SFG3987

Second Serbia Health Project

Additional Financing

ENVIRONMENTAL MANAGEMENT FRAMEWORK DOCUMENT

FINAL
Belgrade, January 2018

Contents

LIST OF ABBREVATIONS

ALIMS	Medicines and Medical Devices Agency of Serbia
AF	Additional Financing
AZUS	Agency for Accreditation of Health Care Institutions of Serbia
DRG-s	Diagnostic Related Group System
EA	Environmental Assessment
e-HDF	e-Health Development Framework
EIA	Environmental Impact Assessment
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
SSHP	Second Serbia Health Project
T2DM	Type 2 Diabetes Mellitus
VOI	Autonomous Province of Vojvodina
WB	The World Bank
WMP	Waste Management Plan
µSv	microsievert
MeV	megaelectron volt
Gy	Grey

EXECUTIVE SUMARY

The Government of Serbia has requested a support from the World Bank in implementation of the Second Serbia Health Project (SSHP). 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 four components: Component 1 – Improving Health Financing; Component 2 – Promote Efficient Purchasing of Health Products and maintenance of Medical Equipment; Component 3 – Support Quality improvement in Service Delivery including for Management of Cancer Treatment; and Component 4: Support Project Management, Monitoring and Evaluation 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.

The Project is rated environmental category B. Most of the Project Components are environmentally neutral; however, Component 3 will include installation of the medical equipment (linear accelerators) into already existing, purpose-built facilities (bunkers) that will be modified, to suit specifications of the new equipment. The related civil works activities will be undertaken within existing hospitals and medical centers throughout Serbia, and are not expected to have any long-term, significant negative environmental impact. The EMF document sets the guidance framework for preparation of site-specific EMPs, to be prepared when the sites and proposed equipment have been identified.

Linear accelerators for treatment of cancer do not contain any radioactive substances, but instead use electricity to generate either high-energy x-rays or accelerated electrons that can be precisely targeted on cancerous tissue. When not in operation, no harmful radiation is generated, although the treatment room itself requires shielding of the walls, doors, and ceiling to prevent escape of scattered radiation during the radiotherapy treatment. The solution applied is similar to the arrangement used to protect staff using diagnostic x-ray equipment, although the higher energy of therapy beams requires a radiation vault (bunker) with thick concrete walls (up to 2.5 m) to provide adequate radiation shielding.

The issues related to civil works and construction of radiation vaults (bunkers) 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 hospital users and staff. 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, in addition, 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 potential for negative impact will exist during operation of the accelerator equipment, in case that Serbian standard for ionizing radiation and nuclear safety is not adequately applied. The Project will, as a part of the design and permitting process, ensure for each piece of equipment that relevant standards are applied and design is certified by the Institute of Occupational Health of Serbia. Additionally, the Word Bank EHS Guidelines and ILO Code of Practice “Radiation Protection of Workers (Ionizing Radiation)” will apply to all sites under Project Component 3. As a rule, whenever the Serbian and World Bank standards and guidance documents differ on environment, health and safety issues, the more stringent ones will be applied. According to comparison made between the national and World Bank EHS Guidelines, there are no substantial differences between the two standards, since the Serbian legislation adopted the recommendations of the International Commission on Radiological Protection (ICRP), the standards of International Agency for Atomic Energy (IAAE) and the best international practice in this area.

For the reference, both Serbian and World Bank standards for safety from ionizing radiation, and their comparison, are attached in Annexes 2 and 3.

Within the parent project, sub-component 3.2, four (4) locations: Institute for Oncology and Radiology of Serbia, Nis Clinical Centre, Kragujevac Clinical Center and Kladovo Health Center have been designated for purchase and installation of linear accelerators. For that purpose, specially sheltered bunkers were planned to be constructed and in case of existing ones, to be reconstructed or adapted. During the preparation of technical project documentation for sheltered bunkers construction and / or

reconstruction, site-specific Environmental Management Plans (EMPs) have been prepared for each location. The EMPs were included in the bidding document (Tender Dossier) and subsequent, in construction contract. The construction works of bunkers for LINAKs accommodation are in progress and are expected to be completed by June 2018.

1. DESCRIPTION OF PROJECT COMPONENTS INCLUDING DESCRIPTION OF TYPE OF ACTIVITIES ELIGIBLE FOR FINANSING

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

The activities that are financed within the SSHP and with the support of the World Bank, are structured into four components.

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

This component supports reforms to improve the quality, efficiency, and transparency of HIF financing for primary care and hospitals. The component finances 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 supports 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 supports reforms to strengthen transparency of and incentives for efficiency of HIF financing for public hospitals. The major focus is 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 aim 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 supports technical assistance to strengthen primary health care financing systems. The grants scheme seeks 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 are 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 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 supports 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 supports 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 supports 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 MoH, HIF and IPH.

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

This sub-component supports 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 aims to strengthen cross-cutting systems of performance management and information technology that are pertinent across both sub-components, and provides financing of goods, civil works, technical assistance, training and equipment.

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

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

- Clinical practice guidelines and pathways. Under this component National clinical practice guidelines are being developed, aligned to international evidence but closely linked with the HIF budget envelope. Additional clinical pathways are being developed to ensure coverage of key conditions that represent the main burden of disease in Serbia.
- Quality improvement support. Activities under this subcomponent provide funding for training and TA, 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 aim to 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 supports the purchase and installation of six 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 Institute for Oncology and Radiology of Serbia, Clinical Centre Kragujevac, Clinical Centre Nis and Health Centre Kladovo. 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 are procured together with extended warranties, to ensure four years of full-capacity operation and software updates. This component also supports training and technical assistance to improve monitoring of patient outcomes,

including through strengthening the national cancer registry system. In addition, the 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 4: Monitoring, Evaluation, and Project management (US$ 3 million). This component provides financing of 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 has been provided. Also, study tours in countries with similar reforms have been included.

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 equipment is necessary in clinical practice in the 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 staff 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 the 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.

1.2.2 Scope of additional financing

Additional financing will ensure further improvement of cancer management. Proposed activities under the AF and within the Subcomponent 3.2: Improve Cancer Management, are as follows:

1. The Serbian Comprehensive Cancer Management Strategy covers prevention, diagnostics and treatment. Although efforts have been made in the past by the MoH, with support from the World Bank and European Commission, to address screening and early detection of leading malignant diseases (cervical, colon and breast cancer), no significant progress has been achieved to date. Diagnosed cancer cases are predominantly stages III or IV. Comprehensive approach to cancer control is needed to improve and align cancer prevention and enhance efficiency so as to (a) establish and strengthen early disease detection system; (b) promote use of digital technologies in cancer registration and patient treatment data collection, transfer, treatment decisions, and analytics against an internationally recognized format; (c) institutionalize more vigorous health promotion activities; and (d) put in place appropriate infrastructure and advanced treatment modalities for tertiary level cancer treatment, which hampers the effectiveness and efficiency in the use of human and financial resources.

2. Improvement of National Coverage of Radiotherapy Services. Six linear accelerators (LINAC), varying in technical specifications and requirements, and three CT-simulators have been procured for the four oncology institutions in Serbia (Belgrade, Kragujevac, Nis and Kladovo) under the parent project and full installation should be completed by March 2018. In parallel, the Government of Serbia has purchased

four LINACs from the budget aiming to achieve international standards for radiotherapy coverage.

About 11,000 people in the northern province of Vojvodina (VOI) are affected by cancer annually, 4,000 of whom need radiation or combined chemotherapy and radiotherapy. On a monthly level, more than 200 patients for whom the oncological committee has indicated radiation therapy are registered in the list of appointments. In September 2017, the waiting list for radiation therapy at the VOI included 368 patients. Approximately 60 percent of patients from the waiting list are breast cancer patients followed by gynecological and colorectal cancers. To date, VOI has not benefitted from the radiotherapy procurement. It is proposed that retroactive financing will be considered for the procurement of the equipment for VOI under the proposed AF.

To achieve full territorial radiotherapy coverage and provide equity, access and standardized quality of cancer treatment across the country, the proposed AF would finance two new LINACS and rehabilitation of the two bunkers for VOI. The VOI's Radiotherapy Clinic has qualified staff and is fully equipped for new accelerators. Due to Government's prerogative to secure equity in access and quality of cancer treatment throughout the country, this activity would be subject to retroactive financing.

Climate Change and Disaster. Given that this subcomponent will support the rehabilitation of two bunkers for the LINACs, climate change and geophysical hazards (such as flood as in 2014) could impact the structural integrity, materials, siting, longevity and overall effectiveness of the investments. However, this is considered as low risk as climate and geophysical hazards, such as flood, are not likely to impact overall project activities. Nevertheless, the planned works for the two bunkers will incorporate climate and natural disasters resilience considerations (e.g., resilience to floods, extreme temperature increases, etc.).

3. Improvement of Timely Diagnostics in Oncology. While the original project has supported Serbia in meeting international standards in treatment, the needs for diagnostics equipment have been put aside, as the MoHs focus was on providing conditions for timely treatment and addressing waiting lists for cancer treatment. Now that international standards in radiotherapy in Serbia will be met during the length of the project (SSHP and AF), conditions will be in place for addressing issues of under-diagnostics and late diagnostics. It is of utmost importance to increase the quality of diagnostics for timely and efficient cancer management.

In 52.2 percent of the cases, the disease is diagnosed in an advanced stage, with regional and distant metastases present. Such late diagnostics not only adversely affects treatment outcome, but increases the health care system expenses as well due to requirement of applying more and costlier treatment options. The latest data from the Institute of Public Health show that Serbia is among the countries with the lowest number of CT scanners and MRIs. Improved and early diagnostics in oncology is important not only because diagnosing and treating cancer at an early stage can save lives, but also because of its budgetary implications. Fiscal impacts of such health care policy are also significant, having in mind that savings could be achieved through reduced funds for high-cost oncology drugs. Such approach increases the quality of care and efficiency in public spending on health. Providing opportunities for timely cancer treatment and clearing waiting lists, thanks to the provision of LINACs, will create space for early, improved diagnostics which calls for additional modern equipment (mainly MRI and scanners). The proposed AF could support the MoH in addressing this issue provided that the MoH fulfill the following conditions of disbursements, all satisfactory to the Bank: (i) adoption of a comprehensive National Cancer Strategy; (ii) adoption of a Network Optimization Plan; and (iii) institutionalization of a sustainable Medical Equipment Maintenance System.

The proposed AF would finance procurement of CT scanners and MRIs, but the precise number and distribution of new diagnostic equipment will be subject to a comprehensive needs analysis. Procurement of diagnostic equipment as well as the PET Center would be conditioned (conditions of disbursement) by the implementation of a National Cancer Management Strategy, a Health Care Network Optimization Plan, and the institutionalization of a medical equipment maintenance system for defined new high cost equipment.

This sub-component would finance works, goods, technical assistance, and training

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 SSHP 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 SSHP.

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 Environmental Protection (MoEP) 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), Institute of Occupational Health of Serbia, and the Ministry of Construction, Transport and Infrastructure . The Medicines and Medicals Devices Agency of Serbia (MMDAS) has an important role in 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 activities to be funded as a part of the Project, unless they are placed within or in the vicinity of the nature or culture protected areas/objects. In such cases the Project Proponent is obliged to submit so-called "Request for Decision about Need for Environmental Impact Assessment" (RDNEIA) to the MoEP. 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. Additionally, since SSHP 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 of Health Care (''Official Gazette of RS'' No. 107/2005, 72/2009, 88/2010, 99/2010, 57/2011, 119/2012, 45/2013 - other laws, 93/2014, 96/2015 and 106/2015),
- Law on Medical Devices (''Official Gazette of RS'', No. 105/17)
- Law of Ionizing radiation and on Nuclear Safety (''Official Gazette of RS'' No 36/09, 93/12),
- Rules on limits of exposure to ionizing radiation and measurements to assess the level of exposure to ionizing radiation (Official Gazette RS, No. 86/11),
- Regulation on the limits of radioactive contamination of person, workplace and environment and the methods of decontamination (Official Gazette RS, No 38/11),
- Law on Environmental Protection ("Official Gazette of RS" No. 135/04, 36/09, 72/09, 43/11 and 14/16),

- 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, 88/10 and 14/16),
- The Law on Occupational Safety and Health ("Official Gazette of RS" No. 101/05, 91/2015 and 113/17 – other law),
- Law on Planning and Construction ("Official Gazette of RS" No. 72/09, 81/09, 56/10, 24/11, 121/12, 42/13, 50/13, 98/13, 132/2014 and 145/2014),
- Law on Nature Protection, ("Official Gazette of RS" No. 36/09, 88/10, 91/10 and 14/16),

Law on Strategic EIA ("Official Gazette of RS" No. 135/2004 and 88/2010), 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 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 Medicines and Medical Devices Agency of Serbia (ALIMS), the production and trade of drugs and medical devices and monitoring in these areas, operation of ALIMS 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.

2.4.5 Law on Environmental Protection

Law on Environmental Protection (LEP) is adopted in 2004. The LEP is currently the main legislation relating to environment protection in Serbia. The Law on Environmental Protection is fully harmonized with Council Directive 2003/105/EC, which amends Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances (Seveso II Directive).

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, 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, SSHP is categorized as project belonging to environmental category B, due to activities that are to be undertaken under Project Component 3.

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. Application of EHS Guidelines is obligatory for all Bank financed activities. Whenever EHS Guidelines and requirements of national legislation differ, the more stringent ones will be applied.

3. POTENTIAL ENVIRONMENTAL IMPACTS

During the implementation of Project Component 3, including additional financing of activities under the subcomponent 3.2, 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 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 3 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 activities within the additional financing of subcomponent 3.2. The related civil works will be undertaken within existing hospitals and medical centers in VOI , 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. For guidance and more specific information on potential impacts and possible mitigation measures, please refer to Sample Environmental Checklist, which is attached as an Annex to this EMF.

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.

Linear accelerators for treatment of cancer do not contain any radioactive substances, but instead use electricity to generate either high-energy x-rays or accelerated electrons that can be precisely targeted on cancerous tissue. When not in operation, no harmful radiation is generated, although the treatment room itself requires shielding of the walls, doors, and ceiling to prevent escape of scattered radiation during the radiotherapy treatment. The solution applied is similar to the arrangement used to protect staff using diagnostic x-ray equipment, although the higher energy of therapy beams requires a radiation vault (bunker) with thick concrete walls (up to 2.5 m) to provide adequate radiation shielding.

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 according 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 according 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, as indicated in this EFD, and environmental checklist, and relevant Serbian legislation, and World Bank EHS Guidelines - to reduce or avoid negative environmental impact and/or negative impact on human health and occupation safety. The full permitting and licensing process, as required by the national and international standards, will be observed and subject to review and No Objection by the Bank. Whenever the standards of national and international practices differ, more stringent ones will be applied as a rule. For the each facility, the environmental, health and safety standards, and relevant mitigation measures, will be part of the site-specific EMPs, to be prepared using this EMF as guidance.

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). The potential for negative impact will exist during operation of the accelerator

equipment, in case that Serbian standard for ionizing radiation and nuclear safety is not adequately applied. The Project will, as a part of the design and permitting process, ensure for each piece of equipment that relevant standards are applied and design is certified by the Institute of Occupational Health of Serbia. Additionally, the Word bank EHS Guidelines and ILO Code of Practice "Radiation Protection of Workers (Ionizing Radiation")" will apply to all sites under Project Component 3. As a rule, whenever the Serbian and World Bank standards and guidance documents differ on environment, health and safety, the more stringent ones will be applied.

Ionizing radiation that occurs while using the equipment is a major operational concern. Accordingly, the table (Table 1: Review comparison between the World Bank EHS Guidelines and Serbian legislation for the ionization radiation, ANNEX 2) shows review comparisons between *Rules on limits of exposure to ionizing radiation and measurements to assess the level of exposure to ionizing radiation (Official Gazette RS, No. 86/11 on 18.11.2011.) from Serbian legislation* and *Radiation protection of worker – ionized radiation (International Labor Organization 1987, ISBN 92-2-105996-0) from* World Bank EHS Guidelines, their compliance, as well as the conditions under which one of them applies in the Project. According to all relevant information and comparison made, it can be concluded that there are no substantial differences between the standards, because Serbian legislation adopted the recommendations *of the International Commission on Radiological Protection (ICRP), the standards of International Agency for Atomic Energy (IAAE) and the best international practices in this area.*

For the reference, both Serbian and World Bank standards for safety from ionizing radiation, and their comparison, are attached in Annex 2 and Annex 3.

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 3. 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's implementation team will prepare the more detailed Environmental Mitigation and Monitoring Plan (EMP) – fully compliant with the WB OP4.01, that must include, as its integral part, the EMP Checklist. The EMP-checklist will be implemented in three 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 3 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 staff and 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

Draft EMF document has been prepared by SSHP Team under the Ministry of Health during January 2018. EMFD has been prepared in order to ensure application of the good environmental practices and project compliance with the requirements of the World Bank and national legislation. The objectives for additional financing have not been changed in accordance to the objectives stated in parent project, and thus preparation of EMFD for additional financing has been based on the EMF Document developed in 2013 for the purpose of the parent project. On January 25, 2018 SSHP/MoH announced Public Consultations for the general public, bodies and organizations interested in EMFD for the Project. Public and other interested parties and organizations were invited to participate in process of public consultation on draft EMF document. Prior to announcement in the newspapers, the EMFD was published on Ministry of Health web sites. Hard copy of EMFD was also available at the premises of SSHP, at DZ „Savski venac", Pasterova St. 1, Belgrade, within 3 days starting from January 25, 2018.

Public Consultation and presentation of EMF document was held in the in the DZ „Savski Venac", on January 30, 2018, from 10:00 AM to 11:30 AM. In total three (3) participants attended the public consultation, of which two (2) were representatives of respective institutions and one (1) was citizen representing interested public. There were no comments regarding the advertised EMF Document at the public consultation, and the participants supported the entire health care reform project with the

emphasis on the procurement of medical equipment for the treatment and early diagnosis of cancer. More information is attached in Annex 5.

6. IMPLEMENTING ARRANGEMENTS

An Environmental Management Framework (EMF) Document, including a sample Environmental Management Plan (EMP)/Checklist was prepared for the Project. Site specific EMPs/Checklists will be prepared during the subsequent phases, when the locations of investments are finalized. EMPs will become part of the bidding documents and resulting contracts.

Monitoring and reporting on contractor's compliance with site-specific EMPs on the proposed Project will be undertaken on a monthly basis by the supervising engineer/environmental specialist and reports sent to the Project Implementation Team (PIT). Reporting from PIT to the Bank will be undertaken at least twice per year, and more frequently in case of particular issues or problems. Review of the environmental compliance monthly reports and reality check on sample sub-projects will be undertaken by the Bank's safeguards specialist at least once per year, during the regular implementation support missions, and more often in case of specific issues/needs.

The requirements for the environmentally-related activities under the Project will include:

(i) preparation of draft site-specific EMPs by the Project Implementation Team;
(ii) review and approval of site-specific EMPs by the Bank's team;
(iii) inclusion of site-specific EMP as a part of the Bidding Document, and subsequent contract;
(iv) execution of EMP-related measures by the respective contractor(s);
(v) monitoring and reporting of compliance with EMP-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).

ANNEX 1: Draft Format for EMP/EMF for Construction and Rehabilitation Activities for ECSHD Projects

PART 1: INSTITUTIONAL & ADMINISTRATIVE				
Country				
Project title				
Scope of project and activity				
Institutional arrangements (Name and contacts)	WB (Project Team Leader)	Project Management	Local Counterpart and/or Recipient	
Implementation arrangements (Name and contacts)	Safeguard Supervision	Local Counterpart Supervision	Local Inspectorate Supervision	Contactor
SITE DESCRIPTION				
Name of site				
Describe site location			Attachment 1: Site Map [ ]Y [ ] N	
Who owns the land?				
Geographic description				
LEGISLATION				
Identify national & local legislation & permits that apply to project activity				
PUBLIC CONSULTATION				
Identify when / where the public consultation process took place				
INSTITUTIONAL CAPACITY BUILDING				
Will there be any capacity building?	[ ] N or [ ]Y if Yes, Attachment 2 includes the capacity building program			

PART 2: ENVIRONMENTAL /SOCIAL SCREENING			
Will the site activity include/involve any of the following:	**Activity**	**Status**	**Additional references**
	A. Building rehabilitation	[ ] Yes [ ] No	See Section **B** below
	B. New construction	[ ] Yes [ ] No	See Section **B** below
	C. Individual wastewater treatment system	[ ] Yes [ ] No	See Section **C** below
	D. Historic building(s) and districts	[ ] Yes [ ] No	See Section **D** below
	E. Acquisition of land[1]	[ ] Yes [ ] No	See Section **E** below
	F. Hazardous or toxic materials[2]	[ ] Yes [ ] No	See Section **F** below
	G. Impacts on forests and/or protected areas	[ ] Yes [ ] No	See Section **G** below
	H. Handling / management of medical waste	[ ] Yes [ ] No	See Section **H** below

ACTIVITY	**PARAMETER**	**MITIGATION MEASURES CHECKLIST**
A. General Conditions	Notification and Worker Safety	(a) The local construction and environment inspectorates and communities have been notified of upcoming activities (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) (c) All legally required permits have been acquired for construction and/or rehabilitation (d) All work will be carried out in a safe and disciplined manner designed to minimize impacts on neighboring residents and environment. (e) Workers' PPE will comply with international good practice (always hardhats, as needed masks and safety glasses, harnesses and safety boots) (f) Appropriate signposting of the sites will inform workers of key rules and regulations to follow.
B. General Rehabilitation and /or Construction Activities	Air Quality	(a) During interior demolition use debris-chutes above the first floor (b) Keep demolition debris in controlled area and spray with water mist to reduce debris dust (c) Suppress dust during pneumatic drilling/wall destruction by ongoing water spraying and/or installing dust screen enclosures at site (d) Keep surrounding environment (side walks, roads) free of debris to minimize dust (e) There will be no open burning of construction / waste material at the site (f) There will be no excessive idling of construction vehicles at sites
	Noise	(a) Construction noise will be limited to restricted times agreed to in the permit (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
	Water Quality	(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.
	Waste management	(a) Waste collection and disposal pathways and sites will be identified for all major waste types expected from demolition and construction activities. (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. (c) Construction waste will be collected and disposed properly by licensed collectors (d) The records of waste disposal will be maintained as proof for proper management as designed. (e) Whenever feasible the contractor will reuse and recycle appropriate and viable materials (except asbestos)

[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.

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
C. Individual wastewater treatment system	Water Quality	(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
D. Historic building(s)	Cultural Heritage	(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.
E. Acquisition of land	Land Acquisition Plan/Framework	(a) If expropriation of land was not expected and is required, or if loss of access to income of legal or illegal users 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
F. Toxic Materials	Asbestos management	(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 & 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
	Toxic / hazardous waste management	(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
G. Affects forests and/or protected areas	Protection	(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.
H. Disposal of medical waste	Infrastructure for medical waste management	(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 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

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

ANNEX 2: Table 1: Review comparison between the World Bank EHS Guidelines and Serbian legislation for the ionization radiation

Order Number	*Rules on limits of exposure to ionizing radiation and measurements to assess the level of exposure to ionizing radiation, Official Gazette RS, No. 86/11 on 18.11.2011*	*Radiation protection of worker – ionized radiation, International Labor Organization 1987, ISBN 92-2-105996-0*
1	*Radiation risk for the full body or individual organs is determined via the effective dose or tissue equivalent doses and the* ***corresponding likelihood ratios adopted by the International Committee for Radiation Protection: 2007 Recommendations of the International Commission on Radiation Protection Publication No. 103*** *(The 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication 103).* *The equivalents dose for the exposure limit of individual organs professionally exposed persons are:* • *the lens of the eye 150 mSv / year;* • *the skin of 500 mSv / year (refer to the equivalent dose averaged over the surface of any part of skin the size of 1 cm², which is exposed to ionizing radiation);* • *the extremities (hands, forearms, feet and ankles) 500 mSv / year.* *For the purpose of assessing the radiation safety of professionally exposed persons, the risk is descriptively classified in the following way:* 1. *large - estimated annual effective dose greater than 20 mSv ;* 2. *increased - the estimated annual effective dose greater than 6 mSv ;* 3. *moderate - the estimated annual effective dose greater than 1 mSv, and* 4. *negligible - the estimated annual effective dose less than or equal to 1 mSv .* *The effective dose is professionally exposed persons:* 1. *very high, if it is greater than 50 mSv for a year ;* 2. *high, if it is greater than 20 mSv for a year;* 3. *increased, if it is greater than 6 mSv for a year;* 4. *low, if it is less than or equal to 6 mSv for a year;* 5. *very low, if it is less than or equal to 2 mSv for a year;* 6. *negligible if it is less than or equal to 1 mSv for a year.*	*Primary dose limits are individual-related values that apply to the annual doses received by worker from radiation sources related to work. These are as follows:* • *Limit for the annual effective dose equivalent – 50 mSv,* • *Limit for annual dose equivalent in any organ or tissue (expect lens of the eye) – 500 mSv, and* • *Limit for annual dose in the lens of the eye – 150 mSv.* *The dose equivalents indicated above are the mean dose equivalent over the organ or tissue. In the case of skin, the dose equivalent resulting from skin contamination is average over 100 cm2, but if the contamination is very uneven, and is suspected to arise from an unplanned exposure, the dose equivalent should be averaged over 1 cm2. In the case of external exposure of the skin, the dose equivalent recorded by one or few dosimeters is deemed to represent the dose to the skin. The effective dose equivalent is the quantity defined in the glossary at the end of this code.*

	The effective dose of the population : *1. increased , if greater than 1 mSv for a year;* *2. low, if it is greater than 0.3 mSv for a year;* *3. very low, if it is less than or equal to 0.03 mSv for a year;* *4. negligible if it is less than or equal to 0.01 mSv for a year.* *Limit of effective dose for occupational exposed persons is 100 mSv in five consecutive years (mean 20 mSv per year), with the additional restriction that in any year an effective dose does not specify the value of 50 mSv.* *Limit of effective dose refers to the sum of external exposure dose for a defined period of time and the expected effective dose of internal exposure from radionuclides entered the body in the same period.*	
2	*Professionally exposed persons are classified according to operating conditions and levels of exposure to ionizing radiation in two following categories:* *1 Category A: Persons who are professionally employed in a controlled area and one that can receive an effective dose greater than 6 mSv per year or an equivalent dose greater 3/10 of the prescribed dose limits for individual organs of occupationally exposed persons;* *2 Category B: Persons who professionally or occasionally work in the supervised area or occasionally in a controlled area and that the effective dose received by less than 6 mSv per year.*	*For the purpose of this code there are two classes of working conditions for workers engaged in radiation work:* • *Working Condition A – where the annual exposures might exceed three-tenths of the dose limits (point 1),* • *Working Condition B – where it is the most unlikely that the annual exposures will exceed three tenths of the dose limits.* *The employer should make provisions to ensure that a pregnant woman does not work under Working Condition A. There is a risk of inducing mental retardation confined to a limited period of pregnancy makes it necessary that no substantial irregularities to the dose rate occur for pregnant women working under Working Condition B.* *It may be convenient for radiation control purposes to classify workers engaged in radiation work according to their exposure condition.* *The employer should, with the advice of the radiation protection officer classify workers as:* • *Workers engaged in radiation work A: these are radiation workers working under Working Condition A,* • *Workers engaged in radiation work B: these are radiation workers working under Working Condition B.* *The employer should keep the classification of workers engaged in radiation work under review to accommodate changes in working practices*
3	*The professional exposure is prohibited for the person younger than 16 years.* *For the persons under the age of 18 is prohibited in the control zone, expect during the training and regular education under mandatory supervision*	*No person under the age of 16 should be considered to be a worker engaged in radiation work for the purpose of this code.* *No worker, student, apprentice or trainee under the age of 18 should be allowed to engage in radiation Working Condition A, such person may only, therefore, work in Working Condition B.*
4	*Occupationally exposed persons must meet health requirements and shall to carry*	*The employer should provide health surveillance of workers engaged in radiation*

	out a medical examination prior to appointment, at work, in the case of accident, if necessary, upon cessation of the nuclear facility or source ionizing radiation. Medical examinations of persons referred to is a health institution that it meets the requirements prescribed by the regulations governing the health protection. (Law of ionized) *Evaluation of external radiation exposure levels of professionally exposed persons is provided by personal dose equivalents measured by passive dosimeters personally and/or results of measuring of intensity of the ambient dose equivalent in the workplace according to the methodology (Appendix 2). Measurement of personal dose equivalent using passive personal dosimeters for the full body and limbs to assess the level of exposure to ionizing radiation is carried out at least once a month for workers of category A and at least once every three months for workers category B.*	*work and ensure that all assessments to protect the health of workers are carried out. Such health surveillance of workers engaged in radiation work should be based on the general principles of occupational health.* *Health surveillance for normal condition of work should include:* • *Health assessment appropriate to the specific task to be performed, before the worker begins the assignment,* • *Periodic health surveillance during the assignment,* • *Special health surveillance when needed and as prescribed by the competent authority for workers engaged in radiation work A,* • *Assessment when a pregnancy is reported,* • *Other health assessments as required by the competent authority.*

ANNEX 3: Rules on limits of exposure to ionizing radiation and measurements to assess the level of exposure to ionizing radiation, Official Gazette RS, No. 86/11 on 18.11.2011. and Radiation protection of worker – ionized radiation, International Labor Organization 1987, ISBN 92-2-105996-0

http://www.srbatom.gov.rs/srbatom/doc/vazeca_akta/RULEBOOK%20ON%20LIMITS%20OF%20EXPOSURE%20TO%20IONIZING%20RADIATION%20AND%20MEASUREMENTS%20FOR%20ASSESSMENT%20THE%20EXPOSURE%20LEVELS.pdf

ANNEX 4: Proposed components of the Additional Financing

COMPONENT 1: Improvement of Health Financing (Euro 3.0 million)

This component will comprise two sub-components in addition to supporting citizen engagement (CE) activities related to patient rights, including the development and implementation of a strategy and action plan to: (i) improve systems aimed at protecting patient rights (e.g. designated patient rights representatives, systems for collecting and managing grievances); (ii) build patient awareness of their rights and the mechanisms through which they can provide feedback/complaint on any issues; and (iii) build capacity of service providers to understand their roles and responsibilities with respect to patient rights.

Sub-component 1.1: Support Hospital Financing Reforms. New financing model for hospitals based on DRG will roll out in 14 pilot hospitals in January, 2018. Three initial quality indicators for hospital treatment are being defined and alongside two key performance indicators will serve as a basis for hospital financing. This activity received strong support from the MoF, which will contribute sufficient funds in the 2018 Budget towards incentive payment. Roll-out of the DRG-based payment to all hospitals in Serbia (total of 71) is planned for 2019. Specific activities envisaged under the AF would include: i) Integration of clinical pathways developed under the project into hospital information systems; ii) Further definition of admission criteria based on the European version of Appropriateness evaluation protocol and adaptation to national level; iii) Introduction of initial hospital matrix for performance monitoring and incentive for hospital physicians and clinical teams, and iv) Improvement of regulatory framework to recognize and define performance, expenditures and to account DRG into budgeting.

Sub-component 1.2: Strengthen Primary Health Care Financing. Financing model for PHC has improved by the introduction of quality indicators in the formula. The new payment system where portion of the salaries of PHC teams will be directly linked to performance-based on 10 quality indicators will be introduced in 2020. The MoH and the Health Unions have come to an agreement that all further salary increases in the health sector would account towards the variable or performance-based portion of the salary. This would apply to the planned 10 percent salary increase in January 2018. Further monitoring, evaluation and upgrade of the financing formula is of utmost importance for the success of this reform and needs to go together with addressing regulatory framework to recognize and allow for such changes. This will also require strengthening of managerial skills of heads of PHC facilities.

New proposed sub-component 1.3: Develop a Health Care Network Optimization Plan (Masterplan). Within the umbrella of the National Health Care Development Plan 2020-2025, the proposed AF will support the development of a health care network master plan. Due to fragmentation and documented under-utilization of capacities, there is a dire need for Network Optimization Plan (Masterplan) for public health institutions which would, at minimum, define:

- optimal capacity for the network of health institutions to correspond to the needs of population;
- functional and organizational integration of primary care centers and regional hospitals into adequate health centers;
- rationalization of hospital and PHC capacities, including human resources strategy, with appropriately redefining services and capacities based on needs;
- volume and scope of services, which would provide efficiency, quality and safety of care; and
- the provision of appropriate regulatory framework to allow for such restructuring.

Activities under this sub-component may also include supporting the development of palliative care, outpatient care at hospitals (i.e. small surgery under local anesthesia, chemotherapy, internist care, etc.), and any other interventions towards a more efficient utilization of existing capacities. Advocacy activities will also be supported under the AF. This component would finance technical assistance and training.

Subcomponents 1.1. and 1.2. will be affected by the overall reform of public sector salaries system that will come into force in full by January 1, 2020. The new system of public sector salaries will come into force on January 1, 2019 with provisions related to performance based portion of salary becoming effective on January 1, 2020. This means that the full implementation of DRG and PHC related salary incentive scheme would be possible after January 1, 2020. The Law on public sector employees envisages that all public-sector employees (including in public health care) will be remapped to a new salary matrix during 2018. During 2019, criteria for performance based part of the salary will have to be developed in order to be able to implement the new system in full on January 1, 2020. Specific legal and regulatory actions are under discussions with the MoH, MoF and the Ministry of Public Administration and Local Self Government. Scale-up activities will be defined once actions are agreed between the Bank and Government.

COMPONENT 2: Name of the component is changed from *Efficient Purchasing of Pharmaceuticals and Medical Products* to *Improve Access to Quality Health Care* (Euro 1.5 million)

Sub-component 2.1: Establish a Centralized Procurement System. This sub-component would be renamed to "Improve access to medicines". Original activities regarding the establishment of a centralized procurement system for pharmaceuticals are expected to be completed as planned by the end of the original Loan (September 30, 2019) and will therefore not require further support from the AF. However, under the AF,

this sub-component would support the establishment of e-health, and the continuation of activities on the rationale use of antibiotics in line with the National Program for the Control of Antibiotic-Resistant Bacteria and its Action Plan.

Sub-component 2.2: Strengthening Health Technology Assessment Capacity. Pharmaceutical policies interventions focusing on building the capacity of the HIF Pharmaceutical Department – training for the implementation of pharmacoeconomic analysis and health technology assessment (HTA) is already provided under the original project. Due to the complexity of institutionalizing HTA to transit from ad hoc analysis to a formal process under which decision-making is based on the HTA, it is critical that technical assistance and overall support continue in the following areas:

- Identify and train key actors
- Perform HTA and EBM Situation Analysis
- Build an international HTA experience, acquire knowledge and develop expertise for local HTA implementation
- Define HTA institutionalization and institutional arrangements
- Establish an appropriate HTA process and identify priority areas
- Translate research results into recommendations for decision making
- Build and gain experience in strategic planning

Sub-component 2.3: Improve Medical Equipment Maintenance Systems. One of the main SSHP goals is to develop a strategic approach to maintenance of medical equipment aimed at developing a cost-effective system, which represents one of the priorities for the delivery of good quality health services in Serbia. The total replacement value of the equipment installed in Serbian health care facilities is estimated at about US$800–900 million. An internationally accepted figure for the annual cost of a good maintenance program is 6–8 percent of the equipment capital value, which would correspond to an expenditure of US$56–63 million per year – much higher than the budget currently allocated for maintenance. This explains, in part, the large number of unrepaired devices in hospitals. Hospitals also encounter difficulties procuring spare parts for high-tech equipment, contributing to equipment “downtimes” of several months. Despite fiscal constraints, the problem cannot be ignored, as it reduces patient access to lifesaving technology and contributes to a progressive depletion of the medical technology assets in the national health care system.

While preliminary assessment of the current distribution of medical equipment, procedures for maintenance and repairs management, costs and allocation of funds for maintenance, and procurement of spare parts and services will be completed under the ongoing SSHP, the proposed AF would support the MoH:

- in establishing an entity for medical technology management, including definition of its role and staffing;
- in the selection, through International Competitive Bidding (ICB) mechanisms, of an Independent Service Organization, to provide highly qualified multi-vendor maintenance services in one or more pilot hospitals;
- Based on this pilot, the AF would provide technical support to MoH should it consider a possible extension of the service to other health care facilities – either through an expanded private contract, or through the creation of a public/private company for medical technology management, which could be jointly owned by the Government and an Independent Service Organization. This component would finance goods, technical assistance, training.

COMPONENT 3: Strengthen Quality of Service Delivery (Euro 19.0 million)

Sub-component 3.1: Strengthen Quality Improvement Systems. Clinical Pathways. It is expected that the 32 clinical pathways, currently being piloted in selected health care institutions, will be officially adopted and implemented during SSHP. An additional 16 clinical pathways for PHC centers will also be developed and implemented. The proposed AF will support the need to integrate primary and secondary health care clinical pathways (for cancer and cardiovascular diseases at a minimum) to improve management of chronic diseases, which represent the major burden on health. It will also help improve health care quality and enable better management of waiting times for patients with malignant diseases. The AF will also support the update of existing clinical practice guidelines and develop new ones. Given the complexity of using integrated pathways, health care managers and professionals will also receive extensive training.

National Registry needs to be developed for top chronic non-communicable diseases (NCDs) in parallel with corresponding databases which would allow for monitoring and evaluation of outcomes. The next step, to be financed under the AF, would be the development of Disease Management Program for the most frequent NCDs.

The Serbian Health Care Development Plan that ended in 2015 is an expert and a policy document serving as basis for providing direction for the development of the health care system in line with the overall social development. This document outlines the principal objectives and directions of health care development in Serbia and is based on the health care's general social importance and the need for representatives of the society to take position regarding health care objectives and policies. The plan is an instrument for the further development of the health care system policies and changes which will take place in the future (until 2025).

The Health Care Development Plan is also an important prerequisite for the adoption of national programs and strategies in different areas of health care. The proposed AF will support the evaluation of the outcome of the 2015 Health Care Development Plan, which will be followed by the development of an Action Plan. The outcome of this evaluation should underpin the development of the new Health Care Development Plan 2020-2025. This sub-component would finance technical assistance, training, and operating costs.

Sub-component 3.2: Improve Cancer Management. Proposed activities under the AF are as follows:

4. The Serbian Comprehensive Cancer Management Strategy covers prevention, diagnostics and treatment. Although efforts have been made in the past by the MoH, with support from the World Bank and European Commission, to address screening and early detection of leading malignant diseases (cervical, colon and breast cancer), no significant progress has been achieved to date. Diagnosed cancer cases are predominantly stages III or IV. Comprehensive approach to cancer control is needed to improve and align cancer prevention and enhance efficiency so as to (a) establish and strengthen early disease detection system; (b) promote use of digital technologies in cancer registration and patient treatment data collection, transfer, treatment decisions, and analytics against an internationally recognized format; (c) institutionalize more vigorous health promotion activities; and (d) put in place appropriate infrastructure and advanced treatment modalities for tertiary level cancer treatment, which hampers the effectiveness and efficiency in the use of human and financial resources.

5. Improvement of National Coverage of Radiotherapy Services. Six linear accelerators (LINAC), varying in technical specifications and requirements, and three CT-simulators have been procured for the four oncology institutions in Serbia (Belgrade, Kragujevac, Nis and Kladovo) under the parent project and full installation should be completed by March 2018. In parallel, the Government of Serbia has purchased four LINACs from the budget aiming to achieve international standards for radiotherapy coverage.

About 11,000 people in the northern province of Vojvodina (VOI) are affected by cancer annually, 4,000 of whom need radiation or combined chemotherapy and radiotherapy. On a monthly level, more than 200 patients for whom the oncological committee has indicated radiation therapy are registered in the list of appointments. In September 2017, the waiting list for radiation therapy at the VOI included 368 patients. Approximately 60 percent of patients from the waiting list are breast cancer patients followed by gynecological and colorectal cancers. To date, VOI has not benefitted from the radiotherapy procurement. It

is proposed that retroactive financing be considered for the procurement of the equipment for VOI under the proposed AF.

To achieve full territorial radiotherapy coverage and provide equity, access and standardized quality of cancer treatment across the country, the proposed AF would finance two new LINACS and rehabilitation of the two bunkers for VOI. The VOI's Radiotherapy Clinic has qualified staff and is fully equipped for new accelerators. Due to Government's prerogative to secure equity in access and quality of cancer treatment throughout the country, this activity would be subject to retroactive financing.

Climate Change and Disaster. Given that this sub-component will support the rehabilitation of two bunkers for the LINACs, climate change and geophysical hazards (such as flood as in 2014) could impact the structural integrity, materials, siting, longevity and overall effectiveness of the investments. However, this is considered as low risk as climate and geophysical hazards, such as flood, are not likely to impact overall project activities. Nevertheless, the planned works for the two bunkers will incorporate climate and natural disasters resilience considerations (e.g., resilience to floods, extreme temperature increases, etc.).

6. Improvement of Timely Diagnostics in Oncology. While the original project has supported Serbia in meeting international standards in treatment, the needs for diagnostics equipment have been put aside, as the MoH's focus was on providing conditions for timely treatment and addressing waiting lists for cancer treatment. Now that international standards in radiotherapy in Serbia will be met during the length of the project (SSHP and AF), conditions will be in place for addressing issues of under-diagnostics and late diagnostics. It is of utmost importance to increase the quality of diagnostics for timely and efficient cancer management.

In 52.2 percent of the cases, the disease is diagnosed in an advanced stage, with regional and distant metastases present. Such late diagnostics not only adversely affects treatment outcome, but increases the health care system expenses as well due to requirement of applying more and costlier treatment options.

The latest data from the Institute of Public Health show that Serbia is among the countries with the lowest number of CT scanners and MRIs. Improved and early diagnostics in oncology is important not only because diagnosing and treating cancer at an early stage can save lives, but also because of its budgetary implications. Fiscal impacts of such health care policy are also significant, having in mind that savings could be achieved through reduced funds for high-cost oncology drugs. Such approach increases the quality of care and efficiency in public spending on health. Providing opportunities for timely cancer treatment and clearing waiting lists, thanks to the provision of LINACs, will create space for early, improved diagnostics which calls for additional modern equipment (mainly MRI and scanners). The proposed AF could support the MoH in

addressing this issue provided that the MoH fulfill the following conditions of disbursements, all satisfactory to the Bank: (i) adoption of a comprehensive National Cancer Strategy; (ii) adoption of a Network Optimization Plan; and (iii) institutionalization of a sustainable Medical Equipment Maintenance System.

The proposed AF would finance procurement of CT scanners and MRIs, but the precise number and distribution of new diagnostic equipment will be subject to a comprehensive needs analysis. Procurement of diagnostic equipment as well as the PET Center would be conditioned (conditions of disbursement) by the implementation of a National Cancer Management Strategy, a Health Care Network Optimization Plan, and the institutionalization of a medical equipment maintenance system for defined new high cost equipment.

This sub-component would finance works, goods, technical assistance, and training.

COMPONENT 4: Monitoring, Evaluation and Project Management (1.5 million Euro)

The proposed AF will cover the additional three-year extension period of day-to-day management, monitoring and evaluation, audits of the project. This component will also support activities (linked to all components) directed to the Roma population. It will finance operating costs, studies, and training.

ANNEX 5: Report on Public Consultation

SECOND SERBIA HEALTH PROJECT (SSHP)

REPORT ON PUBLIC CONSULTATIONS

for

ENVIRONMENTAL MANAGEMENT FRAMEWORK DOCUMENT

„Second Serbia Health Project – Additional Financing“, subcomponent 3.2:

PURCHASE AND INSTALLATION

OF LINEAR ACCELERATORS, CT SIMULATORS, CT SCANNERS, PET/CT SCANNERS, MRIs, CYCLOTRON FACILITY

- Environmental Category B -

Belgrade, January 2018

1. BACKGROUND

The Government of Serbia has requested a support from the World Bank for additional financing and consequently extension of the activities within Second Serbia Health Project. The request refers to additional financing from the IBRD loan in the amount of 25 million EUR (equivalent to US $ 29.3 million) to the Republic of Serbia for the Second Health Development Project of Serbia (P129539) . The original loan of 29.1 million euros (equivalent to $ 40 million) was approved by the Board of Executive Directors on February 25, 2014, and came into force on May 8, 2015, and the closing date is September 30, 2019. The proposed additional funding (AF) would finance the realization of expanded activities that are in line with the activities of the parent project. These activities would support a comprehensive reform program in the health care system to improve efficiency, improve quality, ensure greater transparency, and rationalize oversized healthcare institutions with an integrated approach to address cancer management and cover radiotherapy services. Providing modern diagnostics within the project will be fully in line with the expanded reform program, including the optimization of the health network and the development of a long-term comprehensive national cancer strategy.

Subject of this EMFD will be provided as a part of additional financing of Component 3: Support Quality improvement in Service Delivery including for Management of Cancer Treatment.

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.

Sub-component 3.2: Improve Cancer Management

The proposed AF would finance two new LINACS and rehabilitation of the two bunkers for Vojvodina Oncology Institute (VOI). The VOI's Radiotherapy Clinic has qualified staff and is fully equipped for new accelerators. While the original project has supported Serbia in meeting international standards in treatment, the needs for diagnostics equipment have been put aside, as the MoHs focus was on providing conditions for timely treatment and addressing waiting lists for cancer treatment. The proposed AF would finance procurement of CT scanners and MRIs, but the precise number and distribution of new diagnostic equipment will be subject to a comprehensive needs analysis. Procurement of diagnostic equipment as well as the PET Center would be conditioned (conditions of disbursement) by the implementation of a National Cancer Management Strategy, a Health Care Network Optimization Plan, and the institutionalization of a medical equipment maintenance system for defined new high cost equipment.

The Project has been classified as Environmental Category B. i.e. a project requiring an EMP pursuant to IFIs Safeguard Policies. According to the current Serbian legislation, particularly following Serbian Law on EIA (Official Gazette of RS, No 135/04, 36/09) – EIA is not required for this kind of medical equipment.

SSHP Project Team prepared draft EMF document for the purchase and installation of linear accelerators, CT simulators, CT scanners, PET/CT Scanners, MRIs and Cyclotron, which was submitted to WB for comments and remarks during January 2018. EMFD has been prepared in order to ensure application of the good environmental practice and project compliance with the requirements of the World Bank which will ensure Second Serbia Health Project - Additional financing.

In parallel with public consultation, on January 30, 2018 WB comments on EMF document were delivered to the SSHP Environmental Specialist.

As regards to public consultation, on January 25, 2018 SSHP announced invitation for Public Consultations for the public, bodies and organizations interested in EMFD for purchase and installation of linear accelerators, CT simulators, CT scanners, PET/CT Scanners, MRIs and Cyclotron. Public and other interested parties and organizations were invited to participate in process of public consultation on draft EMF document. Parallel with the announcement in the newspapers, the EMFD was published on Ministry of Health's web site, and informed the public of the time and place of public consultations. Insight into the EMP document was ensured on following addresses:

- the premises of the SSHP Coordination Unit, DZ „Savski venac", Pasterova St. 1, Belgrade, on working days from 09:00 AM to 15:00 PM (local time), within 3 days starting from January 25, 2018.
- on MoH web site: www.zdravlje.gov.rs

Public Consultation and presentation of EMP document were held in the premises of the SSHP Coordination Unit, DZ „Savski Venac", on January 30, 2018, from 10:00 AM to 11:30 AM.

2. REPORT ON PUBLIC CONSULTATION, BELGRADE, JANUARY 30TH, 2018

In accordance with OP/BP 4.01, MoH/SSHP has prepared EMF document for purchase and installation of linear accelerators, CT simulators, CT scanners, PET/CT Scanners, MRIs and Cyclotron.

The in-country disclosure of the EMF document started on January 25, 2018 when invitation to the interested parties were published in the daily newspaper "Politika", inviting the public, authorities and relevant institutions to have an insight into the proposed document on purchase and installation of of linear accelerators, CT simulators, CT scanners, PET/CT Scanners, MRIs and Cyclotron and environmental impact of the project, with presented mitigation and monitoring measures. Parallel with the announcement in the newspapers, document was placed at MoH web site.

Disclosure of draft EMP document finished on January 30, 2018 when the public meeting was held in premises of SSHP Coordination Unit.

There were three (3) attendees on public consultation meeting: Mr Vojisalav Antic, Mr Igor Komar and Mr Miro Urosevic.

On behalf of SSHP the meeting was attended by Mrs Biljana Kozlovic – SSHP Project Coordinator, Mr Nikola Kerleta, SSHP Specialist for procurement, Mrs Zana Cvetkovic, - SSHP Assistant for procurement and Mrs Milica Duronjic, SSHP Specialist for environmental protection. Also, a public consultation was attended by Mrs Zlata Bilandzija – Masinoprojekt.

The meeting started according to schedule at 10:00 AM, and ended at 11:30 AM.

The public consultation meeting started with short presentation regarding the parent project and objectives and activities planned to be implemented under the AF, provided by Mrs Biljana Kozlovic, and short presentation regarding the draft EMF, including its purpose, objectives, content and scope. After presentations, attendees were invited to comment and discuss the draft EMF Document.

There were no comments regarding the draft EMF Document for additional financing, and the participants supported the entire health care reform project with the emphasis on the procurement of medical equipment for the treatment and early diagnosis of cancer.

The public consultation ended at 11:30 AM.

Република Србија
Министарство здравља
Други пројекат развоја здравства Србије
зајам бр. 8338-YF

Сагласно оперативној политици Светске банке (ОП 4.01)

Министарство здравља
„Други пројекат развоја здравства Србије" (ДПРЗС) позива на

ЈАВНЕ КОНСУЛТАЦИЈЕ

јавност, органе и организације заинтересоване за

ОКВИРНИ ДОКУМЕНТ О ЗАШТИТИ ЖИВОТНЕ СРЕДИНЕ

за „Други пројекат развоја здравства Србије – додатно финансирање", поткомпонента 3.2:

КУПОВИНА И ИНСТАЛАЦИЈА ЛИНЕАРНИХ АКЦЕЛЕРАТОРА, ЦТ СИМУЛАТОРА, ЦТ СКЕНЕРА, ПЕТ/ЦТ СКЕНЕРА, МРИ УРЕЂАЈА И ЦИКЛОТРОНСКОГ ПОСТРОЈЕЊА

У ЗДРАВСТВЕНИМ УСТАНОВАМА У СРБИЈИ КОЈЕ ПРУЖАЈУ УСЛУГЕ ИЗ ОБЛАСТИ ОНКОЛОГИЈЕ

Увид у предметни документ може се извршити:

- у просторијама Јединице за координацију ДПРЗС, ДЗ Савски венац, Пастерова 1, поткровље, Београд, сваког радног дана од 9 до 15 часова, у року од 3 радна дана од објављивања овог обавештења
- на интернет страници Министарства здравља www.zdravlje.gov.rs

Примедбе и мишљења у вези са документом подносе се у писаној облику достављају на адресу Јединице за координацију ДПРЗС, ДЗ Савски венац, Пастерова 1, Београд. Примедбе се могу доставити и електронском поштом на адресу office_pcu@zdravlje.gov.rs

Дана 30. 1. 2018. године, са почетком у 10 часова, у просторијама Јединице за координацију пројекта, ДЗ Савски венац, Пастерова 1, поткровље, Београд, биће одржане јавне консултације и презентација предметног документа.

За додатне информације можете се обратити на следећу адресу:

Министарство здравља
„Други пројекат развоја здравства Србије"
Пастерова 1
11000 Београд, Република Србија,
Тел./факс +381 11 / 36 06 406
Имејл: zana.cvetkovic@zdravlje.gov.rs

Republic of Serbia
Ministry of Health
Second Serbia Health Project
Loan Number 8338- YF

In accordance with the WB Operational Policies (OP 4.01)

Ministry of Health
"Second Serbia Health Project" (SSHP) issues an invitation for

PUBLIC CONSULTATIONS

for the public, bodies and organizations interested in

ENVIROMENTAL FRAMEWORK DOCUMENT (EFD)

for the "Second Serbia Health Project – Additional Financing", subcomponent 3.2:

PURCHASE AND INSTALLATION OF LINEAR ACCELERATORS, CT SIMULATORS, CT SCANNERS, PET/CT SCANNERS, MRIs, CYCLOTRON FACILITY

FOR ONCOLOGY HEALTH CARE INSTITUTIONS

Interested parties can get an insight into the EFD on following addresses:

- the premises of the SSHP Coordination Unit, DZ Savski venac, Pasterova St. 1, attic, Belgrade, on working days from 9:00 AM to 15:00 PM (local time), within 3 working days from the date of public announcement of this invitation;
- the Ministry of Health website: www.zdravlje.gov.rs

Remarks and suggestions in regards to the EFD shall be submitted in written form to the SSHP Coordination Unit, DZ Savski venac, Pasterova St. 1, Belgrade. Remarks can also be sent to the following address: office_pcu@zdravlje.gov.rs

Public consultations and presentation of the subject EFD will be organized on January 30th, 2018, at 10:00PM (local time), at the premises of SSHP Coordination Unit, DZ Savski venac, Pasterova St. 1, Belgrade.

Should you need any additional information, please contact:

"Second Serbia Health Project"
Pasterova Street 1
11000 Belgrade, Serbia
Tel./fax +381 11 / 36 06 406
e-mail: zana.cvetkovic@zdravlje.gov.rs

11300764-1

Republic of Serbia
MINISTRY OF HEALTH

SERBIA HEALTH PROJECT

Belgrade, 30.1.2018.

LIST OF PARTICIPANTS FOR
PUBLIC CONSULTATIONS HELD FOR
THE PUBLIC, BODIES AND ORGANIZATIONS INTERESTED IN
ENVIROMENTAL FRAMEWORK DOCUMENT (EFD) FOR
THE SECOND SERBIA HELATH PROJECT ADDITIONAL FINANCING,
SUBCOMPONENT 3.2: PURCHASE AND INSTALLATION OF LINEAR ACCELERATORS, CT SIMULATORS, CT SCANNERS, PET/CT SCANNERS, MRIs, CYCLOTRON FACILITY FOR ONCOLOGY HEALTH CARE INSTITUTIONS

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3.	Miko Ivković				
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5.					