health and safety of population. In some cases, the presence of asbestos, lead or other medical or possibly hazardous waste (if found during rehabilitation works), may require specific handling procedures, which will be defined in site-specific EMPs that are to be prepared for each facility when the locations become known.
During the Project preparation it will be confirmed whether any of the buildings chosen for rehabilitation are designated cultural property. As provided for in the EMF, in these cases the site-specific EMPs will include clauses related to heritage protection and conservation. The civil engineering works will have to be reviewed and approved by competent national cultural heritage institutions.

The Project may also fund construction of new facilities (bunkers) to house linear accelerators. These facilities will be constructed within the existing hospital buildings (without change of footprint), or in adjacent buildings – within the existing hospital compounds.

The impact specifically to be taken into account also include the potential radiation source's influence of equipment, as well as potential influence on waste management during the entire cycle - from procurement to warehousing. The potential environmental impact mitigation measures must also follow the same stages:

- From procurement to installation,
- Replacing old equipment with new,
- Preparation, planning and construction of new objects
- The storage of old equipment,
- The utilization,
- Primary disposal, and
- The storage.

The main considerations while dealing with waste management are outlined below:

**From procurement to installation**

The equipment is considered as product until the installation. The product will be packed by the manufacturer's standards. After unpacking, the equipment will be installed according to the manufacturer's instructions, which will be translated to the Serbian language by the competent authority. In this step, it is packaging waste that will be generated, not the hazardous waste, according to Directive 2008/98/EC and national law and by-law, and will be treated as secondary raw material or will be recycling.

**Replacing old equipment with the new one**

In this step, the old equipment has to be declared as waste, in any of the following technical reasons: devices limitation, inability to repair, radiation construe as the risks to the environment and human health, etc. In these circumstances, it is necessary to choose the appropriate object or indoor
facility where it is possible to store these devices. Then, the waste's owner (the Institution that is the owner of equipment) must engage an accredited laboratory for waste classification and characterization, as well as to prepare the Waste Management Plan (WMP), in accordance to national law and by-laws. The institution is obligated to find a temporary storage location for its waste for the period of 12 months. The primary waste disposal must be performed inside the object for temporary storage, in accordance to national legislative and Directive EU.

**Construction of new objects or upgrade of existing facilities**

In accordance to national and international recommendations (International recommendation for linear accelerator) for protection against ionizing radiation, preparation for planning and designing the new objects or for rehabilitation/upgrade of the existing facilities is necessary. In this case the project will use only the recommended materials for isolation of primary and secondary radiation sources, and will use other specific recommendations and procedures for the projects and specific standards for the objects, and will apply the relevant environmental mitigation measures to reduce or avoid negative environmental impact and/or negative impact on human health and occupation safety.

**The storage of old equipment**

During the 12 months, the waste’s owner will separate the waste on different types of waste, such as electronic/electric, and any other type of waste or secondary raw materials, materials for recycling, etc. Also, the owner will engage an authorized waste operator for final waste disposal.

**The utilization**

At the time when the device is switched to normal operating mode, there will be possibility for a potential environment impact, which will be in accordance to national and international recommendations (International recommendation for linear accelerator) for protection against ionizing radiation. At this stage, there will also be a possibility for potential impact on human health (machine operators and users).

**Primary disposal**

This step is identical with the stage of replacing old equipment with the new devices.

**The storage**

This step is identical with the step of storage of old equipment.
4. ENVIRONMENTAL MANAGEMENT APPROACH

The WB ECA safeguards team has developed an alternative to the Environmental Management Plan (EMP) format document for the objects that presented a low-risk topology, such as hospital rehabilitation activities. The EMP is in the form of checklist-type format, which has been development as “sample of good practice” and designed as “user friendly” document. It is compatible with WB safeguard requirements. The blank format of the sample checklist is attached in the Annex of this document. The EMP-checklist has following items:

- **Part 1** presents the “site passport”, which describes the sub-project specifics in terms of physical location, the institutional and legislative aspects, the restoration works, inclusive of the need for a capacity building program and description of the public consultation process. This section could be up to two pages long. Attachments for additional information can be supplemented if needed.

- **Part 2** includes the environmental and social screening in a simple Yes/No format followed by mitigation measures for any given activity.

- **Part 3** is a monitoring plan for activities during project construction and implementation. It retains the same format required for standard WB EMPs.

The EMP checklist, and particularly parts 2 and 3 must be included in the bidding documents for the prospective works.

4.1 Application of the EMP-Checklist and EMF on the Project

The Project implementation team will have to ensure adequate application of the EMP – checklists for all activities that may have an environmental impact. This particularly applies, but is not limited to, activities under Component 4. For the upgrade of the existing facilities, there will be a need for the EMP Checklist alone, but for the new bunkers/facilities or equipment, the project will prepare the more detailed Environmental Mitigation and Monitoring Plan, that must include, as its integral part, the EMP Checklist. The EMP-checklist will be implemented in four phases:

1. Typical environmental issues listed in the checklist and likely to be encountered in the sub-projects will be identified, corresponding requirements of the Republic of Serbia or WB guidelines outlined, and steps to fulfill these requirements are explained in a practical and easy-to-follow manner. The latter will include attachment of sample permit and license application forms, listing of relevant authorities in correct order whom sub-project proponents and or contractors need to contact for each of the typical environmental issues.
Furthermore, monitoring requirements as per Republic of Serbia or WB guidelines will be presented for each issue. These documents will be made available to potential sub-project applicants in printed form as well as electronically on the project website.

2. The contract with the selected bidder will highlight the contractor's obligations for environmental measures. Additionally, the completed tabular EMP will be attached to the contract and, analogous to all technical and commercial terms, signed by the contract parties.

3. Works implementation phase. The environmental specialist will check environmental compliance on site using Part 3 of the EMP-checklist alongside other quality criteria.

4.2 Monitoring and Reporting of Component 4 related activities

Part 3 of the EMP-checklist will be developed site specifically and in necessary detail, defining clear criteria and parameters which will be included in the works contracts, reflect the status of environmental practice on the construction site and can be observed/measured/quantified/verified by the environmental specialist during the execution of relevant activities.

Such parameters and criteria include workers’ use of personal protective equipment on the site, noise and dust generation and prevention, protection of the ionized radiation, amount of water used and discharged by site, presence of proper sanitary facilities for workers, waste collection of separate types (electrical/electronic waste, packaging waste, foils, mineral waste, wood, metals, plastic, hazardous waste, e.g. asbestos, paint residues), waste quantities, proper organization of disposal pathways and facilities, or reuse and recycling wherever possible.

Specific issues that will also be taken care of relate to management of the site (as hospitals must continue operating during the execution of works), and health and safety of population.

The documented compliance with the environmental checklist, or EMP, as relevant, will be a condition for full payment of the contractually agreed remuneration, the same as technical quality criteria or quantity surveys. To assure a degree of leverage on the contractor’s environmental performance an appropriate clause will be introduced in the works contracts, specifying penalties in case of noncompliance with the contractual environmental provisions, e.g. in the form of withholding a certain proportion of the payments, its size depending on the severity of the breach of contract. For extreme cases a termination of the contract shall be contractually tied in.
4.3 Reporting of the Project Related Activities

The requirements for undertaking and reporting on the Project in respect to environmentally-related activities will include:

(i) preparation of draft site-specific EMPs and checklists, as appropriate, for each specific location/hospital, by the Project Implementation Team;
(ii) review and approval of site-specific EMPs and checklists by the Bank’s team;
(iii) inclusion of site-specific EMP and checklists as a part of the Bidding Documents, and subsequent contract;
(iv) execution of EMP-related measures by the respective contractor(s);
(v) monitoring and reporting of compliance with EMP and checklist-related measures by supervising engineer/environmental specialist (to the Project Implementation Team);
(vi) reporting on compliance with EMP to the Bank (by the Project Implementation Team)

5. PUBLIC CONSULTATION

To be completed after public consultation
## ANNEX 1: Draft Format for EMP/EMF for Construction and Rehabilitation Activities for ECSHD Projects

### PART 1: INSTITUTIONAL & ADMINISTRATIVE

<table>
<thead>
<tr>
<th>Country</th>
<th>Project title</th>
<th>Scope of project and activity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Institutional arrangements (Name and contacts)</th>
<th>WB (Project Team Leader)</th>
<th>Project Management</th>
<th>Local Counterpart and/or Recipient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safeguard Supervision</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local Counterpart Supervision</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local Inspectorate Supervision</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contractor</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### SITE DESCRIPTION

<table>
<thead>
<tr>
<th>Name of site</th>
<th>Describe site location</th>
<th>Attachment 1: Site Map [ ] Y [ ] N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Who owns the land?</th>
<th>Geographic description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### LEGISLATION

<table>
<thead>
<tr>
<th>Identify national &amp; local legislation &amp; permits that apply to project activity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

### PUBLIC CONSULTATION

<table>
<thead>
<tr>
<th>Identify when / where the public consultation process took place</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

### INSTITUTIONAL CAPACITY BUILDING

<table>
<thead>
<tr>
<th>Will there be any capacity building?</th>
<th>[ ] N or [ ] Y if Yes, Attachment 2 includes the capacity building program</th>
</tr>
</thead>
</table>
### PART 2: ENVIRONMENTAL /SOCIAL SCREENING

Will the site activity include/involve any of the following:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Status</th>
<th>Additional references</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Building rehabilitation</td>
<td></td>
<td>See Section B below</td>
</tr>
<tr>
<td>B. New construction</td>
<td></td>
<td>See Section B below</td>
</tr>
<tr>
<td>C. Individual wastewater treatment system</td>
<td></td>
<td>See Section C below</td>
</tr>
<tr>
<td>D. Historic building(s) and districts</td>
<td></td>
<td>See Section D below</td>
</tr>
<tr>
<td>E. Acquisition of land(^1)</td>
<td></td>
<td>See Section E below</td>
</tr>
<tr>
<td>F. Hazardous or toxic materials(^2)</td>
<td></td>
<td>See Section F below</td>
</tr>
<tr>
<td>G. Impacts on forests and/or protected areas</td>
<td></td>
<td>See Section G below</td>
</tr>
<tr>
<td>H. Handling / management of medical waste</td>
<td></td>
<td>See Section H below</td>
</tr>
</tbody>
</table>

#### ACTIVITY PARAMETER MITIGATION MEASURES CHECKLIST

**A. General Conditions**

<table>
<thead>
<tr>
<th>Notification and Worker Safety</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) The local construction and environment inspectorates and communities have been notified of upcoming activities</td>
<td></td>
</tr>
<tr>
<td>(b) The public has been notified of the works through appropriate notification in the media and/or at publicly accessible sites (including the site of the works)</td>
<td></td>
</tr>
<tr>
<td>(c) All legally required permits have been acquired for construction and/or rehabilitation</td>
<td></td>
</tr>
<tr>
<td>(d) All work will be carried out in a safe and disciplined manner designed to minimize impacts on neighboring residents and environment.</td>
<td></td>
</tr>
<tr>
<td>(e) Workers’ PPE will comply with international good practice (always hardhats, as needed masks and safety glasses, harnesses and safety boots)</td>
<td></td>
</tr>
<tr>
<td>(f) Appropriate signposting of the sites will inform workers of key rules and regulations to follow.</td>
<td></td>
</tr>
</tbody>
</table>

**B. General Rehabilitation and/or Construction Activities**

<table>
<thead>
<tr>
<th>Air Quality</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) During interior demolition use debris-chutes above the first floor</td>
<td></td>
</tr>
<tr>
<td>(b) Keep demolition debris in controlled area and spray with water mist to reduce debris dust</td>
<td></td>
</tr>
<tr>
<td>(c) Suppress dust during pneumatic drilling/wall destruction by ongoing water spraying and/or installing dust screen enclosures at site</td>
<td></td>
</tr>
<tr>
<td>(d) Keep surrounding environment (side walks, roads) free of debris to minimize dust</td>
<td></td>
</tr>
<tr>
<td>(e) There will be no open burning of construction / waste material at the site</td>
<td></td>
</tr>
<tr>
<td>(f) There will be no excessive idling of construction vehicles at sites</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Noise</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Construction noise will be limited to restricted times agreed to in the permit</td>
<td></td>
</tr>
<tr>
<td>(b) During operations the engine covers of generators, air compressors and other powered mechanical equipment should be closed, and equipment placed as far away from residential areas as possible</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Water Quality</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) The site will establish appropriate erosion and sediment control measures such as e.g. hay bales and/or silt fences to prevent sediment from moving off site and causing excessive turbidity in nearby streams and rivers.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Waste management</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Waste collection and disposal pathways and sites will be identified for all major waste types expected from demolition and construction activities.</td>
<td></td>
</tr>
<tr>
<td>(b) Mineral construction and demolition wastes will be separated from general refuse, organic, liquid and chemical wastes by on-site sorting and stored in appropriate containers.</td>
<td></td>
</tr>
<tr>
<td>(c) Construction waste will be collected and disposed properly by licensed collectors</td>
<td></td>
</tr>
<tr>
<td>(d) The records of waste disposal will be maintained as proof for proper management as designed.</td>
<td></td>
</tr>
<tr>
<td>(e) Whenever feasible the contractor will reuse and recycle appropriate and viable materials (except asbestos)</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) Land acquisitions includes displacement of people, change of livelihood encroachment on private property this is to land that is purchased/transferred and affects people who are living and/or squatters and/or operate a business (kiosks) on land that is being acquired.

\(^2\) Toxic / hazardous material includes and is not limited to asbestos, toxic paints, removal of lead paint, etc.
<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>PARAMETER</th>
<th>MITIGATION MEASURES CHECKLIST</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. Individual wastewater treatment system</td>
<td>Water Quality</td>
<td>(a) The approach to handling sanitary wastes and wastewater from building sites (installation or reconstruction) must be approved by the local authorities (b) Before being discharged into receiving waters, effluents from individual wastewater systems must be treated in order to meet the minimal quality criteria set out by national guidelines on effluent quality and wastewater treatment (c) Monitoring of new wastewater systems (before/after) will be carried out</td>
</tr>
<tr>
<td>D. Historic building(s)</td>
<td>Cultural Heritage</td>
<td>(a) If the building is a designated historic structure, very close to such a structure, or located in a designated historic district, notify and obtain approval/permits from local authorities and address all construction activities in line with local and national legislation (b) Ensure that provisions are put in place so that artifacts or other possible “chance finds” encountered in excavation or construction are noted, officials contacted, and works activities delayed or modified to account for such finds.</td>
</tr>
<tr>
<td>E. Acquisition of land</td>
<td>Land Acquisition Plan/Framework</td>
<td>(a) If expropriation of land was not expected but may occur, that the bank task Team Leader is consulted. (b) The approved Land Acquisition Plan/Framework (if required by the project) will be implemented</td>
</tr>
<tr>
<td>F. Toxic Materials</td>
<td>Asbestos management</td>
<td>(a) If asbestos is located on the project site, mark clearly as hazardous material (b) When possible the asbestos will be appropriately contained and sealed to minimize exposure (c) The asbestos prior to removal (if removal is necessary) will be treated with a wetting agent to minimize asbestos dust (d) Asbestos will be handled and disposed by skilled &amp; experienced professionals (e) If asbestos material is be stored temporarily, the wastes should be securely enclosed inside closed containments and marked appropriately (f) The removed asbestos will not be reused</td>
</tr>
<tr>
<td>F. Toxic Materials</td>
<td>Toxic / hazardous waste management</td>
<td>(a) Temporarily storage on site of all hazardous or toxic substances will be in safe containers labeled with details of composition, properties and handling information (b) The containers of hazardous substances should be placed in an leak-proof container to prevent spillage and leaching (c) The wastes are transported by specially licensed carriers and disposed in a licensed facility. (d) Paints with toxic ingredients or solvents or lead-based paints will not be used</td>
</tr>
<tr>
<td>G. Affects forests and/or protected areas</td>
<td>Protection</td>
<td>(a) All recognized natural habitats and protected areas in the immediate vicinity of the activity will not be damaged or exploited, all staff will be strictly prohibited from hunting, foraging, logging or other damaging activities. (b) For large trees in the vicinity of the activity, mark and cordon off with a fence large tress and protect root system and avoid any damage to the trees (c) Adjacent wetlands and streams will be protected, from construction site run-off, with appropriate erosion and sediment control feature to include by not limited to hay bales, silt fences (d) There will be no unlicensed borrow pits, quarries or waste dumps in adjacent areas, especially not in protected areas.</td>
</tr>
<tr>
<td>H. Disposal of medical waste</td>
<td>Infrastructure for medical waste management</td>
<td>(a) In compliance with national regulations the contractor will insure that newly constructed and/or rehabilitated health care facilities include sufficient infrastructure for medical waste handling and disposal; this includes and not limited to: - Special facilities for segregated healthcare waste (including soiled instruments “sharps”, and human tissue...</td>
</tr>
</tbody>
</table>
or fluids) from other waste disposal; and
- Appropriate storage facilities for medical waste are in place; and
- If the activity includes facility-based treatment, appropriate disposal options are in place and operational

<table>
<thead>
<tr>
<th>PART 3: MONITORING PLAN</th>
<th>Phase</th>
<th>What (Is the parameter to be monitored?)</th>
<th>Where (Is the parameter to be monitored?)</th>
<th>How (Define the frequency / or continuous?)</th>
<th>When (Is the parameter being monitored?)</th>
<th>Why (Is the parameter being monitored?)</th>
<th>Cost (if not included in project budget)</th>
<th>Who (Is responsible for monitoring?)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>During activity supervision</td>
<td></td>
<td></td>
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