FRAMEWORK ENVIRONMENTAL MANAGEMENT PLAN

FOR

Health Sector Reform – Improving Health System Quality and Efficiency Project

FINAL VERSION

February 2014
Executive Summary

This project, Health Sector Reform - Improving Health System Quality and Efficiency Project, aims at strengthening prevention and health promotion, rationalizing the health service delivery, increasing secondary specialized ambulatory services, and promoting the implementation of clinical pathways for the most prevalent non-communicable diseases (NCDs). To achieve this over a six-year period, the proposed operation will focus on three main areas: (a) rationalization of the health facility network; (b) strengthening of prevention, health promotion, and the primary care level; and (c) improvement of health sector governance and stewardship.

The project will be financed by the World Bank (WB). The project will be managed centrally by a Project Management Unit (PMU), within the Ministry of Health.

This Environmental Management Plan (EMP) describes the overall management system which has been put in place and which will govern the activities of the Health Sector Reform - Improving Health System Quality and Efficiency Project. The purpose of the EMP is to set out the environmental standards and procedures that must be followed, where relevant, and applied in a transparent and consistent manner. This EMP is intended to fulfill these pre-requisites.

Section 2.1 of the EMP summarizes the main pieces of EU environmental legislation that apply or may apply to the Health Sector Reform - Improving Health System Quality and Efficiency Project. These include Directives on Environmental Impact Assessment (EIA), waste management, water, air quality, protection against radiation and noise and energy efficiency and product safety. The majority of these Directives have already been transposed into Romanian legislation (section 2.2). As indicated in section 2.3, one of the transition periods that has been agreed with the European Commission concerned the incineration of waste, which was granted on account of the problems with existing incinerators for medical waste. Section 2.4 summarizes additional Romanian legislation of relevance to the implementation of Health Sector Reform - Improving Health System Quality and Efficiency Project, including legislation on building authorizations, radiation protection, and medical waste management.

The likely main environmental issues and impacts from the implementation of Health Sector Reform - Improving Health System Quality and Efficiency Project are discussed in section 3. These are divided into those relevant to the construction phase and those relevant to the operational phase of the rehabilitated units. During construction, the main impacts relate to waste management, especially inert and non-hazardous demolition waste, as well as possible hazardous waste (including asbestos, CFCs, PCB/PCTs). Measures to prevent/minimize noise, dust, water pollution and to ensure health and safety during the construction phase are also identified. During the operational phase, the main impacts relate to radiation protection and waste management, especially the safe disposal of clinical waste (both infectious and non-infectious).

Without claiming to pre-judge any decision by the competent authorities, it is considered unlikely that any of the rehabilitation plans under the Health Sector Reform - Improving Health System Quality and Efficiency Project will fall within the
scope of the EIA Directive (Directive 2011/92/EU repealing Directive 85/337/EEC). All changes and new investments are to be made in accordance with the building permit which is issued on the basis of an administrative act issued by the environmental protection authority. However, this possibility cannot be excluded at this stage, and site-specific assessment will have to be carried out at each unit that is to be rehabilitated. Thus the procedures for determining whether an EIA may be required are set out in section 4. The PMU will inform the WB should any of the rehabilitation projects covered in Health Sector Reform - Improving Health System Quality and Efficiency Project fall within the scope of the EIA Directive. The procedures to be followed to obtain the necessary construction permits and environmental permits are also explained.

As detailed in section 5, the PMU will take responsibility for ensuring that all contractors are familiar with the provisions of this EMP, and that all contracts comply with the relevant provisions of the EMP. The roles and responsibilities of the State environmental authorities are also discussed.
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## Abbreviations

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<tr>
<td>ABC</td>
<td>Automated Brightness Control</td>
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<td>CA</td>
<td>Competent Authority</td>
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<td>CFcs</td>
<td>Chlorofluorocarbons</td>
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<td>EA</td>
<td>Environmental Assessment</td>
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<td>EEE</td>
<td>Electrical and Electronic Equipment</td>
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<td>EIA</td>
<td>Environmental Impact Assessment</td>
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<td>EIS</td>
<td>Environmental Impact Statement</td>
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<td>ELVs</td>
<td>Emission Limit Values</td>
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<td>EMP</td>
<td>Environmental Management Plan</td>
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<td>GD</td>
<td>Government Decision</td>
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<td>GEO</td>
<td>Government Emergency Ordinance</td>
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<td>GO</td>
<td>Government Ordinance</td>
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<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>HCFCs</td>
<td>Hydrochlorofluorocarbons</td>
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<td>HTA</td>
<td>Health Technology Assessment</td>
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<td>LEPA</td>
<td>Local Environmental Protection Agency</td>
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<td>LTC</td>
<td>Long-Term Care</td>
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<td>M&amp;E</td>
<td>Monitoring and Evaluation</td>
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<td>MECC</td>
<td>Ministry of Environment and Climate Changes</td>
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<td>MO</td>
<td>Ministerial Order</td>
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<td>MoH</td>
<td>Ministry of Health</td>
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<td>NAMMD</td>
<td>National Agency for Medicines and Medical Devices</td>
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<td>NCD</td>
<td>Non-Communicable Disease</td>
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<td>NCNAC</td>
<td>National Commission for Nuclear Activities Control</td>
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<td>ODS</td>
<td>Ozone-Depleting Substances</td>
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<tr>
<td>PCB/PCT</td>
<td>Polychlorinated biphenyls and polychlorinated terphenyls</td>
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<td>PMU</td>
<td>Project Management Unit</td>
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<td>QC</td>
<td>Quality Control</td>
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<td>QMP</td>
<td>Quality Management Program</td>
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<td>RSA</td>
<td>Radiologic Security Authorization</td>
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<td>RSN</td>
<td>Radiologic Security Norms</td>
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<td>SDC</td>
<td>Swiss Agency for Development and Cooperation</td>
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<td>TRC</td>
<td>Technical Review Committee</td>
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<td>UWWT</td>
<td>Urban Waste Water Treatment</td>
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<td>VOC</td>
<td>Volatile Organic Compound</td>
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<td>WB</td>
<td>World Bank</td>
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<td>WEeee</td>
<td>Waste Electrical and Electronic Equipment</td>
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1 Introduction

1.1 Content of this EMP

As an overall management system, this EMP will set out:

- a description of the project (sections 1.1 & 1.2)
- the relevant organizational structure for the project (section 1.3)
- EU and Romanian environmental legislation and standards which are to be followed (section 2)
- a listing of the environmental impacts caused by the project during the demolition, construction and operational phases (section 3); a determination regarding such impacts is made following the environmental impact assessment
- the environmental procedures which are to be carried out at each health care unit being rehabilitated (section 4),
- the persons having responsibilities for ensuring that the EMP is put into action, as well as the resources which these persons will have (section 5) and
- the review processes which will be put in place to ensure that all persons involved are acting in accordance with the EMP (section 5)
- conclusions (section 6)
- Romanian Environmental Guidelines (Annex 1)
- Romanian Radiation Protection Guidelines (Annex 2)
- Checklist for Small Works for Building Repair and Remediation (Annex 3)

1.2 Background

This project, Health Sector Reform - Improving Health System Quality and Efficiency Project, aims at strengthening prevention and health promotion, rationalizing the health service delivery, increasing secondary specialized ambulatory services, and promoting the implementation of clinical pathways for the most prevalent non-communicable diseases (NCDs). To achieve this over a six-year period, the proposed operation will focus on three main areas: (a) rationalization of the health facility network; (b) strengthening of prevention, health promotion, and the primary care level; and (c) improvement of health sector governance and stewardship. The project will be financed by the World Bank (WB) and will be managed centrally by a Project Management Unit (PMU), within the Ministry of Health.

The project will establish an order of priority of the works to be carried out, starting with the medical units in possession of an operating license.

The four project components are the following:

1. Hospital network rationalization
2. Ambulatory care strengthening
3. Health sector governance and stewardship improvement
4. Project Management and Monitoring and Evaluation

The first component of the Project, Hospital network rationalization, aims at the rationalization of the health care service delivery network through strengthening hospitals’ support systems and services, such as diagnostic services, by: a) redefining the hospital’s role in the health care system, (b) merging services and reducing the number of single specialty
hospitals; (c) improving the quality of care in hospitals functioning in a multi-building setting by moving them into single buildings with integrated diagnostic and interventional platforms, and (d) concentrating the resources available on the regional and county level.

This subcomponent would include civil works (in the facilities’ current sites), medical and other equipment, technical assistance, and training. Civil works would include the (a) rehabilitation of intensive care units, (b) rehabilitation of operating (surgery) rooms, (c) rehabilitation of emergency departments, (d) improvement of Diagnostic Imaging Services, (e) creation of 4 new burn units (with about 6 beds each within a regional hospital), and (f) development of regional radiotherapy units.

The second component, **Ambulatory care strengthening**, aims to support secondary ambulatory and primary care through the two subcomponents:

**Sub-component 1: Implementing Specialized Secondary Ambulatory** aims at creating the conditions to increase secondary specialized services (higher volume–lower cost–greater quality) and reduce the admissions rate in hospitals for patients who can be treated in outpatient settings and it would support: (i) establishment of hub centers for ambulatory diagnostic and treatment including (a) improvement of Diagnostic Imaging Services, (b) implementing day care and ambulatory surgeries/procedures, and (c) cancer screening centers; (ii) implementation of mobile units for cancer screening to support the cancer screening program to reach hard to cover areas; and (iii) improvement of regional pathology and cytology laboratories.

**Sub-component 2: Enhancing primary health care services at community level**, addressing especially those who are “priority populations,” including low-income groups; minority groups (i.e., Roma population); the elderly; and individuals with special health care needs, such as individuals with disabilities, in need of chronic or end-of-life care, or living in inner-city or rural areas. The component would support the scaling up of multifunctional rural centers currently under implementation with the support of the Swiss Agency for Development and Cooperation (SDC), and in implementing different types of long-term care currently being provided as regular hospital services: (i) Community Care Centers and (ii) Differentiated Long-Term Care (LTC): palliative care (including care for chronic neurological cases requiring mechanical ventilation equipment, other chronic long-term health care, and terminal care) and social LTC.

The third component, **Health sector governance and stewardship improvement**, aims to support sector governance and stewardship improvement to bridge the gap between policy and practice and to increase the capacity for conducting and improving the quality of medical care services. Activities include: (i) Improvement of Health Care Quality: Update of Clinical guidelines, implementing quality control; (ii) Strengthening Health Technology Assessment (HTA); and (iii) Strengthening the communications strategy.

The fourth component, **Project Management and Monitoring and Evaluation**, aims to support the Project Implementation Unit to provide day-to-day project management, including the fiduciary tasks of the Project and Monitoring and Evaluation.

### 1.3 Main investment components

The main physical investment components of the Health Sector Reform - Improving Health System Quality and Efficiency Project are:

- a) rehabilitation of intensive care units
b) rehabilitation of operating (surgery) rooms

c) rehabilitation of emergency departments

d) improvement of Diagnostic Imaging Services

e) creation of 4 new burn units (with about 6 beds each within a regional hospital)

f) development of regional radiotherapy units

g) establishment of hub centers for ambulatory diagnostic and treatment

h) community care centers.

1.3.1 Environmental Category

The project is classified under the Environmental Category B in accordance with World Bank operational policies and requires the preparation of an Environmental Management Plan (EMP).

In addition to the overall project EMP which identifies the range of possible problems, individual EMPs will be drawn up for each sub-investment (construction) and administrative permit (as needed) issued by the local (county) environment protection agencies will be obtained. The immediate impact of the proposed investment activities on the environment would be limited and can be divided into construction impacts and operational impacts. Potential adverse environmental impacts from construction activities and from operations of proposed investments are summarized below and are restricted in scope and severity.

These risks are anticipated in advance of project implementation and addressed by local regulations and direct mitigation activities in the design, planning and construction supervision process as well as during the operation of the facilities.

1.4 Project implementation

The project will be managed centrally by a Project Management Unit (PMU) of the Ministry of Health (MoH) under the special coordination of the Minister of Health. The PMU is headed by a Project Director and employs 18 other staff:

- Component coordinators (x2)
- Procurement officers (x5)
- Architect (x1)
- Monitoring & Evaluation (M&E) experts (x4), out of which one environmental monitoring expert
- Financial coordinator
- Financial experts (x2)
- Accountant
- Office manager
- Car driver

The PMU is subordinated to the Minister of Health. The PMU will have specific responsibilities, related to the management of the counterpart funds of the loan. The Project will be coordinated by a State Secretary and Technical Working Groups will be established by ministerial order to ensure technical support to the project.
Establishment of Environmental Expertise within the Project Management Unit

The Monitoring & Evaluation Specialists assisted by the technical support staff would be responsible for the coordination and supervision of measures imposed by Environment Protection Agencies through the issued administrative acts and monitoring programs on the environmental impact activity.

They will work in close cooperation with Local Environment Protection Agencies and they will ensure: a) the coordination of environmental training for staff, designers and local contractors; b) the dissemination of existing environmental management guidelines and develop guidelines in relation to issues not covered by the existing regulations, in line with EU standards for implementation, monitoring and evaluation of mitigation measures; c) that contracts for the construction and supply of equipment include reference to appropriate guidelines and standards; and d) that periodic site visits are conducted in order to inspect and approve plans and monitor compliance.

1.5 Preparation and purpose of the EMP

The aim of this Environmental Management Plan (EMP) is to describe in a generic way the overall management system which has been put in place and will govern all activities falling under the rehabilitation of the emergency departments, anesthesia and Intensive Care units, operating rooms, specialized ambulatories, and rural primary care facilities falling under the Health Sector Reform - Improving Health System Quality and Efficiency Project. The purpose of this EMP is to set out the environmental standards and procedures which are to be followed, where relevant, and to be applied in a transparent and consistent manner, at each of the individual units to be rehabilitated during the course of the project.

The design of the EMP is meant to facilitate the early identification of significant environmental effects, of unforeseen adverse effects, as well as the undertaking of appropriate remedial actions.

Where legislation has been adopted but not yet implemented, e.g. because of transition periods agreed with the European Commission, the EMP sets out the arrangements to be followed during any such interim periods.

This document was first drafted by the central PMU staff following consultation with other institutions and Ministries. It has undergone public consultation and it was sent for review to the NCNAC (National Commission for Nuclear Activities Control) and to the Ministry of Environment and Climate Changes. The document has been revised through the incorporation of the suggested modifications and comments received from the MECC. The present final version plan has been approved by the MECC.

2 Legislation

2.1 General overview of EU legislation

A number of EU Directives and Regulations are of relevance to the implementation of the EMP. These are listed in the box below:
These directives are summarized below and are grouped into six environmental sectors.

### 2.1.1 Environmental Impact Assessment

**Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment** requires that all projects which are likely to have significant effects on the environment by virtue, *inter alia*, of their nature, size or location must be made subject to an environmental impact assessment (EIA) before development consent is granted. Annex I to the

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Directive lists those projects for which an EIA will always be required. In comparison, Annex II lists projects which may require an EIA. In determining whether an Annex II project will require an EIA, the criteria set out in Annex III must be taken into account by the competent authority when making this screening decision.

Where an EIA is required, it shall identify, describe and assess the direct and indirect effects of a project on the population, flora and fauna; soil, water, air, climate and the landscape; material assets and cultural heritage. It will also assess the interactions between these factors.

Project developers must submit to the competent authority a notification pursuant to Annex no. 1 to MO no. 135/2010, to include all the relevant information for the project concerned (not all projects will be subject to the full environmental impact assessment). For projects requiring an EIM, the notification will include:

- Description of the project;
- Outline of the main alternatives studied by the developer and an indication of the main reasons for this choice, taking into account the environmental effects;
- Description of the environmental aspects likely to be significantly affected by the proposed project, including, in particular, the population, fauna, flora, soil, water, air, climatic factors, material assets, including the architectural and archaeological heritage, landscape and the interrelationship between the above factors;
- Description of the likely significant effects of the proposed project on the environment;
- Description by the developer of the forecasting methods used to assess the effects on the environment;
- Description of the measures envisaged to prevent, reduce and where possible offset any significant adverse effects on the environment
- Non-technical summary of the information provided as above;
- Indication of any difficulties (technical deficiencies or lack of know-how) encountered by the developer in compiling the required information.

The Directive requires that the public and environmental authorities are given an opportunity to comment on the environmental statement before a decision is made. The competent authority must take any such comments into account before making its decision whether to grant or refuse the development consent. The environmental statement, the decision including reasons and conditions, and a description, where necessary, of the main measures to avoid, reduce and, if possible, offset the major adverse effects must be made available to the public.

2.1.2 Waste
The EU framework directive on waste, namely Directive 2008/98/EC, which sets the basic requirements, replaces the Directives 75/442/EEC on waste and 91/689/EEC on hazardous waste. It establishes a waste hierarchy that shall apply as a priority order in waste prevention and management legislation and policy, namely:

(a) prevention;
(b) preparing for re-use;
(c) recycling;
(d) other recovery, e.g. energy recovery; and
(e) disposal.

The most important requirement of the Directive is that waste is capitalized or disposed of without endangering people’s health or the environment. There is an absolute prohibition against
dumping or uncontrolled disposal of waste. Member States must put in place an integrated and adequate network of disposal installations, and must dispose of waste at the nearest such installation. To this end, competent authorities must draw up and made public waste management plans. Establishments which carry out capitalization and/or recovery operations must obtain a permit from the competent authority. Such establishments must keep appropriate records, and will be subject to periodic inspection by the competent authorities. Waste holders must have waste handled by authorized waste collectors or by a firm that carries out capitalize or disposal operations.

The mixing of hazardous waste with non-hazardous waste or with other categories of hazardous waste is prohibited. Where hazardous waste is already mixed with other wastes, substances or materials, separation must be effected where technically and economically feasible. Establishments or undertakings that produce, collect, treat, capitalize, dispose of or transport hazardous waste must keep appropriate records. Hazardous waste must be properly packaged and labeled in the course of its collection, transport and temporary storage. Additionally, plans for management of hazardous waste must be drawn up and made public.

The EU also has legislation on specific waste streams, three of which are relevant to the Health Sector Reform - Improving Health System Quality and Efficiency Project.

**Directive 96/59/EC**, amended by Regulation (EC) No 596/2009, regulates the controlled disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT), the decontamination or disposal of equipment containing PCB/PCT and/or the disposal of used PCB/PCT in order to eliminate them completely. Necessary measures must be taken to ensure that, as soon as possible, used PCB/PCT are disposed of, and that PCB/PCT and equipment containing PCB/PCT are decontaminated or disposed of. Inventories must be compiled of equipment with PCB/PCT volumes of more than 5 dm³. All undertakings that are engaged in the decontamination and/or the disposal of PCBs and/or equipment containing PCBs must obtain a waste management license/permit. All used PCBs and equipment containing PCBs which are subject to the above inventories must be transferred as soon as possible to licensed undertakings, and at the same time taking all necessary precautions to avoid the risk of fire. The topping up of transformers with PCB-containing oils and the separation of PCBs from other substances for the purpose of reusing the PCBs is prohibited. The Directive sets out the conditions under which transformers containing more than 0.05% by weight of PCB are to be decontaminated.

**Directive 94/62/EC**, as amended, on packaging and packaging waste lays down measures primarily aimed at preventing the production of packaging waste, and the additional fundamental principles of increasing the re-use, recycling and recovery of such waste. These measures include minimum standards for packaging materials and targets for the recycling and capitalization of packaging waste. Member States have to set up systems for the return and/or collection of used packaging and/or packaging waste, and the reuse or recovery of the packaging/packaging waste collected, so that specified targets will be met.

**Directive 2002/96/EC**, as amended, on waste electrical and electronic equipment (WEEE) applies to all electrical and electronic equipment listed in Annex IA of the Directive, including, *inter alia*, large household appliances, small household appliances, IT and telecommunications equipment, medical devices, and monitoring and control instruments. The Directive requires that appropriate measures are taken to minimize the disposal of WEEE as unsorted municipal waste.
and to achieve a high level of separate collection of WEEE. All collected WEEE must be transported to authorized treatment facilities; and the collection and transport should be carried out in such a way as to optimize reuse and recycling of components or whole appliances capable of being reused or recycled. Producers, or third parties acting on their behalf, must set up systems for the treatment of WEEE using best available treatment, recovery and recycling techniques. Hospitals, Emergency departments, ICUs and operating theaters are likely to have, from time to time, WEEE for disposal, and must ensure their collection and treatment where such collection and treatment services are available. The Directive 2002/96/EC is repealed by Directive 2012/19/EU, with effect from 15.02.2014.

The last possibility under the waste hierarchy is that waste is safely disposed of. The EU regulates the two main methods of waste disposal, namely, landfill and incineration.

**Directive 1999/31/EC on the landfill of waste** sets out stringent operational and technical requirements on waste and landfills, so as to prevent or reduce the negative effects on the environment. Landfills must be categorized into one of three classes: for hazardous waste, for non-hazardous waste and for inert material. Only waste (other than inert waste) that has been subject to treatment may be landfilled. Only hazardous waste that fulfils the relevant waste acceptance criteria set out in Annex II may be accepted by a hazardous waste landfill. A non-hazardous waste landfill may be used for municipal waste, non-hazardous waste of any other origin that meets the relevant waste acceptance criteria set out in Annex II, and for stable non-reactive hazardous waste, but exclusively on the basis of a laboratory test report confirming the non-hazardous nature of the waste, with the exception of municipal waste from this requirement. Inert waste landfills may only be used for inert waste.

Certain types of waste may not be landfilled, these include:
- Liquid waste
- Waste which, in the conditions of the landfill, is explosive, corrosive, oxidizing, highly flammable or flammable
- Hospital and other clinical wastes arising from medical or veterinary establishments, which are infectious or which are non-identified or new chemical substances from research and developing or teaching activities
- Tires, subject to certain exceptions
- Any other types of waste not fulfilling the waste acceptance criteria provided under Decision 2003/33/EC.

The landfill must hold a landfill permit which includes conditions on the operation of the landfill, including post-closure monitoring requirements. Waste acceptance procedures are established, as well as control and monitoring procedures.

**Directive 2000/76/EC on incineration of waste** also sets rigorous operational conditions and technical requirements for waste incineration and co-incineration plants. All incineration and co-incineration plants must be authorized by the relevant environmental protection authority. The Directive establishes emission limit values (ELVs) for emissions to air and discharges to water. Infectious medical waste must be placed straight in the furnace without first being mixed with other categories of waste and without direct handling. **Directive 2000/76/EC is repealed by Directive 2010/75/EU, with effect from 7.01.2014.**
2.1.3 Water

*Directive 98/83/EC on the quality of water intended for human consumption* (i.e. drinking water) aims to protect human health from the adverse effects resulting from any contamination of water intended for human consumption, by ensuring the water is clean and wholesome.

As a general rule, the Directive requires that drinking water meets specific chemical and microbiological standards. The quality of the drinking water must be monitored on a regular basis. If the drinking water constitutes a potential danger to the population, then its distribution must be prohibited or its use restricted. In such cases the consumers must be informed and given necessary advice. The potential deficiencies in the drinking water distribution system could cause non-compliance with the requirements of the Directive. Member States bear the responsibility for the quality of drinking water supplied to the population (including to hospitals), regardless of the reasons that might cause non-compliance with the quality requirements.

*Directive 91/271/EEC, as amended by Directive 98/15/EC on urban waste water treatment* (UWWT), concerns the collection, treatment and disposal of urban waste water and the treatment and disposal of biodegradable waste water from certain industrial sectors (mainly the agro-food industry). Its aim is to protect the environment from damage due to discharges of such waste waters.

Waste water treatment plants must be designed, constructed, operated and maintained so as to ensure sufficient performance under all normal climatic conditions prevalent at their locations. The points of discharge of the treated waste water must be chosen, as far as possible, so as to minimize the effects on the receiving water. The Directive sets out a timetable by which different sized agglomerations must comply with the treatment requirements set out in the Directive.

The discharge of all treated municipal waste water and the discharge of industrial waste water in sewers and treatment plants must be subject to prior rules and/or specific authorization. Treated waste water may be recirculated whenever appropriate, if such measures prove technically and environmentally feasible.

2.1.4 Air

*Directive 1999/13/EC, as amended by Directive 2004/42/CE, regulates emissions of volatile organic compounds (VOCs)* from certain paints and varnishes and vehicle refinishing products. The Directive applies to the products set out in Annex I. These products can only be marketed in the Community if they have a VOC content not exceeding the limit values set out in Annex II of the Directive. Products falling within the scope of the Directive and which are shown to have been produced before the dates laid down in Annex II and do not meet the limit values, may be placed on the market for a period of one year following the date on which the requirement applying to that product comes into force.

The scope of Regulation (EC) No. 1005/2009 is to lay down rules on the production, import, export, placing on the market, use, recovery, recycling, reclamation and destruction of substances that deplete the ozone layer (ODS, listed in Annex I), on the reporting of information related to those substances and on the import, export, placing on the market and use of products and equipment containing or relying on such substances. The Regulation provides that ODS contained in refrigeration, air-conditioning and heat pump equipment, equipment containing solvents or fire protection systems and fire extinguishers shall, during the maintenance or servicing of equipment or before the dismantling or disposal of equipment, be recovered for
destruction, recycling or reclamation. Controlled substances and products containing such substances shall only be destroyed by approved technologies listed in Annex VII of the Regulation or, in the case of controlled substances not referred to in that Annex, by the most environmentally acceptable destruction technology not entailing excessive costs, provided that the use of those technologies complies with Community and national legislation on waste and that additional requirements under such legislation are met. The Regulation sets rules for temporary storage and destruction of ODS and prohibits the export of equipment containing ODS.

**Directive 2009/148/EC** has as its aim the protection of workers against risks to their health, including the prevention of such risks, arising or likely to arise from exposure to asbestos at work. In the case of any activity likely to involve a risk of exposure to dust arising from asbestos or materials containing asbestos, this risk must be assessed in such a way as to determine the nature and degree of the workers’ exposure to dust arising from asbestos or materials containing asbestos. There are some exceptions (worker exposure is sporadic and of low intensity where the work involves short, non-continuous maintenance activities in which only non-friable materials are handled removal without deterioration of non-degraded materials in which the asbestos fibers are firmly linked in a matrix; encapsulation or sealing of asbestos-containing materials which are in good condition; and air monitoring and control, and the collection of samples to ascertain whether a specific material contains asbestos), and in such situations, a personnel warning system must be in place.

The Directive lays down a maximum airborne concentration of asbestos to which the workers may be exposed. The exposure of workers to dust arising from asbestos or materials containing asbestos at the place of work must be reduced to a minimum and in any case below the limit value laid down. Any waste containing asbestos must be placed in suitable sealed packing with labels indicating that it contains asbestos; such waste shall then be dealt with in accordance with the Directive on hazardous waste.

**Directive 87/217/EEC**, as subsequently amended, lays down measures for prevention and reduction of environmental pollution by asbestos. The demolition of buildings, structures and installations containing asbestos and the removal therefrom of asbestos or materials containing asbestos involving the release of asbestos fibres or dust, must be done applying all the necessary measures to ensure that no significant asbestos environmental pollution is produced. Additionally measures must be taken in order to ensure that:

- in the course of the transport and deposition of waste containing asbestos fibres or dust, no such fibres or dust are released into the air and no liquids which may contain asbestos fibres are spilled;
- where waste containing asbestos fibres or dust is landfilled at sites licensed for the purpose, such waste is so treated, packaged or covered, with account being taken of local conditions, that the release of asbestos particles into the environment is prevented.

### 2.1.5 Protection against radiation

**Directive 96/29/Euratom** has provisions concerning basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.

This Directive shall apply to all practices which involve a risk from ionizing radiation emanating from an artificial source or from a natural radiation source in cases where natural radionuclides
are or have been processed in view of their radioactive, fissile or fertile properties. All these practices have to be reported, excepting certain cases specified in the directive. Prior authorization is necessary for certain specific practices, which involve a risk from ionizing radiation emanation including: the deliberate administration of radioactive substances to persons, and the exposure of persons for medical treatment and the use of accelerators except electron microscopes. The disposal, recycling or reuse of radioactive substances or materials containing radioactive substances arising from any practice subject to the requirement of reporting or authorization is subject to prior authorization, excepting when they comply with clearance levels established by national competent authorities.

**Directive 97/43/Euratom** provides general principles regarding health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, following medical diagnosis or treatment. Medical exposure shall be justified in advance. All doses due to medical exposure for radiological purposes shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information. Written protocols for every type of standard radiological practice shall be established for each equipment. Practitioners must have adequate theoretical and practical training. Measures must be taken with a view to avoiding unnecessary proliferation of radiological equipment. All radiological equipment in use is kept under strict surveillance regarding radiation protection and an up-to-date inventory of radiological equipment for each radiological installation must be available to the competent authorities. All necessary measures must be taken in order to reduce the probability and the magnitude of accidental or unintended doses of patients from radiological practices.

### 2.1.6 Energy Efficiency and Product Safety

*The scope of Directive 2010/31/EU, being a recast of Directive 2002/91/EC is to promote the improvement of the energy performance of buildings.* Member States must set minimum energy performance requirements for buildings, based on the methodology set out in the Directive. New buildings must meet these minimum standards. When existing buildings undergo major renovation, the energy performance of the building or the renovated part thereof must be upgraded in order to meet these minimum standards in so far as this is technically, functionally and economically feasible. Energy performance certificates should be made available when buildings are constructed, sold or rented out. The Directive also lays down requirements for the regular inspection of boilers and central air-conditioning systems in buildings.

**Directive 2010/31/EU** is a follow-up measure to **Directive 89/106/EEC, as amended, on construction products and to Directive 92/42/EEC, as amended, on efficiency requirements for new hot-water boilers.** Construction products may only be placed on the market if they are fit for their intended use. In this regard they must have such characteristics that the works in which they are to be incorporated can satisfy the essential requirements with regard to: mechanical resistance and stability; safety in the event of fire; hygiene, health and the environment; safety in use; protection against noise; and energy economy and heat retention. Directive 92/42/EEC establishes the essential requirements to be met by new hot-water boilers fired with liquid or gaseous fuels.
**Directive 2001/95/EC on general product safety** applies where there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned. The Directive imposes a general safety requirement on any product placed on the market for consumers, or likely to be used by consumers. A product is deemed safe once it conforms to any specific Community legislation. In the absence of such Community legislation, the product must comply with specific national legislation or with voluntary national standards which transpose the European standards. In the absence thereof, the Directive sets out mechanisms by which the safety compliance of the product may be determined, including compliance with codes of good practice.

**Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment,** has a similar scope to Directive 2012/19/EU on WEEE, in that it applies to all EEE set out in Annex I of that Directive. Member States shall ensure that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II of the Directive: lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE). This applies to medical devices and monitoring and control instruments which are placed on the market from 22 July 2014. The Annexes III and IV to the Directive contains certain exceptions to this obligation.

### 2.2 Correlation of EU and Romanian legislation

The following table lists the Romanian legislation which transposes the relevant European environmental Directives.

<table>
<thead>
<tr>
<th>EU Legislation</th>
<th>Transposing Romanian legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Environmental Impact Assessment</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Waste</strong></td>
<td></td>
</tr>
<tr>
<td>EU Legislation</td>
<td>Transposing Romanian legislation</td>
</tr>
<tr>
<td>---</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
(replaces the Directive 2000/76/EC on incineration of waste, which is in effect until 7 January 2014)                                                                 | MO 135/2010  
MO 818/2003 modified and completed by MO 1158/2005  
Law no. 278/2013 on industrial emissions                                                                                                                                 |
L 211/2011  
Law no. 278/2013 on industrial emissions                                                                                                                                 |
L 211/2011  
MO MEC 128/2004 modified by MO MEC 918/2009  
MO MMP/MECMA/MAI 2742/3190/305/2011                                                                                                                                 |
GD 1037/2010  
<p>| Water                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                           |</p>
<table>
<thead>
<tr>
<th>EU Legislation</th>
<th>Transposing Romanian legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Air</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Protection against radiation</strong></td>
<td></td>
</tr>
<tr>
<td>EU Legislation</td>
<td>Transposing Romanian legislation</td>
</tr>
<tr>
<td>----------------</td>
<td>----------------------------------</td>
</tr>
</tbody>
</table>
MO-MOH381/05.04.2004  
MO-MOH431/16.04.2004  
MO-MOH1065/21.11.2003  
MO-MOH186/21.09.2004  
MO-MOH 1334/19.10.2004  
O–NCNAC 94/14.04.2004  
O–NCNAC 173/16.10.2003 |
GD 962/2007  
GD 1043/2007  
GD 55/2011 |
MO MDRAP 1817/2013  
MO MTCT MAI 1822/394/2004  
MO MTCT MAI 133/1234/2006  
MO MTBT 2190/2004 |
EU Legislation | Transposing Romanian legislation
--- | ---
 | MO MDRAP 1817/2013
 | MO MTCT MAI 1822/394/2004
 | MO MTCT MAI 133/1234/2006
 | MO MTBT 2190/2004

**Noise**


**Note:** if not specified otherwise, “MO” in the above table refers to Ministerial Order of the Minister of Environment

### 2.3 Transition periods

Romania has been granted a transition period by the European Commission for certain “investment-heavy” environmental Directives which are discussed in section 2.1. The purpose of the transition period is to enable Romania to complete implementation of certain obligations at a post-accession date.

The following table lists the directives for which transition periods have been granted:

<table>
<thead>
<tr>
<th>EU Directive</th>
<th>End date of Transition Period</th>
<th>Obligations for which extra time has been needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directive 1999/31/EC on landfill of waste</td>
<td>31 Dec 2013</td>
<td>Article 5(3)(a) bans liquid waste from being landfilled, but this will be allowed until 2013 in certain specified landfills. Similarly, Article 5(3)(b) bans waste having certain properties (corrosive and oxidising) from being landfilled, but this will be allowed until 2013 in certain specified landfills. Annex I point 2 second indent requires the prevention of surface water from entering landfilled waste. However, until 2013, this provision will not be enforced in 23 facilities for hydro-transportation of non-hazardous waste and in 5 tailing ponds.</td>
</tr>
<tr>
<td></td>
<td>16 July 2017</td>
<td>Article 14(c) requires the necessary works to be taken in accordance with the conditioning plan to ensure all existing municipal landfills comply with the Directive by 16 July 2009. However, the transition period allows 101 existing municipal non-hazardous waste</td>
</tr>
</tbody>
</table>
Landfills until 16 July 2017 to reach compliance. Interim milestones have been set. Also points 2 (on water control and leachate management), 3 (on protection of soil and water), 4 (on gas control) and 6 (on stability) of Annex 1 will not apply fully to 101 municipal non-hazardous waste landfills until 16 July 2017.

<table>
<thead>
<tr>
<th>Directive</th>
<th>31 Dec 2013</th>
<th>31 December 2013 is the deadline for the overall target of 60% for energy recovery by utilization or incineration at waste incineration plants, the overall recycling target of 55%, the 22.5% recycling target for plastics and the 60% recycling target for glass</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directive</td>
<td>31 Dec 2018</td>
<td>The transition period granted provides Romania with a period of time to gradually bring both its collecting systems and its urban waste water treatment facilities in line with the Directive. Under article 3, the collecting systems of agglomerations in excess of 10 000 l.e. (i.e. 61.9% of the total biodegradable load) must become compliant by <strong>31 December 2013</strong>. The collecting systems of agglomerations of less and 10 000 l.e. (i.e. 38.1% of the total biodegradable load) must become compliant by <strong>31 December 2018</strong>. Pursuant to articles 4 and 5, the treatment and disposal of urban waste water must become compliant by 31 December 2015 for urban agglomerations in excess of 10 000 l.e. (i.e. 61.9% of the total biodegradable load), and by 31 December 2018 in urban agglomerations of less than 10 000 l.e. (i.e. 38.1% of the total biodegradable load).</td>
</tr>
</tbody>
</table>

### 2.4 Other relevant Romanian legislation

In addition to the Romanian legislation which transposes the EU legislation listed above, a number of other pieces of Romanian legislation may be of relevance to the implementation of this project. These are summarized below.

**GEO 195/2005 approved by Law no. 265/2006 on environment protection, as subsequently amended and supplemented**

Its objective is to regulate in matters of environmental protection, an objective of major public interest, on the basis of the strategic principles and elements leading to sustainable social
development, creating a unified framework meant to lay down the principles governing the entire environmental protection activity and designing regulatory guidelines for economic activities.

2.4.1 Law no. 50/1991 concerning the authorization of the execution of construction works

Law no. 50/1991 has been modified by Law no. 453/2001, Law no. 401/2003, Law no. 199/2004, and Law no.119/2005. It was re-published with all existing modifications on 13th of October 2004. The main requirements of the Law are listed below:
- it stipulates that the execution of construction works is allowed only on the basis of a construction permit
- the construction permit is issued at the request of the building’s owner
- the construction permit is a document of the local authority, based on which are implemented all the measures requested by law regarding the position, the design, the execution and the functioning of the building in case
- the law stipulates also the works for which a construction permit is required: namely; construction, reconstruction, consolidation, modification and expansion for existing buildings, change of building destination, or repairs.
- approvals and licences as required by the urban planning certificate, together with the opinion of the competent environmental protection authority or, as the case may be, the latter’s administrative act shall be annexed to the construction permit and become an integral part thereof.

2.4.2 Law no. 10/1995 regarding quality in constructions

Law no. 10/1995 was modified by Law no 587/2002. The main requirements of the Law are:
- all the processes and materials used in constructions are verified under established quality standards, in order to be safe for the human health
- construction quality is the sum total of a building’s performance while in operation for the purpose of meeting the requirements of its users and of the community throughout the duration of the building’s life cycle
- the law institutes the quality assurance system in construction works in order to secure the construction and operation of buildings of suitable quality for the protection of human life, people’s property, society as well as the environment
- quality assurance system in construction is implemented in different ways, depending on the category of importance, the regulations and the procedures specific for each building
- classification of buildings by categories of importance is made according to their complexity, destination, safety risk as well as according to economic considerations.

All the above mentioned obligations fall to the parties involved in the design, the execution and the utilization of buildings, as well as in the further use thereof, in keeping with their specific responsibilities. Such parties include: investors, researchers, designers, design evaluators, manufacturers and providers of construction products, constructors, owners, users, technical experts in charge of construction, other technical experts as well as public authorities and professional associations in the field.

2.4.3 Order of Minister of Health no. 1030/2009 regarding the approval of the procedures for sanitary regulation for projects for placement,
development, building and functioning of objectives which run activities with risk for population health

This Order defines the sanitary approval and the sanitary authorization, which must be obtained from the authority in charge. The Ministerial Order makes a distinction between the “sanitary approval” which is the process of sanitary analysis and investigation, a condition that must be met, both from a technical and from a legal point of view, before facilities of interest to the public can be commissioned and operate, a process that checks their compliance with the hygiene and public health rules and the “sanitary permit” which is a legal and technical document issued in written form by the authority in charge.

The necessary documentation required for requesting the sanitary permit includes: the request, the general plan of the position (location, access to the transport network, access to energy network, utilities and land characteristics), the internal configuration plan (functional circuits, their structure, the access to drinkable water network, the waste water collection and disposal system, the solid waste management system, the system for temporary storage and treatment/disposal of any hazardous waste) and proof of payment of the necessary taxes. If required by law, the Environment Impact Assessment will be requested at this stage by the health authority in charge.

2.4.4 Order of Minister of Health no. 1226/2012 concerning the approval of the technical norms for the medical waste management

The main requirements of this Order are:
- technical standards of managing waste resulting from medical activities regulate the manner in which medical waste shall be collected separately by category, packaged, temporarily stored, transported, treated and disposed of, with special attention being given to hazardous waste, in order to prevent environment pollution and health damage.
- the technical norms are compulsory for all the sanitary units, irrespective of their form of organization, where medical activities are conducted that may result in the generation of medical waste.
- the collection, storage and elimination of waste is under the entire responsibility of the medical units from which they are produced.
- health units shall design and implement plans, management strategies and medical procedures that shall prevent dangerous medical waste production or reduce as much as possible the amounts of such waste.
- health units make and implement their own plan for medical waste management, according to their home rules and codes of procedure, based on the regulations in force.
- in each sanitary unit, the activities related to medical waste management are considered professional duties and are stipulated in the job description of each employee.
- Medical waste producers have the following obligations:
  a. to reduce as much as possible the quantity of medical waste, starting from the production phase using all available means;
  b. to promote re-using and re-cycling for the medical waste, where is possible;
  c. to separate the dangerous waste for the non-dangerous waste.

2.4.5 Order of Minister of Health no. 713/2004 regarding the approval of sanitary authorization Norms for the hospitals

This Order is very important from the organizational point of view. In particular:
- it defines the functioning authorization for the hospitals and the necessary standards to be fulfilled in order to obtain this authorization
- annex 1 defines the procedural norms for the sanitary authorization of hospital operation
- annex 2 stipulates the norms of general functional organization of the hospital
- annex 3 stipulates norms concerning the functional structure of the hospital departments and services, including the emergency service, ambulatory sector, operating sector, intensive care sector, roentgen diagnostic service.
- annex 4 stipulates the general Norms of hygiene.

2.4.6 Order of Minister of Health no. 1279 of 14 December, 2012 establishing the Criteria for assessment, functioning conditions and monitoring for equipment for treating by thermal decontamination of medical waste
- sets out the minimum criteria for technical documentation of equipment for thermal decontamination at low temperatures of hazardous medical waste
- reiterates and elaborates on maximum waste reduction requirements
- specifies the three categories of medical waste that may be sterilized as: infectious waste, stinging-cutting waste, and chemical and pharmaceutical wastes according to specific codes
- specifies this thermal sterilization of medical waste is the only accepted procedure for such waste and was permitted until the end of 2008 only, when, following the commissioning of incineration facilities, all hazardous waste, including sterilized waste, will be incinerated, in accordance with the implementation plan of the EU Waste Incineration Directive.

2.4.7 Law no. 111/1996 on safety, regulation, authorization and control of nuclear activities, as subsequently amended and supplemented
The scope of this law is the regulation, authorization and control of nuclear activities performed exclusively for peaceful purposes, in order to comply with the requirements of nuclear security, protection of professionally exposed personnel, of patients, of the environment, of population and of property, with minimum risks in conformity with the regulations and observing the obligations resulting from the agreements and conventions where Romania is party.

The law stipulates that the national competent authority in the nuclear field, which exerts the attributions of regulation, authorization and control provided by this law is the National Commission for Nuclear Activities Control (NCNAC), a public institution of public interest, with legal personality, led by a President coordinated by the Prime Minister.

This law represents the basis for all subsequent legislation and regulations in the field of nuclear activities, including protection against radiation. The most relevant of these regulations for the Health Sector Reform - Improving Health System Quality and Efficiency Project are:
- RSN-11: Radiologic Security Norms in diagnostic radiology and interventional radiology practices, approved by NCNAC Order No. 173/2003, and
2.4.8 Law no. 176/2000 on medical devices, republished in the Official Gazette of Romania no. 79 of 24 January 2005, as subsequently amended and supplemented

This law establishes the legal and institutional framework for medical devices, as well as for the control of the marketing, distribution and provision of services in the field of medical devices.

3 Environmental issues and environmental impact

3.1 Introduction

Section 3 identifies and assesses the potential environmental impact, as well as the environmental issues arising from the implementation and operation of the Health Sector Reform - Improving Health System Quality and Efficiency Project. These have been divided into those that are relevant for the construction phase (demolition and re-building/renovation) and those that are relevant for the operational phase. The legislation in the environmental field must be observed both in the construction and in operational phase. Because of their special impact during the operational phase, the radiation protection issues are treated separately.

As regards each individual site, where the circumstances may be different, and in any event local conditions must be taken into account, a site-specific assessment will be carried out by the contractor before construction works begins, to determine the following aspects:

a) frequently arising environmental problems at the sites (soil erosion, water supply contamination, land slides, etc.);

b) potential environmental impact, if any, due to the project (disposal of waste from construction, construction noise and dust, radiation protection, etc.); and

c) potential requirements, if any, for temporary relocation of services for patients and location of patients and clinical staff during the construction activities.

d) any cultural assets that might be found in the place of construction, and

e) potential foot and vehicle traffic disruption and associated public safety risks

3.2 Construction phase

The environmental issues, including the environmental impact mitigation measures, will be supervised permanently by the Ministry of Health and the health facilities’ staff undergoing rehabilitation works.

No unusual environmental impacts related to construction activities are anticipated under the proposed program given the relatively small size of most of the investments and the siting in existing developed urban areas. These investments are expected to be environmentally beneficial since they will be following new improved planning and design standards; none of the units to be financed is expected to have any large scale, significant and/or irreversible impacts.

The potential environmental impact which might be localized or mitigated during the implementation stage is expected to be minor. In addition, there are environmental regulations in force in Romania, which make control and supervision of construction works mandatory. Contracts and bill of quantities will include clauses for appropriate disposal of construction debris, including hazardous materials that may be encountered. Existing regulations require, and procurement documents will specify, that no environmentally unacceptable materials can be
used. The environmental management checklists (ECA Region Checklist EMP for Small Scale Construction) included in Annex 3 should be made available to contractors engaged in civil works under the project, and should be made an integral part of the civil works contracts.

The environmental impact and the environmental issues that may arise during the construction phase can be further divided into those occurring during demolition and those occurring during the actual re-building/renovation phase. These different aspects are now considered below.

### 3.2.1 Demolition phase

Conditions for environmental placement and monitoring will be imposed as a result of carrying out the activity and site arrangements

<table>
<thead>
<tr>
<th>Environmental impact/issue</th>
<th>Mitigating measures</th>
<th>Institutional responsibility</th>
</tr>
</thead>
</table>
| Possible asbestos waste materials | Identify waste material containing asbestos  
Establish codes for the sorted waste, according to Decision 2000/532/EC establishing a list of wastes  
Employ a licensed waste operator to remove asbestos waste using appropriate safety equipment  
Dispose of asbestos waste at a landfill site licensed to receive such waste | Contractors |
| Inert demolition waste      | Safely sort materials  
Establish codes for the sorted waste, according to Decision 2000/532/EC establishing a list of wastes  
Re-use/recycle waste, where possible  
Remove from site by licensed waste operator  
Dispose of waste to licensed inert landfill, according to the requirements of Decision 2003/33/EC establishing criteria and procedures for the acceptance of waste at landfills | Contractors |
| Other non-contaminated demolition waste | Safely sort materials  
Establish codes for the sorted waste, according to Decision 2000/532/EC establishing a list of wastes  
Re-use/recycle where possible  
Remove from site by licensed waste operator  
Dispose of waste in appropriate licensed landfills, according to the | Contractors |
<table>
<thead>
<tr>
<th>Environmental impact/issue</th>
<th>Mitigating measures</th>
<th>Institutional responsibility</th>
</tr>
</thead>
</table>
| Contaminated demolition waste | - Identify such waste  
- Establish codes for the sorted waste, according to Decision 2000/532/EC establishing a list of wastes  
- Safely separate or keep separate from other wastes  
- Safe disposal either in licensed incinerator, or in a licensed landfill, after adequate treatment, according to the requirements of Decision 2003/33/EC establishing criteria and procedures for the acceptance of waste at landfills | Contractors                  |
| Obsolete electrical and electronic equipment | - Identify any such equipment that may contain CFCs  
- Separate and safe storage of CFC-containing equipment  
- Safe removal/disposal of CFCs in accordance with waste management plan, to an operator licensed for waste collection or treatment  
- All other equipment:  
  - Separate collection  
  - Safe disposal / removal of remaining equipment and parts, according to the waste management plan, to an operator licensed for waste collection and treatment | Contractors                  |
| Equipment containing PCB/PCTs | - Identify such equipment  
- Safe removal from site by licensed waste operator  
- Safe decontamination and disposal of equipment by licensed waste operator | Contractors                  |
| Dust | - Protection of site proximity area by using board fencing or special materials against dust.  
- Protection of soil surfaces  
- Dust control by periodical water sprinkling or other means  
- Keep construction site as isolated as possible | Contractors                  |
<table>
<thead>
<tr>
<th>Environmental impact/issue</th>
<th>Mitigating measures</th>
<th>Institutional responsibility</th>
</tr>
</thead>
</table>
| Noise                      | Minimize noise likely to affect health of the people in the vicinity of the area affected by the construction works by:  
- restricting the time schedule of construction works  
- restricting the time schedule of deliveries and use of heavy equipment | Contractors                  |
| Water pollution            | Protection of domestic waste water network  
Checking the existence of a pretreatment/treatment station of water collected from sectors likely to spill dangerous substances or substances with dangerous bacterial levels  
Special attention to be paid to drainage systems to avoid damage or uncontrolled dumping of demolition materials and to prevent groundwater contamination  
Proper control, collection and disposal of waste water to a treatment station according to the conditions set forth in the connection agreement and subscription agreement with public sewer service operator.  
Collection of any oils for proper treatment and disposal | Contractors                  |
| Aesthetic and landscape aspects | Maintain site in good working condition  
Ensure good security of site | Contractors                  |
| Health and safety          | Ensure workers are properly equipped and trained  
Ensure good security of site | Contractors                  |

Existing building elements (walls, foundations, ground cement slabs etc.) will be carefully demolished and the debris will be sorted and removed as directed by the EMP (to be determined during the preparation phase of the project). All valuable materials (doors, windows, sanitary fixtures, etc) will be carefully dismantled and transported to the storage area assigned for the
purpose. Where feasible, valuable materials will be recycled within the project or sold, only if their assessment/checking exclude any chemical or bacteriological contamination.

Dust from transportation and handling of construction works will be minimized by water and other means such as enclosure of construction sites. To reduce noise, construction will be restricted during certain hours. All debris, construction and wood waste will be stored within the work site. Wood waste will be stored separately and prepared for recycling/recovery or disposal (Attention! Painted or impregnated wood should only be incinerated, not burnt). Open burning and illegal dumping will not be permitted. Proper sites for earth/clay and sand disposal will be determined and prior approval from the relevant authority for disposal will be obtained (Attention! excavated soil, especially soil from medical units dealing with infectious diseases – TBC, AIDS, etc. – must also be examined and treated before being stored). Stock piling of construction debris on site will be avoided and waste will be disposed of on a regular basis, according to the Code, at the appropriate authorized landfill. Debris chutes will be provided to transfer debris from higher floors to the ground.

All wastes shall be managed by licensed waste operators and recovered or disposed of in an environmentally friendly manner. All wastes shall be disposed at appropriate licensed landfill sites or incinerators.

### 3.2.2 Rebuilding/renovation phase

<table>
<thead>
<tr>
<th>Environmental impact/issue</th>
<th>Mitigating measures</th>
<th>Institutional responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste</td>
<td>Appropriate management of domestic and streams waste (packaging waste, DEEE, waste batteries and accumulators, waste PCB/PCT, waste oils, waste tyres), as well as hazardous waste, including medical waste, in case the unit under renovation is still in operation</td>
<td>Contractors</td>
</tr>
<tr>
<td>Air</td>
<td>Purchase of least toxic materials, including paints, varnishes and adhesives, etc.</td>
<td>Contractors</td>
</tr>
<tr>
<td>Water</td>
<td>Selection of least toxic materials, including for piping of drinking water Prevention of groundwater pollution by untreated waste water</td>
<td>Contractors</td>
</tr>
<tr>
<td>Dust</td>
<td>Protection of site proximity area by board or special material enclosures against dust Protection of soil surfaces Dust control by regular water sprinkling or other means Keep construction site as isolated as possible from any operational part of the hospital</td>
<td>Contractors</td>
</tr>
<tr>
<td>Environmental impact/issue</td>
<td>Mitigating measures</td>
<td>Institutional responsibility</td>
</tr>
<tr>
<td>----------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Checking and daily cleaning of construction site</td>
<td>Contractors</td>
<td></td>
</tr>
<tr>
<td>Noise</td>
<td>Minimise noise likely to affect the health of the people in the vicinity of the area affected by the construction works by: - restricting the working hours of the construction site - restricting the time schedule of deliveries and use of heavy equipment</td>
<td>Contractors</td>
</tr>
<tr>
<td>Water pollution</td>
<td>Protection of domestic waste water network Checking the existence of a pretreatment/treatment station of water collected from sectors likely to spill dangerous substances or substances with dangerous bacterial levels Control, collection and disposal of waste water to a treatment station according to the conditions set forth in the connection agreement and subscription agreement with public sewer service operator. Special attention to be paid to drainage systems to avoid damage or uncontrolled dumping of construction materials, as well as prevention of groundwater pollution Collection of any oils for proper treatment and disposal</td>
<td>Contractors</td>
</tr>
<tr>
<td>Aesthetic and landscape</td>
<td>Maintain site in good working condition Ensure good security of site</td>
<td>Contractors</td>
</tr>
<tr>
<td>Health and safety</td>
<td>Ensure workers are properly equipped and trained Ensure good security of site</td>
<td>Contractors</td>
</tr>
<tr>
<td>Ionizing radiation</td>
<td>Careful selection of location for ionizing radiation (radiology and radiotherapy) equipment, and appropriate shielding of equipment.</td>
<td>Contractors</td>
</tr>
<tr>
<td>Energy efficiency and sustainability</td>
<td>Appropriate methods of building insulation to be used Exposed plumbing and pipes to be appropriately insulated</td>
<td>Contractors</td>
</tr>
<tr>
<td>Environmental impact/issue</td>
<td>Mitigating measures</td>
<td>Institutional responsibility</td>
</tr>
<tr>
<td>----------------------------</td>
<td>------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td></td>
<td>Consideration is to be given to the use of solar panels</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consideration to be given to use of other high-efficiency systems for water and space heating</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consideration to be given to locally produced and other sustainable products for construction purposes</td>
<td></td>
</tr>
</tbody>
</table>

**Issues related to new constructions:**

The sites for new constructions will be identified after the project’s approval, and will be located in existing developed urban areas. The land is government-owned and new land is not to be acquired from private owners, nor is resettlement envisaged in order to have access to the land for construction. MOH has documented legal title to all existing health care facilities (buildings), as well as the sites allocated for new construction. There are no illegal occupants on the sites in question.

**Cultural assets**

No cultural or historical assets will be affected by the new constructions. Romania has a well-developed cultural heritage protection system, with responsibility for monitoring and enforcement incumbent on by the Ministry of Culture and National Heritage (MCNH). The legal framework for cultural preservation is outlined in the Law for Preservation of Historical Heritage No. 422/2001, as further amended by Law 468/2003.

During the phase of technical design and obtaining of the environment permit, it will be reviewed if any of the existing health care facilities (buildings) are certified as “cultural or historical heritage”. With respect to the buildings with such status, the procedures outlined in the Law on Historical Heritage will be followed, including for obtaining permit from MCNCP and involving design supervisor engineers who have specific qualifications in the field of historical buildings, certified by MCNH.

If any cultural assets are found during construction (excavation) works (“chance finds”), the measures outlined in the Law 422/2001 as further amended will be undertaken, including instituting a protection zone in compliance with the Law 422/2001, reporting to the local offices of MCNCP and obtaining a special permit for the execution of works in connection with the found cultural assets.

**3.2.3 Special requirements for buildings housing radiology or radiotherapy equipment**

These requirements are described in Annex 2 of this EMP.
### 3.3 Operational phase

<table>
<thead>
<tr>
<th>Environmental impact/issue</th>
<th>Mitigating measures</th>
<th>Institutional responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste management</td>
<td>Appropriate separate collection of:</td>
<td></td>
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<tr>
<td></td>
<td>- municipal- waste type wastes</td>
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<tr>
<td></td>
<td>- hazardous wastes</td>
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<tr>
<td></td>
<td>- non-infectious clinical waste</td>
<td></td>
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<tr>
<td></td>
<td>- infectious clinical waste</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- low-intensity radiated waste</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- radioactive waste</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Proper and safe storage of these different wastes pending collection.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Collection and disposal of wastes in accordance with hospital and local waste</td>
<td></td>
</tr>
<tr>
<td></td>
<td>management plans</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Disposal of wastes by licensed undertakings</td>
<td></td>
</tr>
<tr>
<td>Noise</td>
<td>Adequate consideration for car parking and location of such car parks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adequate consideration to noise issues when considering location etc. for emergency</td>
<td></td>
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<tr>
<td></td>
<td>helicopter landing sites</td>
<td></td>
</tr>
<tr>
<td>Ionizing radiation</td>
<td>Safe use of ionizing radiation (radiology and radiotherapy) equipment. Appropriate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>training to staff</td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>Collection of waste water, their pretreatment and treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>according to legal provisions</td>
<td></td>
</tr>
</tbody>
</table>

Measures shall be put into place to ensure the separate collection of the different categories of waste. In particular, staff will be trained and informed on the mechanisms for safe collection of hazardous wastes, and clinical wastes – both infectious and non-infectious. All wastes shall be managed by licensed waste operators and recovered or disposed of in an environmentally friendly manner. All wastes shall be disposed at appropriate licensed landfill sites or incinerators. Pending collection of hazardous and clinical wastes, they shall be temporarily stored in appropriate, safe and secure areas marked with appropriate warning labels.
Ionizing radiation equipment (radiology, radiotherapy) shall be located in suitable locations and appropriately shielded to avoid unnecessary exposures to staff, patients and visitors. Staff shall be trained for the safe use of such equipment.

4 Procedures

4.1 Introduction
This section of the EMP discusses the procedures that are in place and which must be followed by both the developer and the authorities so as to obtain all necessary permits and agreements for the proposed works on the rehabilitation of the health care units to be carried out.

To obtain the construction permit, the beneficiary is required to obtain an administrative act from the environmental protection authority. Many projects may enter the framing stage.

Likewise, the developer will be required to obtain a construction permit and an administrative act from the environmental protection authority before any works may be carried out. The procedures for obtaining such permits are also detailed.

The operation of the new units may require new or amended operating permits, such as water permits, waste permits etc. The procedures for obtaining these operating permits are described in section 4.3 below. The environmental permit must also be obtained or the existing one must be reviewed, if there were significant changes to the initial data brought by the project.


4.2 Construction phase

4.2.1 Environmental Impact Assessment (EIA)
To be carried out according to the GD 445/2009 and MO 135/2010 approving the methodology for the application of the environmental impact assessment for public and private projects.

4.2.2 Construction permits
For all new developments which will involve modifications or works that are not purely internal, the following requirements must be followed:

Stage 1
First, the developer must apply to the mayor’s office for an urbanization permit. This process is governed under Law 50/1991 modified and completed by Law 453/2001 on the authorization of execution of construction works & measures concerning houses. The urbanization permit is an official act, by which the authorities inform the applicant concerning the property of the

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building/land, the technical and economical issues. Property of the building/land refers to the ownership, the public utilities bondages, etc. The economical issues refer to the actual use of the building and of allowed or non-allowed uses of the building, according to the law. Technical issues refer to the built-up surface as a percent from total surface of the land, the maximum and minimum dimensions of the house lot, the height and the existing utilities. From this paper are established the necessary urbanism criterion and the necessary legal approvals in order to obtain the construction permit. After the urbanization permit has been obtained, a construction approval must be obtained – also from the Mayor - before the works start. So, the urbanization permit is the first phase of the process and the construction permit is the final phase.

Stage 2
The developer sees to obtaining the relevant approvals (mentioned by the urbanization permit) such as:
- telecommunication utilities
- the natural gas network suppliers
- electricity suppliers
- the Fire Commandment
- the water permit
- the environmental permit

All these approvals are included in a unique consent, issued by a Technical Commission of the mayoralty.

Stage 3
The construction approval commits the developer to carrying out the works in agreement with the plan, and not changing the plans. It also fixes a deadline by which the works must be complete. This construction approval process is also governed by Law 50/1991. The documents which must be submitted by the developer in order to obtain a construction approval are listed in Article 7 of Law no 50/1991. After the construction approval is granted the works may commence.

4.2.3 Environmental permit

The developer must apply for the environmental permit from the local LEPA office. The application for the environmental permit must contain information on the owner of the development project and a general description of the works to be carried out. The environmental permit is obtained for the activities that will take place in hospitals after reconstruction on the basis of MO 1798/2007.

4.2.4 Radiologic security authorization

The authorization is issued by the National Commission for Nuclear Activities Control (NCNAC) if the requirements for building, endowment with equipment and specialized personnel and the adequate activity organization are fulfilled according to the specified regulations, as shown in Annex 1 of this EMP.
4.3 Operational phase

4.3.1 Operating permits

All of the permits which the developer was required to obtain so as to be granted the urbanization permit will need to be kept up-to-date and any re-application made before the relevant permit expires.

All conditions upon which the permit was granted must be complied with.

4.3.2 Waste Issues

It is assumed that the majority of emergency departments, intensive care units, operating rooms, burn units, which are under the scope of the Health Sector Reform - Improving Health System Quality and Efficiency Project, will form part of a larger hospital. This means that the hospital will already have a plan for how to handle its waste, and the waste streams generated by the unit will quite simply be handled in accordance with this existing plan (MO no. 1126/2012).

However, if the unit under the scope of the project is a self-contained unit, not attached to a larger hospital, before the unit starts to operate, a plan on the management of all waste produced must be put in place.

Whether the waste plan already exists in the hospital or has been newly created for the renovated unit, in order to comply with EU environmental law, certain standards on waste management must be followed at all of the rehabilitated units.

Firstly, there are general standards applying to all waste as described in section 2.1.2 above (Waste Framework Directive and Hazardous Waste Directive). There are also standards pertaining to specific sorts of waste such as asbestos, PCBs/PCTs, packaging waste and waste electronic and electrical equipment, batteries and accumulators.

Finally, there are the extremely important standards on regulating how waste can be safely disposed of, particularly on the landfill of waste and on waste incineration. Generally speaking, waste from the units must be disposed of either in an incinerator or a landfill that is compliant with the Incineration of Waste Directive or Landfill Directive respectively.

An important category of waste generated by the units will be that of medical waste. There are two very important EU requirements concerning medical waste that must be followed, namely:

- Hospital and other clinical waste which is infectious may not be landfilled;
- Infectious clinical waste must not mixed with other categories of waste and must not be handled directly, it must be placed straight into the incinerating furnace.

In addition to the EU law requirements on medical waste, there are Romanian standards, in Ministerial Order no 1226/2012. These must also be followed at each of the renovated units. A summary of MO 1226/2012 is presented at section 2.4 and guidelines on how to handle medical waste are given in Annex 1, section 13.
4.3.3 Water Issues

There are two key issues regarding water which must be dealt with during the operation of the units.

Firstly, the drinking water which is provided to the operating units, intensive care units, ambulatory care units and emergency care units (or to the larger hospital to which these units are attached) must meet the quality requirements laid down in the Water for human consumption Directive (see section 2.1.3) and in the Romanian transposing legislation.

Secondly, all discharges of used water from the hospital must be collected and treated in accordance with the Urban Waste Water Treatment Directive (see section 2.1.3) and in the Romanian transposing legislation. Romanian legislation on the collection, treatment and discharge of waste waters is found in GD 188/2002, amended and supplemented by GD 352/2005. There is a specific mention in the Romanian legislation that discharges of waste water from sanitary establishments (e.g. hospitals) shall be subjected to prior treatment if it does not comply with the requirements of microbiological standards before it is discharged into the public sewage system.

5 Monitoring

A crucial part in ensuring that this Environmental Management Plan is put into practice is the description of those persons who are responsible for “policing” it, and ensuring that it is in place. Section 5 describes how this EMP will be enforced – by the PMU and also by State environmental officials.

PMU

The PMU will disseminate this EMP to all contractors when they are appointed, as well as to the site supervisors. The PMU will ensure that all contracts with builders, designers, decorators and others involved in implementation of the renovation/rehabilitation aspects of the project will include requirements to respect this EMP and the legal provision concerning the environment.

In addition, the PMU will engage technical specialists who will ensure that all contractual obligations, including conformity with this EMP, are being fulfilled. The technical specialist will act as the representative of the beneficiary and will report to the beneficiary and to the investor, through the PMU.

This technical specialist and the PMU will, so far as within their responsibilities, co-ordinate their activities with the environmental authorities.

The PMU will ensure that the designers and developers of the individual projects will work closely with the relevant agencies to ensure compliance with all relevant legislation, procedures and requirements. The main agencies are the LEPAs, the Environment Guard and the County Public Health Directorates, and their roles and responsibilities are summarized below.
Local Environmental Protection Agencies (LEPAs)

In accordance with the Framework Regulation on the Organization of the Local Environmental Protection Agencies, adopted on the basis of the Governmental Decision 1000/2012 on the Reorganization of the National Environmental Protection Agency, the LEPAs have responsibilities in the fields of authorization and monitoring of the activities with environmental impact, such as:

- issues agreements /authorizations for the activities with significant impact on the environment, based on the current legal provisions;
- authorizes the projects and activities with environmental impact at local level;
- monitors at local level the enforcement of the EIA legislation; and
- monitors the implementation of the County Waste Management Plans.

The National Environmental Guard

The main responsibilities of the Environmental Guard are:

- controls the activities with environmental impact and enforces the sanctions provided in the environmental legislation;
- controls if the environmental legislation and the measures established by the compliance programs, as well as the legal procedures, are properly enforced;
- controls the activities with major/significant impact on the environment, in order to prevent and eliminate the pollution risks;
- where there is a breach of a law or regulation, enforces sanctions (administrative or fines) or collaborates with the judicial authorities (environmental crimes).

County Public Health Directorates

The County Public Health Directorates, among others, are in charge of the sanitary inspections of local level and with the sanitary authorization for the hospitals. In particular, they are responsible for supervision of the collection of medical and contaminated waste.

6 Conclusions

The World Bank, as financer of the Health Sector Reform - Improving Health System Quality and Efficiency Project, has imposed pre-conditions on its loans, *inter alia*, that relevant environmental requirements and standards are complied with.

For the World Bank, this Project is classified as a “Category B” project, and thus requires an Environmental Assessment (EA) to ensure that the project is environmentally and socially sound and sustainable. The EA must examine the potential positive and negative impacts of the project and recommend any measures needed to prevent, minimize, mitigate or compensate for adverse impacts and to improve environmental performance.

As an EU member state, Romania has to comply with all relevant EU environmental legislation, including any transitional periods that have been agreed with the European Commission. If necessary, an EIA will be carried out in accordance with the requirements of the EIA Directive, and that public consultations will take place when required. The EMP has set out the procedures...
to be followed to determine whether an EIA will be required for any specific rehabilitation project within the Health Sector Reform - Improving Health System Quality and Efficiency Project, and the procedures to be followed if such an EIA is required. The EMP has also set out the measures to be taken to ensure that other applicable EU legislation on waste, water, air, radiation protection and product safety will be complied with.

The PMU have committed themselves to ensuring that all contractors are made aware of the contents of this EMP and will make certain that all contracts impose an obligation on contractors to comply with all relevant parts of the EMP.
<table>
<thead>
<tr>
<th>Type of activity</th>
<th>Expected input</th>
<th>Mitigation measure</th>
<th>Type (Methodology) Monitoring</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site clean–up works</td>
<td>Dust and noise Contamination of water and soil</td>
<td>Fence off the construction site Confine noise and vibration generating activities to the daytime. Notify neighbours or local community if work is going to occur outside of those hours. Water usage should be monitored. Ensure the existence of the connection agreement and subscription agreement for waste waters drainage/treatment. Accumulate waste waters in septic tanks and their pretreatment according to the conditions set forth by the legislation regarding the treatment of waste waters. Once filled up, discharge into the operating sewerage network existing at all the sites according to the legislation in force. Minimize waste generation of waste. Avoid waste disposal in the areas at the immediate</td>
<td>On–site inspection during the course of the whole construction process</td>
<td>Contractor</td>
</tr>
</tbody>
</table>

**Construction Phase**

- Contractor: Permanent monitoring for the whole period of construction After completion of clean-up.
- Responsible agency: MoH PMU Supervisor Design company Local government.
<table>
<thead>
<tr>
<th>Groundwork</th>
<th>Generation of dust</th>
<th>Water the site minimum twice daily</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Damage to the existing engineering systems</td>
<td>Vehicle transporting bulk should be covered</td>
</tr>
<tr>
<td></td>
<td>Damage to the existing vegetation</td>
<td>Cover the exiting vegetation with protective box-like grates.</td>
</tr>
<tr>
<td></td>
<td>Damage to topsoil in affected areas around the buildings.</td>
<td>Removal of faded plants and re-planting.</td>
</tr>
<tr>
<td></td>
<td>Damage to cultural/historical monuments.</td>
<td>Remove and store top layer of soil, in case of uncontaminated soil, in designed places, cover to prevent water flushing and after finishing replace it. If the soil is contaminated then it will be transported towards a firm authorized for treatment/disposal of uncontaminated soil.</td>
</tr>
<tr>
<td></td>
<td>Disposal of excavated waste at uncontrolled dumping sites</td>
<td>Limit all works to the designated work sites. In case of chance find of historical/cultural artifacts in the course of earth works, immediately suspend activity on the site and resume works only upon receiving written permission from the client.</td>
</tr>
<tr>
<td></td>
<td>On-site inspection during the course of the whole construction process.</td>
<td>Contractor</td>
</tr>
<tr>
<td></td>
<td>Permanent monitoring for the whole period of construction, After completion of recovery works.</td>
<td>MoH PMU Supervisor</td>
</tr>
<tr>
<td></td>
<td>Design company</td>
<td>Local government</td>
</tr>
</tbody>
</table>
Waste depending on its classification as hazardous, non hazardous or inert is disposed of strictly only in the conditions and sites assigned by local government.

<table>
<thead>
<tr>
<th>Demolition</th>
<th>Dust Generation of the construction waste/debris</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Damage to internal engineering systems</td>
</tr>
<tr>
<td></td>
<td>Dampen down dry areas; cover trucks transporting</td>
</tr>
<tr>
<td></td>
<td>debris while traveling public highways; blacktop</td>
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<tr>
<td></td>
<td>temporary roads to minimize dust. Carefully</td>
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<tr>
<td></td>
<td>demolish existing elements of buildings; pile</td>
</tr>
<tr>
<td></td>
<td>up debris in the designated storage areas and</td>
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<tr>
<td></td>
<td>remove periodically to avoid accumulation of vast</td>
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<td></td>
<td>amounts of waste.</td>
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<tr>
<td></td>
<td>Visual observation. Control for the whole period</td>
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<tr>
<td></td>
<td>of demolition works.</td>
</tr>
<tr>
<td></td>
<td>Contractor</td>
</tr>
<tr>
<td></td>
<td>The whole period of works</td>
</tr>
<tr>
<td></td>
<td>MoH PMU Supervisor</td>
</tr>
<tr>
<td></td>
<td>Local government</td>
</tr>
<tr>
<td>Disposal of</td>
<td>Disposal of waste at uncontrolled dumping</td>
</tr>
<tr>
<td>construction</td>
<td>sites leading to soil and groundwater contamination</td>
</tr>
<tr>
<td>waste</td>
<td>Minimize volumes of generated waste. Crashing</td>
</tr>
<tr>
<td></td>
<td>the disposed concrete blocks for reuse as gravel</td>
</tr>
<tr>
<td></td>
<td>substitute is suggested in case these concrete</td>
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<tr>
<td></td>
<td>are classified as non hazardous. Descend the</td>
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<td></td>
<td>construction waste in closed containers and</td>
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<td>transport in covered body trucks The demolition/</td>
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<td></td>
<td>construction waste is disposed strictly in the</td>
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<td></td>
<td>area assigned by local government. Inert and</td>
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<td></td>
<td>non-hazardous waste</td>
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<td></td>
<td>Visual observation. Control for the whole period of</td>
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<td></td>
<td>demolition works</td>
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<tr>
<td></td>
<td>Contractor</td>
</tr>
<tr>
<td></td>
<td>The whole period of works</td>
</tr>
<tr>
<td></td>
<td>Local government</td>
</tr>
<tr>
<td>Building and renovation works</td>
<td>Accidental spillage of fuel, machine-oil, lubricants, etc</td>
</tr>
<tr>
<td>Use of toxic materials</td>
<td>Exclude usage of asbestos containing construction materials. Avoid the use of PVC (Polyvinyl Chloride) in plumbing lines and waste lines. Exclude usage of asbestos containing construction materials. Avoid the use of PVC (Polyvinyl Chloride) in plumbing lines and waste lines. Use nontoxic material for the exposed plumbing and pipe insulation. Use lead-free solder for water pipes. Locate incoming cables underground.</td>
</tr>
</tbody>
</table>

**OPERATION PHASE**

<table>
<thead>
<tr>
<th>Hospital in operation</th>
<th>In adequate handling of waste water containing hazardous substances, toxic gases and inadequate handling of medical waste during hospital operation. Collection and codisposal non-disinfected medical wastes with household waste at uncontrolled dumping sites leading to soil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assign clear responsibility for waste management to members of management team. Developed a waste management plan for the project assisted hospitals, with the emphasis on minimization of waste production at source and hazardous / non-hazardous waste segregation, source reduction, treatment and proper disposal according to the legal provisions in waste management.</td>
<td></td>
</tr>
<tr>
<td>Waste management responsible person (senior nurse or epidemiologist) carries out daily monitoring of the healthcare waste management system. Periodic evaluation and review of the waste management program</td>
<td></td>
</tr>
<tr>
<td>Hospital administration</td>
<td>Daily Periodic</td>
</tr>
</tbody>
</table>
and groundwater contamination and risk of spread of diseases.

- Train hospital staff, including health care professionals, who produce waste.
- Envision of temporary storage areas for waste disposal in hospital designs for full control of medical waste waiting for off-site transportation.
- Burn infected medical wastes in incinerators in compliance with specifications (in case if incinerators are planning to install).
- Treat infectious waste prior to disposal.
- Dispose of household type waste only in landfill areas assigned by the local governments.
- Ensure that adequate resources are allocated for health care waste management, including plastic bags, waste collection bins, sharp containers, trolleys
Annex 1 Environmental Guidelines

1. Introduction
The Environmental Guidelines section details the specifics to be addressed in the ecological/biologic concept, design and planning of small-scale projects for the upgrading of the health infrastructure. The guidelines cover the approach of the construction and dismantling activities during the following phases: site preparation/organization, dismantling/construction, as well as during the operational phase. They discuss the protection measures required during the site operation phase, the management of waste – including medical waste –, as well as air quality protection, noise protection, rainwater quality protection, but also the monitoring of collected water that is discharged into the sewage system, and issues such as the selection of construction materials and construction methods with limited impact on the environment and energy saving methods under project supported activities. The guidelines are a basis for training, programming, research, discussions and workshops. However, in selecting suitable construction methods and materials for the clinics, great attention should be paid to locally available traditions, skills and resources in the project sites.

2. The site
The site specific assessment and review shall carefully assess the following issues:
- Dust and noise due to the demolition and construction;
- Dumping of construction wastes accidental spillage of machine oil, lubricants, etc;
- Risk from inadequate handling of medical waste or medical radiation hazards; and
- Potential requirements, if any, for temporary relocation of patient services, patients and clinical staff during the construction activities.

Dust from transportation and handling of construction works will be minimized by water and other means such as enclosure of construction sites. To reduce noise, construction will be restricted during certain hours. All debris, construction and wood waste will be stored within the work site. Wood waste will be stored separately and arranged to be recycled instead of disposing it. Open burning and illegal dumping will not be permitted. Proper sites for earth/clay and sand disposal will be determined and prior approval from relevant authority for disposal will be obtained. Stock piling of construction debris on site will be avoided and waste will be disposed of on a regular basis at the authorized government dumping ground. Debris chutes will be provided to transfer debris from higher floors to the ground.

The following remarks are intended to reflect the type of standards and guidelines to be incorporated in the construction and rehabilitation of hospital facilities:

3. Energy Efficiency, Insulation and Ventilation
Insulation will be tailored to the seasonal impacts of climate, internal thermal load, and characteristics of exposure. Vapor barriers will prevent moisture intrusion in the roof insulation and outer wall cavities and using damp course.

Window location will be determined on view, ventilation, light, thermal gain, privacy control and interior space functions.
High-efficiency systems for heating domestic water (including solar systems) and for interior space heating will be selected with maintenance and long term running costs in mind. Plumbing will be coordinated to minimize plumbing and also water service to toilets, kitchen and utility rooms. Water-saving faucets, ring mains and other devices also require consideration. All plumbing lines will preferably be copper, with waste lines in cast iron to avoid PVC outgassing. Exposed plumbing and pipe insulation should be of non-toxic material.

4. Filtration
Using electrostatic, activated charcoal, and high-efficiency filters can greatly improve the indoor air quality. Filters that remove particulates down to 0.3 microns are advisable for capture of microbial agents. Molecular absorbing filters can be used to remove toxic gases originating from internal and external sources. Self-actuating electrostatic filters are possible to clean, less expensive, and use no electricity. Electrical electrostatic filters should have an activated charcoal filter in order to subsequently remove ozone that can be generated by the particles on the filter. When sequential filtering for primary particles, HEPA (high efficiency particulate air filtration) is used, then the use of charcoal, potassium permanganate, or other molecular absorbers plus negative ionization at the delivery point of distribution are desirable. Smoking areas or rooms, if any, will be isolated by partitions and equipped with outside exhaust that creates a negative pressure in the space. Certain medical equipment, copy machines, as well as other reproduction equipment, will be adequately ventilated to remove their particulates and gases. Maintenance, including duct cleaning, filters cleaning and changes, and cleaning positive plate receivers and ionizing tips, will be routine and included in recurrent maintenance budgets.

5. Electrical Systems
Cablurile de intrare ar trebui montate sub pământ. Ar fi prudent ca sursa de alimentare principală și panoul să fie montate la o distanță semnificativă de posturile de lucru și spațiile de așteptare, pentru evitarea câmpurilor electromagnetice. Legarea de protecție la pământ, lângă orice instalăție sanitară, reprezintă o măsură de precauție. Selectarea corpurilor, lămpilor, dispozitivelor și instalațiilor de iluminat care sunt cele mai eficiente din punct de vedere energetic va reduce necesarul de energie, însă poate introduce câmpuri electromagnetice nedorite. Aveți în vedere faptul că apropieria de corpurile de iluminat cu halogen, fluorescente și a altor dispozitive de iluminat foarte eficiente din punct de vedere energetic folosite pentru mese, pardoseală și birouri poate expune la câmpuri electromagnetice dăunătoare.

6. Cabinetry and Wood
Non-toxic finishes are available but expensive. Selecting the least toxic finishes is advised.

7. Finishes
Water-based interior non-toxic, no allergenic paint for drywall or plaster surfaces is preferable to latex or oil-based paints from a respiratory standpoint. Any enamel coating for doors or other surfaces that require a more durable finish is advised to be applied away from interior spaces and be fully aired for over a month before installation. Indoor space should not be occupied until odor and toxins of the paint or finish has been adequately aired.

8. Flooring
Tradition tile, marble, stone and terrazzo floors can be hard to stand and walk upon but have legendary durability. Non-toxic grouts and methods of installation will be used. Cleaning considerations should be included in the decision process.

9. Window Treatments
Vertical blinds provide light control, are easy to maintain, and require minimal stacking room. Horizontal blind can in combination with a white or light ceiling reflect daylight more deeply into a room. Exterior roller blinds, operable from the interior, are particularly effective in controlling solar thermal gain and interior heat loss, and give the benefit of security. Direct solar radiation can be attenuated by fabric mesh.

10. Exterior and Interior Colors
In climates with hot summers, reflective roofs provide a cooling advantage. When cold season occur, darker-colored exterior walls will benefit by low-angle winter solar gains but be less heated by the light angle of the summer sun. White or very light-colored ceilings and interior side walls allow for deeper reflective penetration of natural light. Doors between interior room spaces can act as reflectors. Gloss white lacquer or enamel doors in the path of incoming daylight can lighten adjoining spaces. Interior paints and finishes can affect patients and staff directly. Outdoor finishes with odorous and toxic emissions can also have an effect upon persons indoors through windows, doors and other openings.

11. Demolition work
Existing building elements (walls, foundations, ground cement slabs etc.) will be carefully demolished and the debris will be sorted and removed as directed by the EMP (to be determined during the preparation phase of the project). All valuable materials (doors, windows, sanitary fixtures, etc) will be carefully dismantled and transported to the storage area assigned for the purpose. Valuable materials will be recycled within the project or sold.

12. Selection of Construction Materials and Construction Methods
Environmentally sound goods and services will be selected. Priority will be given to products meeting standards for recognized international or national symbols. Traditionally well-tried materials and methods should be chosen before new and unknown techniques. Construction sites will be fenced off in order to prevent entry of public, and general safety measures would be imposed. Temporary inconveniences due to construction works will be minimized through planning and coordination with contractors, neighbors and authorities. In densely populated areas, noisy or vibration generating activities should be strictly confined to the daytime.

13. Handling of Medical and Non-medical Waste
The Ministerial Order no.1226 was approved on the December 3, 2012 and contains the technical norms regarding the management of the medical waste and also the methods for the data collection regarding the medical waste. Basically it is about the method for collection, wrapping, temporary storing, transportation and disposal of the medical waste. Special norms are in force for dangerous medical wastes to prevent the contamination of the environment and the people’ health.
The segregation of waste is mandatory in all medical units (big, medium and small) and the monitoring procedures are already developed. The waste generated in clinics and hospitals is to be categorized as follows for management purposes:

1. non-dangerous waste (the waste assimilated to domestic waste)
2. dangerous waste

The dangerous waste is classified as follows:
- anatomopatologic waste – this includes human tissue, human pieces resulted from autopsy laboratories, dead bodies, foetus and placenta;
- infectious waste – this includes all waste which contains or was in contact with blood or viruses (syringes, needles, scalpel blades, razor blades, gloves, lines)
- sharps – this includes hypodermic needles and syringes, scalpel blades, razor blades etc;
- chemical and pharmaceutical waste – this includes the expired vaccines, drugs, used substances resulted from laboratories, packaging from dangerous chemical substances, medicines, etc,
- radiation sources which are periodically changed

The non-dangerous waste is the waste assimilated to domestic waste. Domestic waste can be non-organic – plastics, metal cans, cardboard packaging etc – and organic. The only organic waste generated in the clinics will be food waste and garden refuse.

All dangerous waste generated in clinics shall be removed by specialist contractors for disposal as appropriate. It is necessary to provide a fully equipped, lockable area for temporary waste storage in the clinics, to ensure full control of the medical waste waiting for off site transportation. A universal biological hazard symbol will be posted on the door of the storage area.

Waste generated in the clinics and hospitals is segregated as follows:
- Dangerous waste (infectious waste, sharps, chemical and pharmaceutical waste) – Yellow bags;
- Sharps – Special puncture-resistant containers; and
- Non-dangerous waste – Black bags.

For the infectious waste and sharps it will be used a special design meaning “Biological danger”. For chemical and pharmaceutical waste it will be used a special design meaning “Toxic” or “Flammable”. The sharps will be collected in special puncture-resistant containers.

The techniques for treatment of infectious waste are steam sterilization, incineration, microwave or ultraviolet heating systems, ionizing radiation or chemical treatment. The choice of technique depends on which category of infectious waste to be treated. Infectious waste which has been treated, although it is no longer hazardous, will be removed only by incineration and may not be mixed with or disposed of as ordinary solid waste, because they can pose other hazards that are subject to national regulations.
Annex 2 Recommendations on Radiation Protection

1. In diagnostic radiology and interventional radiology

1.1 Authorization requirements

The authorization is obtained from the NCNAC if the requirements for building, endowing, staffing with specialized personnel and appropriate organization of the activity are fulfilled, in accordance with the regulatory acts specified in Annex 1 of RSN-11. The practices of diagnostic and of interventional radiology which can not be authorized by registration, will be authorized by realization phases, as follows:
   a) location;
   b) building;
   c) utilization;
   d) modification.
If the practices are realized in existing buildings, the location and building phases can be merged.

1.2 Building requirements

The radiology laboratory will be composed of, where appropriate, at least:
1. RX room destined to the radiology device.
2. Command room destined to the command pannel, as applicable.
3. Developing room.
4. Undressing and waiting room for patients, as applicable.
5. Image interpretation room.
6. Medical consultation room.
7. Medical personnel room.
8. Archive of films and permanent recordings.
9. Cloakroom, toilets for personnel and toilets for patients, as applicable.

The surface of the RX room has to comply with the requirements of the manufacturer regarding the minimum area necessary for installation and assembling of the respective radiological device. It is not justified the assembling of the radiological device in rooms that are smaller than those recommended by the manufacturer, nor the limitation of the technical capacity of the device because of insufficient area.

If the minimum allowed size for the RX room area is not specified in the RSA of the device, the minimum sizes of the RX rooms, without limiting the technical capacities of the device, must be:
   a) The rooms destined to the radiologic diagnostic devices with one post will have a surface of minimum 20 m² and a square or rectangular shape. The ratio between the two dimensions will be not less than 2/3.
   b) For devices with two posts (radioscopy and radiography) in the same RX room, the area of the room will be not less than 36 m². Location in this room of furniture not strictly connected to the utilization of the device is prohibited.
   c) In the case of devices with several posts or special devices, the space will be increased as appropriate, taking into account the necessity to ensure the protection of the medical staff, a patients and other persons.
d) The RX room destined to an intraoral dental radiology device, with a voltage of maximum 70 kV, will have an area of at least 10.5 m². In the case of location of two intraoral dental radiology devices in the same room, the area will be minimum 16 m², and the devices will work alternatively only.
e) The RX room destined to a panoramic dental radiology device, with a voltage of maximum 90 kV, will have an area of at least 16 m².
f) The RX room destined to a radiology device for mammography will have an area of at least 10.5 m².
g) The RX room destined to an osteodensitometry device, with a voltage of maximum 80 kV, will have an area of at least 16 m².

As a rule, the location of the diagnostic radiologic device will be in the center of the room. The fluoroscopy radiologic device will be installed with the RX tube - image receptor axis parallel with the short axis of the RX room.
In the case of the fluoroscopy radiologic devices, the minimum distance between the focus of the RX tube and the closest lateral wall will be at least 150 cm.

The mobile radiography and radioscopy devices will be used as such.
The utilization of mobile radiologic devices as stationary devices is prohibited.
The button for exposure must be linked to the command panel or to the radiologic device through a cord of minimum 3 m, in order to allow the operator to move away sufficiently from the patient during the exposure.
The utilization of mobile radiologic devices without using adequate radioprotection equipment for professionally exposed persons and the population is prohibited.

The design of the RX room must be so that the useful RX fascicle can not be pointed to any surface which is not adequately shielded.
The RX room must be designed to avoid the direct incidence of the RX fascicle on the access doors.

The doors must fulfill the requirements of a protection shield against the scattered radiation and must be closed when the RX fascicle is emitted.

The RX room will be designed so that the dose output will not exceed:
a) 15 mSv/year at the workplace of the person professionally exposed to X radiation;
b) 1 mSv/year in the spaces where the population may have access.
The shields, other than the RX room walls, will be designed so that the dose output will not exceed 20 μSv/h.

It is mandatory to display the “ionizing radiation danger symbol” on each access door to the RX room, according to the International Organization for Standardization (ISO) recommendation, ISO Publication No. 361. The symbol will be black colored, and the background yellow.

1.3. Radiology equipment requirements

In medical exposures will be used only radiologic devices which:
a) have a Medical Device Certificate, issued by the MoH, according to Law No. 176/2000, republished;
b) have a Radiologic Security Authorization, issued by NCNAC, according to Law No. 111/1996, with subsequent modifications and completions;
c) are periodically tested, at least once a year, in order to check their compliance with the nominal technical parameters.

1.4 Radiology personnel requirements

The holder of the authorization or registry certificate must nominate in writing all the specialists who perform radiology praxis, each having a recognized form of accreditation sufficient to ensure that all relevant activities for radioprotection and security are in accordance with the radioprotection program, with the conditions of the authorization and with the Romanian radioprotection regulations.

The appropriate number of personnel must be reanalyzed as the workload increases, or as new radiologic installations and new techniques are introduced to the radiology laboratory.

All personnel working with radiologic devices in the radiology practice must have the relevant qualifications and practical training in radioprotection.

The investment in radiologic devices must be accompanied by concomitant investment in training and authorization of the personnel involved in diagnostic radiology and interventional radiology practices.

The holder of the authorization or registry certificate must include in the support documents of the authorization application written proofs regarding the qualifications in radioprotection of practicing doctors, of the experts accredited in radiologic protection, of the persons responsible with radiologic security, and of the medical physicists.

1.5 Manipulation requirements

The holder of the authorization or registry certificate must ensure that the appropriate maintenance and checking of the radiologic devices are realized so that the radiologic devices keep their nominal technical parameters during the whole lifetime of the devices according to the technical specifications of the manufacturer, for image quality, radioprotection and security.

The daily, weekly and monthly checkings of the radiologic device are performed according to manufacturer’s instructions by the medical physicist, and if the device is not compliant the authorized service unit will be immediately called.

All the procedures used for the above mentioned checkings are part of the user’s quality assurance program.

All manipulation procedures (installation-assembling, verification, maintenance, service, repair, scrapping/dismantling, etc.) must be included in the quality assurance program of the authorized unit for the manipulation activity.

The service reports which describe the findings regarding the technical condition, as well as the records related to interventions subsequent to these findings to bring the device back in nominal technical parameters, will be backed up as part of the quality assurance program.

During the manipulation operations (installation, assembling, checking, maintenance, service, repair) an expert in radioprotection or medical physics must participate from the beneficiary’s side and ensure that the device is in security conditions.
After any repair and at any periodical checking, performed at intervals no longer than one year, the company authorized for the manipulation of the devise will issue a checking report of the compliance of the device with the nominal technical parameters.

1.6 Operational radioprotection

The holder of the authorization or registry certificate must ensure that all workers are endowed with individual protection equipment against X radiations according to the Norm for provision and utilization of the individual protection equipment against ionizing radiations RP 06/1997.

Only the individual protection equipment authorized according to the law will be used, for which a Radiologic Security Authorization was issued by NCNAC. The individual protection equipment with lead, which can be apron, gloves, protection collar for the thyroid, protection goggles, etc. must comply with the manufacturer’s technical specificationse and with the specific standards. The necessary of individual equipment is established by the expert accredited in radiologic protection.

The protection gloves are useful to protect the hands when they are close to the fascicle, but they will be used with discernment because they can produce the opposite effect during the fluoroscopy with automated brightness control (ABC), when the hands enter the zone covered by the ABC sensor, because this will lead to higher exposure levels for patient and personnel. The holder of the authorization or registry certificate must ensure that:

a) the workers receive an appropriate training regarding the utilization of the individual protection equipment;
b) will perform activities requiring wearing of individual protection equipment only the persons having the medical opinion that they can support without problems its supplementary weight;
c) all equipment is maintained in good condition and is periodically tested at appropriate intervals, as applicable.

In the fluoroscopy and interventional radiology rooms it is recommended to use additional protection devices:
a) protection shields suspended on the ceiling to protect the eyes and thyroid of the practicing doctor during the whole patient visualization period;
b) protection curtains with lead mounted on the patient table.

The geometry with the RX tube above the table is not recommended because it implies a radiation level much higher where the operator stays, compared to the geometry with the RX tube below the table. However if the geometry with the RX tube above the table is used, protection curtains with lead attached to the patient table will be used, in order to reduce the scattered radiation received by the personnel.

All persons in the RX room for fluoroscopy, which don’t stay behind a shielded control pannel, must wear a protection apron with lead.
The holder of the authorization or registry certificate must ensure appropriate protection equipment against radiations, for the patient and for the person who sustains the patient, as applicable.

1.7 Dismantling requirements

For the diagnostic radiology and interventional radiology practices it is not necessary the authorization for the dismantling phase or the authorization for the termination (partial or total) of activity, the dismounting of the radiologic device by a company authorized by NCNAC for manipulation being sufficient. The dismantling of the radiologic device may be done also according to the own procedures of the authorization holder, who will notify the NCNAC regarding this dismantling.

2. In radiotherapy

2.1 Authorization requirements

The authorization is obtained from the NCNAC if the requirements for building, endowing, staffing with specialized personnel and appropriate organization of the activity are fulfilled, in accordance with the regulatory acts specified in Annex 1 of RSN-12.

The radiotherapy practices are authorized by realization phases, as follows:

a) location;
b) building;
c) start up (only for telecobalt therapy devices and linear accelerators);
d) utilization;
e) modification;
f) possession;
g) dismantling

If the practices are realized in existing buildings, the location and building phases can be merged.

2.2 Building requirements

The radiotherapy laboratory for teletherapy and remote controlled brachitherapy devices will be composed of, where appropriate, at least:

a) Treatment room destinated to the radiotherapy device;
b) Command room destinated to the command pannel;
c) Simulator room;
d) Treatment planning room;
e) Source storage, if applicable;
f) Undressing and waiting room for patients;
g) Medical consultation room;
h) Medical personnel room;
i) Cloakroom, toilets for personnel and toilets for patients;
j) Other technical rooms necessary according to the complexity of the device.

In the design phase of the radiotherapy laboratory which uses radiotherapy devices (exposure rooms and the other rooms of the radiotherapy laboratory) the necessary measures for protection
optimization and dose limitation must be ensured, with the view of fulfilling the radiologic security requirements. The design of the laboratory must take into account the classification of areas, the type of activity and the radiotherapy devices intended to be used.

In the design of the radiotherapy laboratory security systems associated with the radiotherapy device and the exposure room will be provided, which will include emergency switches - „exposure stopped”, warning systems and security interconditionings (blocking devices). The radiotherapy laboratory will be mandatory provided with access control system, alarm system, warning system and fire warning system, climatisation system and adequate ventilation.

It is mandatory to display the “ionizing radiation danger symbol” on each access door to the treatment room, simulation room or in the source storage, according to the International Organization for Standardization (ISO) recommendation, ISO Publication No. 361. The symbol will be black colored, and the background yellow.

At the design of the radiotherapy laboratory dose constraints will be used no more than:

a) 10 mSv/year at the workplace of the person professionally exposed to radiation.
b) 20 μSv/week in the areas where the population may have access.

(2) The shields, other than the treatment room walls, will be designed so that the dose output will not exceed 1 μSv/h.

The typical conservative assumptions used in shielding design are:
a) Patient attenuation is usually not taken into consideration.
b) Escape radiation is considered maximum possible.
c) Charge, utilization and occupation factors are usually overestimated.
d) The personnel always stay in the most exposed places of the adjacent rooms.

The area of the exposure room must comply with the requirements of the manufacturer regarding the minimum surface necessary for installation and mounting of the respective radiotherapy device.

The installation of radiotherapy device in rooms smaller than those recommended by the manufacturer, as well as the limitation of the technical capacity of the device because of insufficient areas, is not justified.

When the minimum allowed size of the treatment room area is not specified in the RSA of the respective radiotherapy device, the minimum area of the treatment room, without limiting the technical capacity of the device, must be at least:

a) 16 m² for a teletherapy RX device (with external fascicle) for superficial and contact therapy;
b) 22 m² for a teletherapy RX device (with external fascicle) orthovoltage therapy with electric voltage up to 300 kV
c) 50 m² for a teletherapy gamma device (with external fascicle) with closed radioactive sources, for instance a telecobalt therapy device containing a cobalt – 60 source;
d) 50 m² for medical linear accelerators (linacs)
e) 30 m² for simulators and CT simulators for radiotherapy;
f) 16 m² for brachytherapy (curietherapy) devices with closed radioactive sources.

As a rule, the location of the radiotherapy device will be in the in center of the room.
For existing treatment rooms, where new radiotherapy devices are relocated, also smaller areas than those mentioned above are acceptable, by providing an appropriate justification, by which is demonstrated that the protection of the professionally exposed personnel and of patients is ensured and that the device can be used in optimum conditions.

2.3 Radiotherapy equipment requirements

In medical exposures for therapeutic purposes, will be used only radioactive sources and radiotherapy devices which:

a) have Medical Device Certificate, issued by the MoH, according to Law No. 176/2000, republished or Medical Device Registration Certificate at the utilization site, issued by NAMMD, conform reglementarilor MS;
b) have Radiologic Security Authorization (RSA), issued by NCNAC, according to Law No. 111/1996, with subsequent modifications and completions;
c) are periodically tested, according to manufacturer’s requirements and RSA conditions, in order to check their compliance with the nominal technical parameters.

According to Art. 59 of the Radiologic Security Norms – Authorization Procedures, the technical documentation for radiological security authorization of a radiotherapy device must demonstrate that the radiological security requirements in design and manufacturing of the device are fulfilled.
The radiological security requirements in design and manufacturing of radiotherapy devices are mentioned in Annex No. 6. of RSN-12.

2.4 Radiotherapy personnel requirements

The holder of the authorization or registry certificate must nominate in writing all the specialists who perform radiotherapy praxis, each having a recognized form of accreditation sufficient to ensure that all relevant activities for radioprotection and security are in accordance with the radioprotection program, with the conditions of the authorization and with the Romanian radioprotection regulations.
The appropriate number of personnel must be reanalyzed regularly as the workload increases, or as new techniques and new radiotherapy devices are introduced in the radiotherapy laboratory.

All personnel working with radiotherapy devices in the radiotherapy practice must have the qualifications and relevant practical training in radioprotection.
The investment in radiotherapy devices must be accompanied by concomitant investment in training and authorization of the personnel involved in radiotherapy praxis.
The holder of the authorization must include in the support documents of the authorization application written proofs regarding the qualifications in radioprotection of practicing doctors, of the experts accredited in radiologic protection, of the responsibles with radiologic security, and of the medical physicists.

The holder of authorization must ensure that the personnel have knowledge of:
a) authorization requirements;
b) radiotherapy device utilization procedures;
c) own individual responsibilities;
d) the instructions that must be provided to patients and to the persons caring them;
e) radioprotection policies and procedures;
f) local quality management programs (QMP) and quality control (QC) procedures;
g) analysis of radiological incidents and accidents produced or that may be produced in the institution or elsewhere and the necessary corrective and preventive measures.

2.5 Manipulation requirements

The holder of the authorization must ensure that all manipulation operations: installation-assembling, repair, service, checking, maintenance, dismantling/scrapping, etc., of the radiotherapy devices are performed only by a NCNAC authorized unit, according to the law. The holder of the authorization, by care of the responsible person with radiological security, must keep the technical book of the radiotherapy device during the whole lifetime of the device, until dismantling. The technical book will contain data regarding operations performed for installation-assembling, repair, maintenace, checking, service, and all the services performed until delivery of sources as radioactive waste and dismantling and scrapping of device. The initial, periodic verification reports and those after each intervention on the respective device, for repair, change of parts, will be kept by the authorization holder, to be presented at inspections.

The authorization holder must ensure that the appropriate preventive and corrective maintenance and the checking of radiotherapy devices are performed so that the devices maintain their conformity with manufacturer’s radiological security specifications during the whole lifetime of the devices.

The daily, weekly, monthly checkings of the radiotherapy device are performed according to the manufacturer’s instructions by the medical physicist, and if the device is not compliant the authorized service unit will be immediately called.

The quarterly, semestrial or yearly checkings of the radiotherapy device are performed performed according to the manufacturer’s instructions by the authorized service unit together with the medical physicist. All the procedures used for the above mentioned procedures are part of the user’s QMP, which may include also other tests than those provided by the manufacturer.

The checkings will have records which will be kept for control at least 5 years.

2.6 Operational radioprotection

For the safe use of radiotherapy devices with external fascicle, procedures will be elaborated for area dosimetric surveilance, for interconditioningsr and blocking devices checking, for leakage tests and emergency procedures, for instance, when the source remains totally or partially blocked in exposure position.

In order to observe the above mentioned procedures, appropriate equipment must be available at the user, calibrated and serviceable, and having RSA, that includes:

a) radiation monitor, ionization chamber type, with scale starting from 1 μSv;
b) contaminometer with RSA, adequate endowments for leakage tests (if these tests are not performed by the unit authorized for manipulation)
c) personal digital dosimeters with warning, sensible in the energy range from 20 keV to 10 MeV, with RSA issued by NCNAC, for all the professionally exposed personnel who is involved in radiotherapy.

In a radiotherapy laboratory, the following are considered as controlled areas:

a) the room where a medical linear accelerator is installed and its command room;
b) the room where a teletherapy RX (with external fascicle) device is installed and mounted and its command room;
c) the room where a teletherapy gamma device (with external fascicle) with closed radioactive sources is installed and mounted and its command room;
d) the room where a radiotherapy simulator or a CT simulator is installed and its command room;
e) the room destined to a remote controlled brachytherapy (curietherapy) device and its command room;
f) the room where manual brachytherapy procedures are performed;
g) rooms for manual brachytherapy patients;
h) radioactive sources storage room.
i) adjacent technical rooms where the functional components of the radiotherapy device are located.

Each room of the radiotherapy laboratory must be used according to its specific destination only. The doors of treatment rooms must be normally closed during the therapeutic procedures.

The authorization holder must ensure that all workers are endowed with individual protection equipment against radiations, according to the Norm for provision and utilization of the individual protection equipment against ionizing radiations RP 06/1997. Only the individual protection equipment authorized according to the law will be used, for which a Radiologic Security Authorization was issued by NCNAC.

The individual protection equipment with lead, which in the case of manual brachytherapy can be apron, gloves, protection goggles, etc. must comply with the manufacturer’s technical specifications and with the specific standards.

The necessary of individual equipment is established by the expert accredited in radiologic protection and is approved by NCNAC in the authorization and control process.

The protection equipment that is utilized must be periodically checked according to the utilization instructions and the conditions in their RSA.

2.7. Transportation of radioactive sources

The suppliers of teletherapy sources and of brachytherapy sources must ensure the transportation thereof under their responsibility if their are authorized for transportation, or through a transportation unit specially authorized according to the law.

The teletherapy sources and the brachytherapy sources enter effectively in beneficiary’s patrimony only after the finalization of charging of the radiotherapy device with sources or source change, as applies, and only after the performance of the acceptance tests.

Charging of sources in radiotherapy devices and the transportation of sources outside the hospital is performed only with a unit authorized according to Law No. 111/1996 with subsequent modifications and completions, to the Fundamental Norms for safe transport of radioactive materials and to the Norms for radioactive materials transport - authorization procedures.


2.8 Dismantling requirements

For the radiotherapy practice where RX-therapy devices are used it is not necessary the authorization for the dismantling phase or the authorization for the termination (partial or total) of activity, the dismounting of the radiologic device by a company authorized by NCNAC for manipulation being sufficient. As an exception, in case of dismantling an RX-therapy device, the disassembly and dismantling thereof may be done according to the own procedures of the authorization holder, who will notify the NCNAC regarding this dismantling.

The sources that where not used or are out of use fall under the authorization regulations for possession or dismantling, as applies, or they will be returned to the manufacturer or will be delivered to a unit authorized according to the law to taking them over. Regarding the returning or delivery of out of use sources, the authorization holder must provide the following information regarding the content of each package or container:
- The radionuclide, number and activity of the sources.
- A description of the source structure/construction.
- A copy of the approval certificate for radioactive material in special form, as applies.
- A description of the package.
- A copy of the approval certificate for A or B(U) type package, as applicable, or the declaration of conformity with the Fundamental Norms for radioactive materials safe transport.
- Details of any special arrangement if necessary, including multilateral approvals, if necessary.
- A copy of transport documents (which have to be sent by fax or e-mail, before the unpacking of packages, if possible).
- Obtaining of dispatch authorizations, as applies, according to the Norms for radioactive materials transport - authorization procedures.

The authorization holder must notify the NCNAC regarding any transfer of radiotherapy sources or devices, or regarding the delivery as radioactive waste of the out of use sources. The authorization holder is responsible for the sources until their delivery to another appropriate authorization holder or to an authorized radioactive waste storage. The authorization holder must:

a) request from NCNAC the authorization for transfer or for dismantling of the radiotherapy device before starting any activity. The depleted uranium used as shielding material must be treated as radioactive waste and nuclear material in the same time being applicable the Norms for nuclear warranties control.

b) to ensure the necessary resources for the transfer of nuclear materials and dispose of the sources as radioactive waste, when the radiotherapy device is scrapped.
Annex 3 Checklist for Small Works for Building Repair and Remediation

ROMANIA
Ministry of Health

HEALTH SECTOR REFORM - IMPROVING HEALTH SYSTEM QUALITY AND EFFICIENCY PROJECT

Environmental Management Plan / Checklist for Small Works for Building Repair and Remediation

General Guidelines for use of EMP checklist:

For low-risk topologies, such as school and hospital rehabilitation activities, the ECA safeguards team developed an alternative to the current EMP format, in order to provide an opportunity for a more streamlined approach to preparing EMRs for minor rehabilitation or small-scale construction works in the health, education and public services sectors. The checklist-type format has been developed to provide an “example of good practices” and designed to be user friendly and compatible with the safeguard requirements.

The EMP checklist-type format attempts to cover typical core mitigation approaches to civil works contracts with small, localized impacts. It is accepted that this format provides the key elements of an Environmental Management Plan (EMP) or Environmental Management Framework (EMF) to meet the World Bank Environmental Assessment requirements under OP 4.01. The checklist is meant to be applicable as guidelines for the small works contractors and to constitute an integral part of the bidding documents for contractors carrying out small civil works under Bank-financed projects.

The checklist has three sections:

Part 1 includes a descriptive part that sets out the project characteristics and specifies the institutional and legislative aspects, the technical project content, the potential need for a capacity building program and a description of the public consultation process. This section could be up to two pages long. Attachments with additional information can be provided when needed.

Part 2 includes an environmental and social screening checklist, where activities and potential environmental issues can be checked in a simple Yes/No format. If any given activity/issue is triggered by checking “yes”, a reference is made to the appropriate section in the following table, which contains clearly formulated management and mitigation measures.

Part 3 represents the monitoring plan for activities during project construction and implementation. It retains the same format required for EMRs proposed under normal Bank requirements for B Category projects. The purpose of this checklist is that Part 2 and Part 3 be included into the bidding documents for contractors and be priced during the bidding process and that their implementation be diligently supervised during works execution.
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A) General Project and Site Information

B) Safeguards Information

C) Mitigation Measures

Monitoring Plan
EMP Checklist for Construction and Rehabilitation Activities

PART A: GENERAL PROJECT AND SITE INFORMATION

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

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

<table>
<thead>
<tr>
<th>Activity/Issue</th>
<th>Status</th>
<th>Triggered Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Building rehabilitation</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>B. New construction</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>C. Individual wastewater treatment system</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>D. Historic building(s) and districts</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>E. Acquisition of land</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>F. Hazardous or toxic materials</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>G. Impacts on forests and/or protected areas</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>H. Handling / management of medical waste</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>I. Traffic and Pedestrian Safety</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
</tbody>
</table>

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3 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.
4 Toxic / hazardous material includes but is not limited to asbestos, toxic paints, noxious solvents, removal of lead paint, etc.
# PART C: MITIGATION MEASURES

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>PARAMETER</th>
<th>MITIGATION MEASURES CHECKLIST</th>
</tr>
</thead>
</table>
| **0. 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) The Contractor formally agrees that 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. |

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

<table>
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<tr>
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</table>
| **Air Quality** | | (a) During interior demolition debris-chutes shall be used above the first floor  
(b) Demolition debris shall be kept in controlled area and sprayed with water mist to reduce debris dust  
(c) During pneumatic drilling/wall destruction dust shall be suppressed by ongoing water spraying and/or installing dust screen enclosures at site  
(d) The surrounding environment (sidewalks, roads) shall be kept 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 shall 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 waste 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) |

**B. Individual wastewater treatment system**

<table>
<thead>
<tr>
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</thead>
</table>
| **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) Construction vehicles and machinery will be washed only in designated areas where runoff will not pollute natural surface water bodies. |

**C. Historic building(s)**

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>PARAMETER</th>
<th>MITIGATION MEASURES CHECKLIST</th>
</tr>
</thead>
</table>
| **Cultural Heritage** | | (a) If the building is a designated historic structure, very close to such a structure, or located in a designated historic district, notification shall be made and approvals/permits be obtained from local authorities and all construction activities planned and carried out in line with local and national legislation.  
(b) It shall be ensured that provisions are put in place so that artifacts or other possible “chance finds” encountered in excavation or construction are noted and registered, responsible officials contacted, and works activities delayed or modified |
<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>PARAMETER</th>
<th>MITIGATION MEASURES CHECKLIST</th>
</tr>
</thead>
</table>
| **D. Acquisition of land** | Land Acquisition Plan/Framework | (a) If expropriation of land was not expected but 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’s Task Team Leader shall be immediately consulted.  
(b) The approved Land Acquisition Plan/Framework (if required by the project) will be implemented |
| **E. Toxic Materials** | Asbestos management | (a) If asbestos is located on the project site, it shall be marked 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. Security measures will be taken against unauthorized removal from the site.  
(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 shall be placed in an leak-proof container to prevent spillage and leaching  
(c) The wastes shall be 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 |
| **F. Affected forests, wetlands and/or protected areas** | Protection | (a) All recognized natural habitats, wetlands 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) A survey and an inventory shall be made of large trees in the vicinity of the construction activity, large trees shall be marked and cordoned off with fencing, their root system protected, and any damage to the trees avoided  
(c) Adjacent wetlands and streams shall be protected from construction site run-off with appropriate erosion and sediment control feature to include by not limited to hay bales and silt fences  
(d) There will be no unlicensed borrow pits, quarries or waste dumps in adjacent areas, especially not in protected areas. |
| **G. 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 temporary storage facilities for medical waste are in place; and  
- If the activity includes facility-based treatment, appropriate disposal options are in place and operational |
| **H Traffic and Pedestrian Safety** | Direct or indirect hazards to public traffic and pedestrians by construction activities | (b) In compliance with national regulations the contractor will insure that the construction site is properly secured and construction related traffic regulated. This includes but is not limited to  
- Signposting, warning signs, barriers and traffic diversions: site will be clearly visible and the public warned of all potential hazards  
- Traffic management system and staff training, especially for site access and near-site heavy traffic. Provision of safe passages and crossings for pedestrians where construction traffic interferes.  
- Adjustment of working hours to local traffic patterns, e.g. avoiding major transport activities during rush hours or times of livestock movement  
- Active traffic management by trained and visible staff at the site, if required for safe and convenient passage for the public.  
- Ensuring safe and continuous access to office facilities, shops and residences during renovation activities, if the buildings stay open for the public. |
PART D: MONITORING PLAN

<table>
<thead>
<tr>
<th>Phase</th>
<th>What (Is the parameter to be monitored?)</th>
<th>Where (Is the parameter to be monitored?)</th>
<th>How (Define the frequency / or continuous?)</th>
<th>When (Is the parameter being monitored?)</th>
<th>Why (Is the parameter being monitored?)</th>
<th>Cost (if not included in project budget)</th>
<th>Who (Is responsible for monitoring?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>During activity preparation</td>
<td>site access traffic management availability of waste disposal facilities</td>
<td>at the site at the site in site vicinity</td>
<td>check if design and project planning foresee diligent procedures</td>
<td>safety of general public, timely detection of waste disposal bottlenecks</td>
<td>marginal, within budget</td>
<td>Contractor, Engineer</td>
<td></td>
</tr>
<tr>
<td>During activity implementation</td>
<td>hazardous waste inventory (asbestos) construction material quality control (eg. paints / solvents)</td>
<td>on site Contractor’s store / building yard</td>
<td>visual / analytical if in doubt visual / research in toxic materials databases</td>
<td>before start of rehabilitation works before approval to use materials</td>
<td>public and workplace health and safety</td>
<td>marginal, within budget; (prepare special account for analyses at PMU?)</td>
<td>Contractor, Engineer</td>
</tr>
<tr>
<td>During activity supervision</td>
<td>dust generation noise emissions wastewater volumes &amp; quality waste types and volumes</td>
<td>on site and in immediate neighborhood, close to potential impacted residents</td>
<td>visual consultation of locals visual, analytical if suspicious count of waste transports off site</td>
<td>avoidance of public nuisance avoidance of negative impacts on ground/surface waters ensuring proper waste management and disposal</td>
<td>marginal, within budget</td>
<td>Contractor, Engineer</td>
<td></td>
</tr>
</tbody>
</table>

Note: The text in blue illustrates a project in the region