

**Project Fiche – 2008 IPA Horizontal Programme
on Nuclear Safety and Radiation Protection**

1. Basic information

- 1.1 CRIS Number:** 2008/020-350
- 1.2 Title:** Management of unsealed radionuclides in medical establishments
- 1.3 ELARG Statistical code:** 03.64 - Nuclear safety
- 1.4 Location:** Bosnia and Herzegovina

Implementing arrangements:**1.5 Contracting Authority (EC):**

The European Community represented by the Commission of the European Communities for and on behalf of Bosnia and Herzegovina.

1.6 Implementing Agency:

Not applicable

1.7 Beneficiaries:**Ms. Elma Kučukalić-Selimović**

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Financing:

1.8 Overall cost (VAT excluded): EUR 500 000

1.9 EU contribution: EUR 500 000

1.10 Final date for contracting: 2 years following the date of conclusion of the Financing Agreement.

1.11 Final date for execution of contracts: 2 years following the end date for contracting.

1.12 Final date for disbursements: 3 years following the end date for contracting.

2. Overall Objective and Project Purpose**2.1 Overall Objective:**

To improve the safety and security of the management of radionuclides into medical establishments in line with the acquis on radiation protection.

2.2 Project purpose:

The project will consist of assessing current management practices in all medical institutes of Bosnia and Herzegovina that are using radionuclides (with the exception of sealed radioactive sources) and whenever necessary to provide and install equipment that will contribute to reduce occupational exposure. Organisation of training courses on radiation protection is part of the project.

2.3 Link with AP/NPAA/EP/SAA

The sectoral policies of the European/Accession Partnerships with Bosnia and Herzegovina (2006/55/EC) in the field of environment mention the strengthening of the administrative capacity and alignment to the acquis.

The 2007 progress report of the European Commission on Bosnia and Herzegovina stated that "at present the situation in the field of nuclear safety and radiation requires significant improvement in terms of coordination and organisation of the activities at the level of Bosnia

and Herzegovina, equipment, modernisation of facilities, technical capacity and human resources".

2.4 Link with MIPD

The MIPD action entitled "Nuclear Safety and Radiation Protection" mentions that "All IPA eligible beneficiaries are facing radiological issues that are connected with the use of radionuclides for industrial and medical applications. In most Beneficiaries in the Western Balkans management of sealed radioactive sources, for example, dismantling of radioactive lightning rods and operation of centralised storage facilities remains a key issue. Moreover management of radioactive waste in hospitals may require investments and training of the personnel". Therefore this project proposal which deals with medical applications of radionuclides, including the management of the resulting radioactive waste is fully in line with the MIPD activities.

2.5 Link with National Development Plan

Not applicable

2.6 Link with national/ sectoral investment plans

Not applicable

3. Description of project

3.1 Background and justification:

There are five medical establishments that are using radionuclides for diagnostic and therapy purposes in Bosnia and Herzegovina, i.e.

- Institute of Nuclear Medicine at the Clinical Centre of Sarajevo University;
- Department of Nuclear Medicine at the Clinical Centre of Banja Luka;
- Cantonal Hospital Zenica;
- Clinical Centre Mostar;
- Clinical Centre Tuzla.

The Institute of Nuclear Medicine at the Clinical Centre of Sarajevo University uses radionuclides in diagnostic and therapy purposes. Two main radionuclides are commonly used: I-131 and Tc-99m. Clinical Centre of Sarajevo University plans to open a therapy ward for treatment of malignant and benign thyroid diseases via administration of I-131.

The Department of Nuclear Medicine at the Clinical Centre of Banja Luka is using I-125, I-131, Ga-27 and Tc-99m for diagnostic and therapy purposes and already operates a unit for the treatment of thyroid diseases. By the end of 2008 it is planned to add Tl-201, Sm-153, Sr-89, P-32, In-111 and Y-90.

Department for Nuclear Medicine at the University Clinical Centre in Tuzla uses radionuclide in diagnostic (Tc-99m) and therapeutic purposes (I-131, outpatient). It owns one gamma camera, which is currently out-of-order.

Department for Nuclear Medicine in Mostar has one gamma camera. It uses Tc-99m and Tl-201 for diagnostic purposes, as well as I-131 for outpatient therapy.

Department for Nuclear Medicine at the Cantonal Hospital in Zenica has one gamma camera, and it uses Tc-99m for diagnostic and I-131 for outpatient therapy.

None of these hospitals, except in Banja Luka, have I-131 therapy ward.

In all hospitals application of radionuclides should become more and more important during the next years and therefore particular attention should be paid to radiation protection of the personnel working in the respective nuclear medicine departments.

At present, handling and storage of radionuclides to be administered to patients is performed with makeshift equipment. Although occupational exposure is controlled by personal TL dosimeters, there is no dose-rate meters available on the spot, and storage rooms for radionuclides are not equipped with proper furniture and devices that could protect personnel and ensure security of the open radioactive sources. Moreover discharges of liquid radioactive waste into the sewage system are performed on the basis of estimates of residual activity and not on measurements. Finally laboratories with fume-hoods where radionuclides are handled and divided into doses for patients need refurbishment and/or modernisation to be in line with international safety standards in particular with the Euratom Directive 96/29.

3.2 Assessment of project impact, catalytic effect, sustainability and cross border impact

The project will contribute to reduce occupational exposure in the nuclear medicine departments of the hospitals in Bosnia and Herzegovina. It will also enable a better control of the releases of radioactivity into the environment. Finally it will improve the security of the storage of open radioactive sources. To become sustainable this project should also comprise a training component of the personnel that could be organised jointly with the International Atomic Energy Agency (IAEA). The only possible cross border impact of the project could derive from a better control of the discharges of radionuclides from hospitals into the sewage system and thereby into the river system.

3.3 Results and measurable indicators:

Results and measurable indicators in relation with activity 1:

1) A clear assessment of the needs to refurbish and/or modernise the controlled areas of the nuclear medicine departments of the:

- Institute of Nuclear Medicine at the Clinical Centre of Sarajevo University;
- Department of Nuclear Medicine at the Clinical Centre of Banja Luka;
- Cantonal Hospital Zenica;
- Clinical Centre Mostar;
- Clinical Centre Tuzla;

in order to decrease occupational exposure.

2) The reception, installation and testing of the equipment needed to refurbish and/or modernise the nuclear medicine departments.

3) The organisation of training courses in close cooperation with the IAEA.

Results and measurable indicators in relation with activity 2:

The delivery of pieces of equipment in full compliance with the identification of the needs and the determination of technical specifications performed under activity 1.

3.4 Activities:

Activity 1: One service contract concerning the analysis of the current management practices of radionuclides in the:

- Institute of Nuclear Medicine at the Clinical Centre of Sarajevo University;
- Department of Nuclear Medicine at the Clinical Centre of Banja Luka.
- Cantonal Hospital Zenica;
- Clinical Centre Mostar;
- Clinical Centre Tuzla.

This activity will also comprise the identification of the needs in terms of equipment, including the determination of the technical specifications of the measuring radiation devices (e.g. mobile dose-meters, beta-gamma counters, beta-gamma spectrometers, etc). Installation and testing of the equipment is part of this activity as well as the organisation of training courses for the personnel. Regarding this, a close collaboration should be established with the IAEA.

The preparation and/or refurbishment of the rooms that will accommodate the equipment are part of the duties of the beneficiary organisations. The corresponding works and investments will constitute their own contribution to the project (co-funding). Unfortunately, the cost of these works and investments could not be made available in June 2008.

Activity 2: One supply contract for the delivery of equipment. A priori the following pieces of equipment would be needed:

- Shielded laminar flow benches;
- Safe drawers for storing radionuclides with minimum 8 boxes for each hospital;
- Shielded container for storing solid radioactive waste;
- Shielded tank for storing radioactive liquid waste;
- Dose-rate meters for controlled areas;
- Beta-gamma counters for checking the residual activity in tanks and containers;
- Beta-gamma spectrometers for checking purposes;
- Modern fume hoods equipped for handling radionuclides;

However this list may be extended according to the results of activity 1.

3.5 Conditionality and sequencing:

The implementation of this project requires the establishment and functioning of a regulatory body in charge of radiological issues in Bosnia and Herzegovina. Since part of the project will consist of supplying equipment for measuring the residual radioactivity to be released into the environment via the sewage system for liquid waste and via the disposal into a landfill for solid waste, it is important that regulations on discharges limits for both medical establishments are defined before the project starts. Delivery of equipment for handling, storing and measuring radionuclides must comply with the requirements of the regulatory body.

3.6 Linked activities:

During the second quarter of 2007, the tendering procedure for awarding a contract on the assessment of the management of medical radioactive waste in Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, Serbia as well as

Kosovo¹, should start. This project is actually one of the regional projects that were programmed for support by the 2007 IPA horizontal programme on nuclear safety and radiation protection. Its duration is one year; this means that the results should be made available during the third or the fourth quarter of 2009 at the latest. Its outcome may influence the implementation of this project as far as discharge limits for liquid radioactive waste are concerned.

A Phare-funded project on management of radioactive waste in medical establishments of Bulgaria, Croatia and Romania was completed in 2007.

3.7 Lessons learned

The main achievement of the Phare-funded project concerning storage of radionuclides and the need for a better control of the discharges of radioactive waste from hospitals into the environment are fully in line with this project proposal.

4. Indicative Budget (amounts in €)

Activities	TOTAL COST	SOURCES OF FUNDING										
		EU CONTRIBUTION				NATIONAL PUBLIC CONTRIBUTION				PRIVATE		
		Total	% *	IB	INV	Total	% *	Central	Regional	IFIs	Total	% *
Activity 1												
contract 1	100 000	100 000	100	100 000		0	0				0	0
Activity 2												
contract 2	400 000	400 000	100		400 000	0	0				0	0
TOTAL	500 000	500 000	100	100 000	400 000	0	0				0	0

Amounts net of VAT

* expressed in % of the Total Cost

5. Indicative Implementation Schedule (periods broken down per quarter)

Contracts	Start of Tendering	Signature of contract	Project Completion
Contract 1	1 st Q 2009	3 rd Q 2009	4 th Q 2010
Contract 2	1 st Q 2010	2 nd Q 2010	4 th Q 2010

6. Cross cutting issues

6.1 Equal Opportunity

Not applicable

6.2 Environment

Not applicable

6.3 Minorities

Not applicable

¹ under UNSCR 1244/99

ANNEXES

- 1- Log frame in Standard Format
- 2- Amounts contracted and Disbursed per Quarter over the full duration of Programme
- 3- Description of Institutional Framework
- 4 - Related laws, regulations and strategic documents:
- 5- Details per EU funded contract

ANNEX 1: Logical framework matrix in standard format

LOGFRAME PLANNING MATRIX FOR Project Fiche	Programme name and number: 2008 IPA Horizontal Programme on Nuclear Safety and Radiation Protection	2008/020-350
Management of unsealed radionuclides in medical establishments	Contracting period expires: 2 years following the date of conclusion of the Financing Agreement	Disbursement period expires : 3 years following the end date for contracting
	Total budget : EUR 500 000	IPA budget: EUR 500 000

Overall objective	Objectively verifiable indicators	Sources of Verification	
To improve the safety and security of the management of radionuclides into medical establishments in line with the acquis on radiation protection.			
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
Assessment of current management practices in all medical institutes of Bosnia and Herzegovina that are using radionuclides (with the exception of sealed radioactive sources)	Progress reports	Hospitals of concern. Ministries of Health in B&H, EC HQs	
Supply and install equipment that will contribute to reduce occupational exposure.	Procurement procedure	EC HQs	
Organisation of training courses on radiation protection	Attendance certificates of trainees	Hospitals of concern, Ministries of Health	
Results	Objectively verifiable indicators	Sources of Verification	Assumptions
<u>Activity 1</u>			
A clear assessment of the needs to refurbish and/or modernise the controlled areas of the nuclear medicine departments	Progress report	Hospitals of concern. Ministries of Health in B&H	A fully operational regulatory body must be in place
The reception, installation and testing of the equipment needed to refurbish and/or modernise the nuclear medicine departments.	Technical specifications of the equipment to be purchased	Hospitals of concern. Ministries of Health in B&H	Technical specifications of the equipment to be installed are right
The organisation of training courses in close cooperation with the IAEA.	Attendance certificates of trainees	Hospitals of concern, Ministries of Health	Availability of a sufficient number of trainees
<u>Activity 2</u>			
Delivery of pieces of equipment in full compliance with the identification of the needs and the determination of technical specifications performed under activity 1.	Procurement procedure successfully launched. Contract awarded. Progress reports	Hospitals of concern, Ministries of Health	Appropriate technical specifications of the equipment defined
Activities	Means	Costs	Assumptions
Identification of the needs in terms of equipment, including the determination of the technical specifications of the measuring radiation devices (e.g. mobile dose-meters, beta-gamma counters, beta-gamma spectrometers, etc). Installation and testing of the equipment is part of this activity as well as the organisation of training courses for the personnel.	Technical assistance contract	EUR 100 000	
One supply contract for the delivery of equipment	Supply contract	EUR 400 000	

ANNEX II: Amounts (in M €) Contracted and disbursed by quarter for the project

Contracted	Q3 2009	Q4 2009	Q1 2010	Q2 2010	Q3 2010	Q4 2010	Q1 2011	Q2 2011	Q3 2011
Contract 1	0.10								
Contract 2				0.40					
Cumulated				0.50	0.50	0.50	0.50	0.50	0.50
Disbursed									
Contract 1	0.04		0.03		0.03				
Cumulated	0.04	0.04	0.07	0.07	0.10	0.10	0.10	0.10	0.10
Contract 2				0.25	0.08	0.07			
Cumulated				0.25	0.33	0.40	0.40	0.40	0.40
Total cumulated	0.04	0.04	0.07	0.32	0.43	0.50	0.50	0.50	0.50

ANNEX III: Description of Institutional Framework

The new law on radiation safety was promulgated on 28 November 2007. This law requires the establishment in the short-term of a nuclear regulatory agency (NRA). The NRA should cover both political entities and be managed by a director that should be appointed by the Council of Ministers. Its seat will be located in Sarajevo. Two deputy directors would manage NRA regional offices in Banja Luka and Mostar. One of the first tasks of the directors will be the laying down of regulations in the field of radiation safety, nuclear safety, radioactive waste management and transportation of radioactive substances.

Bosnia and Herzegovina has already signed by succession three international conventions:

- Convention on Early Notification of a Nuclear Accident;
- Convention on Physical Protection of Nuclear Material;
- Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency.

All the hospitals are operating under the supervision of the Ministries of Health of both political entities. Until the NRA becomes fully operational, all nuclear medicine departments of hospitals in Bosnia and Herzegovina are regulated according to the Law laid down in the former Yugoslavia.

ANNEX IV: Reference to laws, regulations and strategic documents:

- Nuclear Safety and Radiation Protection action of the multi-country MIPD programme.

- The Federal Law of Protection from Ionising Radiation and Radiation Safety (1999) of Bosnia & Herzegovina.
- The Law on Radiation Protection and Radiation Safety and amendments (2001 and 2003) of the Republika Srpska of Bosnia & Herzegovina.
- Law on Radiation Protection and Nuclear Safety in Bosnia and Herzegovina (came into force on 28 November 2007) – Articles 1, 2, 4, 13, 24 and 26 refer to the system of control over sources of ionising radiation including minor offences and penalties.

ANNEX V: Details per EU funded contract

The Contractor is expected to fulfill all the activities listed in section 3.4 with the support of local companies established in Bosnia & Herzegovina. The Contractor will prepare all technical specifications for the subsequent supply contract to be launched.

The project will be tendered, awarded and implemented in accordance with the PRAG.