



# Combined Project Information Documents / Integrated Safeguards Datasheet (PID/ISDS)

Appraisal Stage | Date Prepared/Updated: 01-Feb-2018 | Report No: PIDISDSA23888



**BASIC INFORMATION**

**A. Basic Project Data**

Country Serbia	Project ID P166025	Project Name Additional Financing for Second Serbia Health Project	Parent Project ID (if any) P129539
Parent Project Name Second Serbia Health Project	Region EUROPE AND CENTRAL ASIA	Estimated Appraisal Date 29-Jan-2018	Estimated Board Date 20-Mar-2018
Practice Area (Lead) Health, Nutrition & Population	Financing Instrument Investment Project Financing	Borrower(s) Ministry of Finance	Implementing Agency Ministry of Health

Proposed Development Objective(s) Parent

The PDO is to contribute to improving the efficiency and quality of the public health system of the Republic of Serbia through the strengthening of: (i) health financing, purchasing, and maintenance systems; and (ii) quality improvement systems and management of selected priority non-communicable diseases.

Components

- Improvement of Health Financing
- Improve Access to Quality Health Care
- Strengthening Quality of Service Delivery
- Monitoring and Evaluation and Project Management

Financing (in US\$, millions)

**SUMMARY**

<b>Total Project Cost</b>	31.10
<b>Total Financing</b>	31.10
<b>Financing Gap</b>	0.00

**DETAILS**

<b>Total World Bank Group Financing</b>	31.10
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World Bank Lending	31.10
Environmental Assessment Category	
Partial Assessment (B)	
Decision	
The review did authorize the preparation to continue	

Other Decision (as needed)

## B. Introduction and Context

### Country Context

1. Serbia continues to face major economic challenges following the 2008-09 financial crisis. The crisis led to a drop in real gross domestic product (GDP) of 3.5 percent in 2009. The timid recovery that followed was not sufficient to prevent the country from experiencing a double-dip recession. The economy contracted by 3.1 percent in 2009, by 1 percent in 2012 and by 1.8 in 2014. While the 2009 recession was mainly due to the severe impact of the international financial crisis, recessions in 2012 and 2014 were primarily caused by natural disasters – a drought in 2012 and severe floods in 2014. Growth picked up in 2016 to reach an estimated 2.8 percent, but then slowed down to 2 percent in 2017. Impressive gains in poverty reduction during the 2000s were also reversed by the crisis. Poverty fell from 13.4 percent in 2002 to 6.1 percent in 2008. However, poverty jumped back to 9.2 percent in 2010, with approximately 230,000 people falling back below the poverty line since the crisis. Further, the poverty rate slightly declined, from 24.1 percent in 2014 to 23.5 percent in 2016. The unemployment rate reached a peak of 24 percent in 2012 but has declined since then with particular success achieved in 2017 with the annual unemployment rate falling to 13.1 percent.
2. Despite the tight fiscal space, the Serbian Government has largely pushed ahead with reforms with a view to international integration. Serbia instituted a 15-month wage and pension freeze in 2009 to maintain fiscal discipline in the face of the crisis, and the Government recently announced new austerity measures. Also in 2011, the European Commission (EC) recommended “candidate” status, an important milestone toward EU membership. The Government has been engaged in negotiations to resolve issues related to Kosovo's unilateral declaration of independence, which will be an important step toward full European Union (EU) integration. The general government deficit was 3.7 percent of GDP in 2015 and 1.4 percent of GDP in 2016, down from 6.6 percent in 2014. The deficit reduction came primarily as a result of increased revenues control of expenditures, with major savings from wage and pension reforms. Fiscal consolidation continued in 2017. Overall, it is expected that in 2017 Serbia will have a fiscal surplus of 0.2 percent of GDP.
3. Further reforms will be needed to increase efficiency and quality to meet the rising demand for health and social services from an ageing population within the constrained fiscal environment. The growing share of population above 65 years (14 percent of total) and the old-age dependency ratio (21 percent of the working-age population) are roughly double the rates observed in other upper middle income countries.



## Sectoral and Institutional Context

4. **Health Care Network.** Fragmentation and under-utilization of capacities in the country have been well identified and documented. The MoH is aiming to address this issue and has asked for Bank's support in this exercise, including designing and implementing measures towards network optimization and functional and organizational integration of PHC and regional general hospitals into health centers, piloting of developing palliative care, opening day hospitals (i.e. small surgery under local anesthesia, chemotherapy, internist care, etc.) and other interventions towards increased and more efficient utilization of existing capacities.
5. PHC centers and hospital system, especially in large urban areas, seem to be rather disconnected from each other. Doctors in specialized hospitals say that they do not have any meaningful contacts with PHC doctor before or after treatment episode in hospital facility. This is causing longer stays in hospitals and duplication of diagnostic testing, inefficiency in the utilization of expensive hospital infrastructure and lower functional outcomes of treatment. Although PHC centers have staff on duty after normal business hours on week days and on Saturdays, very few patients use PHC services as they mostly use emergency (ER) services in hospitals for simple health problems. The hospital managers are overwhelmed with diagnostic work that should be done at PHC centers. The picture seems to be different in the regions where communication and working relations between PHC and hospital care facilities are more effective.
6. There is explicit evidence of duplication and inefficiency within the hospital system. Fragmentation of services do not support patient centered service delivery, which in addition to economical inefficiency is undermining service quality. For example, hospitals offering ER services, even in large catchment area, do not have a full range of required specialties; this causes the need for re-referrals and creates delays in starting timely and appropriate treatments. Hospitals that offer emergency services only a few days a week cause inefficiency in the utilization of emergency services infrastructure. Many hospitals are providing the same type of services resulting with low number of cases per hospital, which raise concerns on the potential lack of sufficient practices and experience needed for good quality services.
7. Hospitals' physical infrastructure and equipment are often outdated with buildings that are 50 to 60 years old; this situation does not provide efficient quality services even if these facilities receive continuous repairs and upgrades. There is an obvious need for substantial investments in hospital infrastructure. In a situation where there exist a fragmented and duplicated service delivery system while considering existing financial status of the Serbian economy, it is difficult to envisage any efficient and meaningful improvements in hospital infrastructure without conducting a comprehensive service delivery system functional mapping and network optimization planning. The network optimization plan could also serve as an instrument to attract other sources of funding from various international partners.
8. **Cancer management in Serbia.** Cancer statistics registration uses outdated paper form with a data collection system that requires several steps in data entries. This process is not efficient and increases the chance for errors. The statistics itself does not include proper internationally comparable disease stage at the time of diagnosis nor does it enables to measure five-year's survival rates. It is therefore impossible to evaluate actual level of detection and treatment of malignant tumors in the country, and consequently it is difficult to measure effectiveness of any interventions that are implemented. Therefore, it should be a priority to develop electronic data collection from health care service providers that contains all necessary data on diagnosis and, if possible, on applied treatment modalities. There is a need to establish a system that enables personalized analysis of death certificates to measure cancer management effectiveness. Relevant parliamentary legislative amendment has recently passed to enable relevant data handling. However, the necessary by-laws and regulations are yet to be prepared and enacted.



9. Cancer-related survival rates are low in Serbia when compared to Western European countries. According to Globocan 2012, the age standardized rate of cancer incidence is 269.7 per 100,000 population in Serbia, which is lower than Western European countries of 292.1. On the other hand, the age standardized cancer-specific mortality rate in Serbia is 147.8 per 100,000 population, which is substantially higher than 105.0 in Western European countries.

### C. Proposed Development Objective(s)

#### Original PDO

The PDO is to contribute to improving the efficiency and quality of the public health system of the Republic of Serbia through the strengthening of: (i) health financing, purchasing, and maintenance systems; and (ii) quality improvement systems and management of selected priority non-communicable diseases.

#### Current PDO

The PDO is to contribute to improving the efficiency and quality of the public health system of the Republic of Serbia through the strengthening of: (i) health financing, purchasing, and maintenance systems; and (ii) quality improvement systems and management of selected priority non-communicable diseases.

#### Key Results

##### Project Development Objectives Indicators:

- 1) Percentage of total acute care hospitalization cases in public hospitals reported accurately based on DRGs;
- 2) Percent reduction in average unit price relative to baseline for the 50 most frequently dispensed multi-source pharmaceuticals that are procured through centralized framework contracts;
- 3) Percentage of registered adult patients in Dom Zdravljas with recorded blood pressure value, BMI, smoking status and recommended tips for healthy behavior in the preceding 12 months in their medical records;
- 4) Percentage of patients starting radiotherapy treatment at public hospitals within 28 days between the date of issuance of treatment protocol and the first radiotherapy session for a) breast, b) cervical, c) prostate, d) lung cancers (disaggregated by gender);
- 5) Percentage of registered insured persons 25 to 69 years of age covered by the targeted examination for early detection of (a) breast, b) cervical; and c) colorectal cancers in the past three years (*new indicator*).

### D. Project Description

10. The following are the scale-up activities to be financed under the proposed AF.

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

11. 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.

12. *Sub-component 1.1: Support Hospital Financing Reforms (Euro 0.9 million).* Introduction of DRG based



financing is a long term and comprehensive reform which takes a number of years to be fully implemented. This reform requires a close inter-governmental coordination mainly between MoH, Ministry of Public Administration and Local Self Government (MPALSG) and MoF. Accurate DRG reporting readiness is a key precondition for the successful reform and is entirely under the mandate of the MoH. Bearing this in mind the parent Project focused on the support to the MoH in strengthening and mainstreaming reporting capacity. 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. The AF activities i), ii) and iii) will further support PDO related to health financing as they will help define quality standards for inpatient treatment which has to supplement DRG based payment in order to mitigate the risk of DRG misinterpretation by health care providers. Activity iv) of the AF will provide additional support to the MoH in adjustment of the regulatory framework which is necessary for proper implementation of DRG based financing.

13. *Sub-component 1.2: Strengthen Primary Health Care Financing (Euro 0.8 million).* Financing model for PHC has improved by the introduction of quality indicators in the formula which was developed with the support from the parent Project. The new payment system where a 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. 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. The AF would support the activities launched under the parent Project by strengthening the managerial skills of heads of PHC facilities which will further support PDO related to health financing in primary health care as managerial skills will be a major factor in securing sustainability of the project results.

14. *New proposed sub-component 1.3: Develop a Health Care Network Optimization Plan (Euro 1.3 million).* Due to fragmentation and documented under-utilization of capacities, there is a dire need for Network Optimization Plan 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 (drafting health care law and secondary legislation needed for the adoption of government decree which would implement health network optimization plan).

15. The proposed AF will provide technical support to (i) develop a health care network optimization plan for public health institutions; (ii) develop palliative care, outpatient care at hospitals and other interventions that may be necessary towards efficient utilization of existing capacities; (iii) carry out advocacy activities. All activities



under this sub- component will support the achievement of PDO as network optimization will significantly contribute to both health financing and quality of health care.

16. **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)**

17. *Sub-component 2.1: Establish a Centralized Procurement System (Euro 0.2 million).* 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 operationalization of e-health system, and provision of technical support for the rational use of antibiotics in line with the draft National Program for the Control of Antibiotic-Resistant Bacteria and its Action Plan. This sub-component would further support the PDO related to improvement of efficiency and quality of purchasing of pharmaceuticals and capitalize on the successful implementation of the centralized procurement system for pharmaceuticals.

18. *Sub-component 2.2: Strengthening Health Technology Assessment Capacity (Euro 0.7 million).* Pharmaceutical policies interventions focusing on building the capacity of the HIF Pharmaceutical Department – training for the implementation of pharmaco-economic 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 training to: (i) perform HTA and EBM Situation Analysis; (ii) build and document an international HTA experience; (iii) acquire knowledge and develop expertise for local HTA implementation; (iv) define institutionalization and institutional arrangements for HTA; (v) establish an appropriate HTA process and identify priority areas; (vi) translate research results into recommendations for decision making; (vii) build experience in strategic planning. Planned activities under this sub-component would further strengthen capacity for HTA and build upon capacity building activities envisaged by the parent project.

19. *Sub-component 2.3: Improve Medical Equipment Maintenance Systems (Euro 0.6 million).* 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 good quality health services delivery 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.

20. 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 be building upon expected results of the parent project support the MoH: (i) in the establishment of an entity for medical technology management; (ii) in the establishment of a maintenance system for high cost equipment, including linear accelerators, CTs, MRIs. AF activities would further underpin the results of the parent project and additionally strengthen capacity for medical equipment maintenance.

21. This component would finance goods, technical assistance, training.

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

22. *Sub-component 3.1: Strengthen Quality Improvement Systems. Clinical Pathways (Euro 0.8 million Euro).* It is expected that the 32 clinical pathways, currently being piloted in selected health care institutions, will be officially adopted and implemented during parent project. An additional 16 clinical pathways for PHC centers will also be developed and implemented during the parent project duration. 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. All AF activities under this sub-component would contribute to the PDO primarily through improvements in health care quality but also support activities related to subcomponents 1.1 and 1.2.

23. 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.

24. This sub-component would finance technical assistance, training, and operating costs.

25. *Sub-component 3.2: Improve Cancer Management (Euro 18.2 million).* Proposed activities under the AF are as follows:

26. The Serbian Comprehensive Cancer Management Strategy (Euro 0.5 million) 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.

27. Improvement of National Coverage of Radiotherapy Services (Euro 5.0 million). 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.

28. 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.

29. 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, one CT-simulator 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.

30. Improvement of Timely Diagnostics in Oncology (Euro 12.7 million). While the original project has supported Serbia in meeting international standards in treatment, the need 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.

31. 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 in Europe. 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 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.

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

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

33. The proposed AF will cover the additional two-year extension period of day-to-day management, monitoring and evaluation, audits of the project. This component will also provide training to Roma health mediators. It will finance operating costs, studies, and training.

### **E. Implementation**

#### **Institutional and Implementation Arrangements**



34. The AF will have the same Project Coordination Unit (PCU) in charge of project implementation and fiduciary and will rely on the same arrangements and requirements as the parent project in terms of planning and budgeting, accounting, financial reporting, internal controls, flow of funds and external audit. The procurement/consultant guidelines applicable to the parent project will apply under the AF.

**F. Project location and Salient physical characteristics relevant to the safeguard analysis (if known)**

The Project will be implemented in health centers and hospitals throughout Serbia. Linear accelerators for treatment of cancer generate low level radio radioactivity. They 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 is similar to the arrangements 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 (2.5 m) to provide adequate radiation shielding. Fourteen high-energy linear accelerators are currently installed in Serbia, with age ranging from 4 to 10 years. The typical life time for this kind of technology in Western Europe can exceed 12 years, but reliability of equipment is compromised by poor maintenance, resulting in frequent disruption of therapeutic activity and relevant increase of waiting lists. Final information on the sites where these equipment would be replaced or upgraded with new equipment is not yet confirmed. Preliminary information indicates that existing bunkers are mostly adequate, although they will require upgrading, without change of the building footprint. In case of construction of new facilities, these will be executed within the existing hospital buildings, or their yards. So the two likely scenarios under the Project are: (i) replacement of old accelerator(s) on existing site(s), with only minor civil works for installation; and (ii) construction of new bunker(s) to house a new or larger accelerator.

**G. Environmental and Social Safeguards Specialists on the Team**

Nikola Ille, Environmental Safeguards Specialist  
Jelena Lukic, Social Safeguards Specialist

**SAFEGUARD POLICIES THAT MIGHT APPLY**

Safeguard Policies	Triggered?	Explanation (Optional)
Environmental Assessment OP/BP 4.01	Yes	The EMF prepared for the Second Health Project (P129539) was updated to cover AF and disclosed in-country in January, 2018. The updated EMF is valid



		and applicable to parent project and the Additional Financing (AF) as well. The site-specific EMPs will be prepared for sites covered under the AF as part of the sub-project designs. The site-specific EMPs will be subject to the same procedure as the EMPs prepared under the Second Health Project.
Natural Habitats OP/BP 4.04	No	No works within or near protected habitats are anticipated.
Forests OP/BP 4.36	No	No works within or near protected forests are anticipated.
Pest Management OP 4.09	No	Not relevant.
Physical Cultural Resources OP/BP 4.11	Yes	During 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.
Indigenous Peoples OP/BP 4.10	No	Not relevant.
Involuntary Resettlement OP/BP 4.12	No	The measures implemented at the project sites include rehabilitation of the existing structures and equipment and do not require land acquisition nor resettlement, nor will it lead to loss of access or income. Accordingly, no social safeguards issues related to land acquisition or resettlement issues are foreseen.
Safety of Dams OP/BP 4.37	No	Not relevant.
Projects on International Waterways OP/BP 7.50	No	Not relevant.
Projects in Disputed Areas OP/BP 7.60	No	Not relevant.

**KEY SAFEGUARD POLICY ISSUES AND THEIR MANAGEMENT**

**A. Summary of Key Safeguard Issues**

1. Describe any safeguard issues and impacts associated with the proposed project. Identify and describe any potential large scale, significant and/or irreversible impacts:

Implementation of the project-funded activities is not expected to have any significant negative environmental impact. The issues related to this type of activities include noise, dust, vibrations, and management of construction waste during civil engineering activities - which could be successfully managed and mitigated by application of good engineering practices. Specific issues that will also be taken care of relate to management of the site (as hospitals



must continue operating during the execution of works), and health and safety of population. In some cases, the presence of asbestos, lead or other medical or possibly hazardous waste (if found during rehabilitation works), may require specific handling procedures, which will be defined in site-specific EMPs that are to be prepared for each facility when the locations become known. This includes the extremely small potential risk of residual radioactivity adhering to walls of existing bunkers, which will be assessed before any civil works relating to existing bunkers. Decommissioning and transport of old radiation equipment will be made in full compliance with the national laws and undertaken by fully licensed contractors. Final disposal of the equipment will be made in Vinca Institute for Nuclear Science, which is licensed and authorized national institution for management and storage of radiation equipment and fuel.

2. Describe any potential indirect and/or long term impacts due to anticipated future activities in the project area: There will be no long-term negative environmental impacts if project activities are executed as designed. The minor temporary negative effects (noise, vibrations, dust, construction-related waste) are of limited duration and can be successfully mitigated by application of good engineering practices and application of site-specific EMPs, which will be based on Environmental Framework Document and tailored for each specific site. Decommissioning of old radiation equipment will be made by fully licensed contractors in accordance with the national legislation and international good practice.

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. However, due to national system of controls and due to stringent internal procedures, this is not likely to occur. 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 World 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. Comparison between WB and national legislation in work with radiation equipment shows that standards are compliant, as they both incorporate international best practice.

3. Describe any project alternatives (if relevant) considered to help avoid or minimize adverse impacts.

Not relevant. The old equipment needs to be decommissioned before installation of the new one.

4. Describe measures taken by the borrower to address safeguard policy issues. Provide an assessment of borrower capacity to plan and implement the measures described.

An Environmental Management Framework (EMF) including a sample Environmental Management Plan (EMP)/Checklist was prepared for the parent Project. The EMF was updated with information relevant to Additional Financing and re-disclosed in January 2018. EMF requires that site-specific EMPs/Checklists be prepared during the facility design and 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 will continue to be undertaken on a monthly basis by the supervising engineer/environmental specialist and reports sent to the Project Implementation Team. 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 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. The Project's implementation team as part of the parent Project has developed an understanding and capacity to successfully deal with the environmentally-related activities, which was documented during Bank's regular implementation support missions. The same team is expected to continue work on this Project. 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).

5. Identify the key stakeholders and describe the mechanisms for consultation and disclosure on safeguard policies, with an emphasis on potentially affected people.

Key stakeholders are: Ministry of Health; Ministry of Energy and Environmental Protection; Institute for Occupational Health of Serbia; Medical centers throughout Serbia.

Potentially affected people are medical staff and patients in hospitals where the equipment is being replaced. Draft of the updated EMF was disclosed at Ministry of Health web site, and announced in daily newspaper. The consultation was undertaken after 5 days in Belgrade. EMF requires preparation of site-specific EMPs for each location where the radiation treatment equipment will be installed. These EMPs will be disclosed at the respective hospitals and will include discussion with medical staff and interested general public in respective hospitals. Public disclosure of EMF in-country was completed on January 30, 2018, with no negative comments. GRM is part of the EMF and includes channeling comments through either contractor (on site, during works execution) or through Project Implementation Team (during design, tendering and construction stage). According to national legislation there are no additional requirements, except the ones included in EMF, for the preparation of EMPs and/or their disclosure.

**B. Disclosure Requirements (N.B. The sections below appear only if corresponding safeguard policy is triggered)**

**Environmental Assessment/Audit/Management Plan/Other**

Date of receipt by the Bank	Date of submission for disclosure	For category A projects, date of distributing the Executive Summary of the EA to the Executive Directors
31-Jan-2018	31-Jan-2018	

**"In country" Disclosure**

Serbia  
30-Jan-2018

Comments

The EMF was disclosed on January 30, 2018 for the AF Second Health Project.

**If the project triggers the Pest Management and/or Physical Cultural Resources policies, the respective issues are to be addressed and disclosed as part of the Environmental Assessment/Audit/or EMP.**

If in-country disclosure of any of the above documents is not expected, please explain why:



**C. Compliance Monitoring Indicators at the Corporate Level (to be filled in when the ISDS is finalized by the project decision meeting) (N.B. The sections below appear only if corresponding safeguard policy is triggered)**

**OP/BP/GP 4.01 - Environment Assessment**

Does the project require a stand-alone EA (including EMP) report?

Yes

If yes, then did the Regional Environment Unit or Practice Manager (PM) review and approve the EA report?

Yes

Are the cost and the accountabilities for the EMP incorporated in the credit/loan?

Yes

**OP/BP 4.11 - Physical Cultural Resources**

Does the EA include adequate measures related to cultural property?

Yes

Does the credit/loan incorporate mechanisms to mitigate the potential adverse impacts on cultural property?

Yes

**The World Bank Policy on Disclosure of Information**

Have relevant safeguard policies documents been sent to the World Bank for disclosure?

Yes

Have relevant documents been disclosed in-country in a public place in a form and language that are understandable and accessible to project-affected groups and local NGOs?

Yes

**All Safeguard Policies**

Have satisfactory calendar, budget and clear institutional responsibilities been prepared for the implementation of measures related to safeguard policies?

Yes

Have costs related to safeguard policy measures been included in the project cost?

Yes

Does the Monitoring and Evaluation system of the project include the monitoring of safeguard impacts and measures related to safeguard policies?

Yes

Have satisfactory implementation arrangements been agreed with the borrower and the same been adequately reflected in the project legal documents?

Yes



**CONTACT POINT**

**World Bank**

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**Borrower/Client/Recipient**

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Nenad Mijailovic  
State Secretary

**Implementing Agencies**

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**FOR MORE INFORMATION CONTACT**

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**APPROVAL**

Task Team Leader(s):	Ana Holt
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**Approved By**

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Practice Manager/Manager:	Enis Baris	31-Jan-2018





Country Director:	Stephen N. Ndegwa	01-Feb-2018
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