

**Project Fiche – IPA centralised programmes**  
**Part II of the Horizontal Programme on Nuclear Safety and Radiation Protection**

**1. Basic information**

- 1.1 CRIS Number:** 2007/019-301
- 1.2 Title:** Management of medical radioactive waste in Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, and Serbia including Kosovo (as defined by UNSCR 1244)<sup>1</sup>
- 1.3 ELARG statistical code:** 06.64 - Nuclear Safety
- 1.4 Location:** Tirana (Albania), Sarajevo (Bosnia and Herzegovina), Skopje (the former Yugoslav Republic of Macedonia), Podgorica (Montenegro), Belgrade (Serbia), and Prishtina (Kosovo)

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

The European Community represented by the Commission of the European Communities for and on behalf of Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, and Serbia including Kosovo

**1.6 Implementing Agency:**

N.A.

**1.7 Beneficiaries:**

Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, and Serbia including Kosovo

**Financing:**

- 1.8 Overall cost (VAT excluded):** €50,000
- 1.9 EU contribution:** €50,000
- 1.10 Final date for contracting:** 30/11/2008
- 1.11 Final date for execution of contracts:** 30/11/2010
- 1.12 Final date for disbursements:** 30/11/2011

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<sup>1</sup> Hereafter referred to as Kosovo

## 2. Overall Objective and Project Purpose

### 2.1 Overall Objective:

To improve radiation protection in the beneficiary countries in line with the provisions of articles 5 and 44 to 47 of the Euratom Directive 96/29.

### 2.2 Project purpose:

To analyse current practices and regulations on management of medical radioactive waste in Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, and Serbia including Kosovo in order to identify possible areas for which improvement and/or optimisation would be desirable.

### 2.3 Link with AP/NPAA/EP/SAA:

- The sectoral policies of the European/Accession Partnerships with Albania (2006/54/EC), Bosnia and Herzegovina (2006/55/EC), the former Yugoslav Republic of Macedonia (2006/57/EC), Montenegro (2007/29/EC), and Serbia (2006/56/EC) in the field of environment mention the strengthening of the administrative capacity, and alignment of the legislation to the acquis.
- In addition the AP with the former Yugoslav Republic of Macedonia and the EP with Montenegro specifically refer to nuclear safety and radiation protection issues.

### 2.4 Link with MIPD:

The MIPD action entitled "Nuclear Safety and Radiation Protection" mentions that "the Western Balkan countries are confronted with a number of radiological issues that are connected with the use of radionuclides for a number of industrial and medical applications and thereby generate so-called institutional radioactive waste". In this context, the MIPD intends to:

- facilitate networking, the sharing of best practices and lessons learned across the beneficiary authorities;
- provide technical assistance to facilitate the preparation and implementation of national legislation and regulations in line with the relevant EU acquis, and best EU practices.

This regional exploratory study will aim at disseminating the information on current regulatory and management practices of medical radioactive waste in each of the five beneficiary countries abovementioned, and on this basis to identify those areas that might be recommended for possible IPA future technical assistance.

## 3. Description of project

### 3.1 Background and justification:

The use of radioactive substances in an unsealed form is widespread in human medicine. They are employed, on the one hand, in nuclear medicine and radiotherapy departments for medical diagnostics and for treating cancers and other diseases by metabolic irradiation, and on the other hand in clinical biology and medical research laboratories. This situation results in significant volumes of radioactive waste, only a small part of which is transferred to centralised radioactive waste facilities, while the major part is stored on site until the activity has decreased to a level enabling the waste to be treated as usual hospital waste.

In the EU in view of the large number of establishments and departments involved and the multiplication of the ways of eliminating the waste, effective regulatory controls were laid down. However, incidents, such as the discovery of radioactive waste in normally accessible areas or of quantities of radioactive iodine in the rivers, etc, although without significant consequence for the public health, have nevertheless alarmed the general public.

Therefore, concern was sometimes expressed by the media regarding management of radioactive waste in medical establishments. The importance of this subject is also reflected in the activities being supported by DG Energy and Transport (TREN) and international organisations, like the International Atomic Energy Agency (IAEA) through the preparation of technical reports and recommendations.

In order to better understand how this kind of radioactive waste is currently managed in medical establishments in Member States (MS) of the European Union, the European Commission organised in 1999 a technical workshop in Brussels. The proceedings of the workshop were published under the reference EUR 19254en (2000). They are available on the website of DG TREN<sup>2</sup>. This workshop highlighted large similarities between EU MS as to the applications of radionuclides for medical purposes and the ranges of radionuclides used. However, it also showed considerable diversity as to the regulations, structures and administrative agencies, the assignments and the terms of application specific for each country.

One of the conclusions of the workshop was to extend investigations notably to candidate or potential candidate countries. This statement was repeated by the representatives of the EU MS nuclear safety authorities on the occasion of the RAMG (Regulatory Authorities Management Group) meeting that took place in 2004 in Brussels.

In this context, the current situation in this particular domain in Bulgaria, Croatia and Romania has recently been peer reviewed within the framework of the Phare nuclear safety project entitled "Management of medical radioactive waste in Bulgaria, Croatia and Romania" that was launched in September 2006. This study was concluded by a technical seminar that took place in Brussels on 4/5 June 2007. The current project aims at extending the investigations to the other candidate and potential candidate countries.

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

This project will enable beneficiary countries to better transpose into their legislation the *acquis* that is related to radiation protection and in particular the provisions of articles 5 and 44 to 47 of the Euratom Directive 96/29. It may also impact on the content of the technical assistance projects that should be implemented within the framework of the nuclear safety and radiation protection action of the IPA regional programme from 2009 onwards. Discharges of radioactive liquid effluents from hospitals into rivers may have a radiological impact on neighbouring countries.

### **3.3 Results and measurable indicators:**

- Methodology to collect and analyse the information and data on management of medical radioactive waste established;
- Radioactive waste generated in a set of representative medical establishments quantified and/or estimated in each of the five IPA eligible countries;
- The regulatory framework currently in force in each of the five beneficiary countries including plans for possible improvements in the near future described;
- Current management practices for medical radioactive waste in each of the five beneficiary countries and analysis of possible discrepancies with the regulations described;
- List of recommendations on how to align the national regulations framework in force in each beneficiary country on the Euratom Directives on radiation protection;
- Current management schemes with best EU practices compared;
- A list of possible topics for which improvement and/or harmonisation would be desirable is established;
- Areas for possible future IPA technical assistance identified.

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<sup>2</sup> <http://europa.eu.int/comm/energy/nuclear/pdf/eur19254.pdf>

### 3.4 Activities:

- Establishment of a methodology for the acquisition of coherent and comparable data on management of radioactive waste in medical establishments in the five beneficiary countries;
- Data collection and analysis in particular on radioactive waste generation and discharges into the environment;
- Identification of main regulatory differences and management practices between these countries;
- Assessment of the compliance of current regulations and management practices with the acquis on radiation protection;
- Comparison of the current management practices with the situation existing in a selection of EU Member States;
- Identification of the areas where improvements would be desirable;
- Preparation and practical organisation of a technical seminar in which recommendations for possible improvements both on regulatory and management practices should be presented and discussed
- Establishment of a possible list of projects which might be supported by IPA in the future.

### 3.5 Conditionality and sequencing:

N.A

### 3.6 Linked activities:

Medical radioactive waste is part of the so-called institutional radioactive waste for which a number of projects were programmed and implemented over the years 2001-2006 within the framework of the Phare nuclear safety programme. Of particular interest is the 2005 Phare nuclear safety project that aimed at assessing management of medical radioactive waste in Bulgaria, Croatia and Romania.

### 3.7 Lessons learned:

Lessons learned from the 2005 Phare nuclear safety project on management of medical radioactive waste have shown that although national regulations generally comply with the Euratom Council Directives on radiation protection, gaps may exist between regulations and practices especially concerning discharges of radioactive waste into the environment (sewage system and landfill). The main reason for the discrepancy is the lack of appropriate instruments (gamma spectrometers) in the hospitals to measure the residual activity of radioactive waste to be discharged. In addition in a number of areas improvement of the current regulatory framework appeared to be desirable.

## 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	650,000	650,000	100	650,000								
<b>TOTAL</b>	<b>650,000</b>	<b>650,000</b>	<b>100</b>	<b>650,000</b>								

\* 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	1Q 2008	2Q 2008	2Q 2009

**6. Cross cutting issues****6.1 Equal Opportunity:**

N.A.

**6.2 Environment:**

There are substantial environmental gains to the beneficiary countries by accomplishment of this project since a better management of medical radioactive waste should decrease the level of radioactivity discharged into the environment.

**6.3 Minorities**

N.A

**ANNEXES**

- 1- Log frame in Standard Format
- 2- Amounts Contracted and Disbursed per Quarter over the full duration of Programme
- 3 - Reference to laws, regulations and strategic documents
- 4- Details per EU funded contract

## ANNEX 1: Logical framework matrix in standard format

LOGFRAME PLANNING MATRIX FOR Project Fiche	Programme name and number: 2007/019-301	Part II of the Horizontal Programme on Nuclear Safety and Radiation Protection
<b>Management of medical radioactive waste in Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, and Serbia including Kosovo (as defined in UNSCR 1244)</b>	Contracting period expires: 30/11/2008	Disbursement period expires: 30/11/2011
	Total budget: <b>€0.65 million</b>	IPA budget: <b>€0.65 million</b>

Overall objective	Objectively verifiable indicators	Sources of Verification	
To improve radiation protection in the beneficiary countries in line with the provisions of articles 5 and 44 to 47 of the Euratom Directive 96/29.			
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
To review current practices and regulations on management of medical radioactive waste in Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, and Serbia including, Kosovo in order to identify possible areas for which improvement and/or optimisation would be desirable.	Recommendations listed in the final report	Production of progress and final reports resulting from the project implementation. Mission reports produced by the Contractor in the five selected countries.	The relevant safety authorities in charge of the management of medical radioactive waste in the five selected countries and notably the Ministries of Health are supposed to fully collaborate to the project, providing all necessary information and data in particular on waste inventories and discharges into the environment.
Results	Objectively verifiable indicators	Sources of Verification	Assumptions
<ul style="list-style-type: none"> <li>Methodology to collect and analyse the information and data on management of medical radioactive waste established;</li> <li>Radioactive waste generated in a set of representative medical establishments quantified and/or</li> </ul>	<p>Progress and topical reports</p> <p>Progress and topical reports</p>	Documentation available in the relevant Ministries and State organisations of the five beneficiary countries and in the archives of DG ELARG/D3	

<p>estimated in each of the five IPA eligible countries;</p> <ul style="list-style-type: none"> <li>• The regulatory framework currently in force in each of the beneficiary countries including plans for possible changes in the near future described;</li> <li>• Current management practices for medical radioactive waste in each of the beneficiary countries and analysis of possible discrepancies with the regulations described;</li> <li>• List of recommendations on how to align the national regulations framework in force in each beneficiary country on the Euratom Directives on radiation protection;</li> <li>• Current management practices with best EU practices compared;</li> <li>• A list of possible topics for which improvement and/or harmonisation would be desirable established;</li> <li>• Areas to be recommended for possible future IPA technical assistance identified.</li> </ul>	<p>Progress and topical reports</p> <p>Progress and topical reports</p> <p>Progress, topical and final reports and minutes of the technical seminar</p> <p>Progress, topical and final reports and minutes of the technical seminar</p>		
<p><b>Activities</b></p>	<p><b>Means</b></p>	<p><b>Costs</b></p>	<p><b>Assumptions</b></p>
<ul style="list-style-type: none"> <li>• Establishment of a methodology for the acquisition of coherent and comparable data on management of radioactive waste in medical establishments in the five beneficiary countries;</li> <li>• Data collection and analysis in particular on radioactive waste</li> </ul>	<p>Service contract</p>	<p>€50,000</p>	

<p>generation and discharges into the environment;</p> <ul style="list-style-type: none"><li>• Identification of main regulatory differences and management practices between these countries;</li><li>• Assessment of the compliance of current regulations and management practices with the <i>acquis</i> on radiation protection;</li><li>• Comparison of the current management practices with the situation existing in a selection of EU Member States;</li><li>• Identification of the areas where improvements would be desirable;</li><li>• Preparation and practical organisation of a <u>technical</u> seminar in which recommendations for possible improvements both on regulatory and management practices should be presented and discussed;</li><li>• Establishment of a possible list of projects which might be supported by IPA in the future.</li></ul>			
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**ANNEX II: Amounts (in €) Contracted and disbursed by quarter for the project**

<b>Contracted</b>	<b>Q3 2007</b>	<b>Q4 2007</b>	<b>Q1 2008</b>	<b>Q2 2008</b>	<b>Q3 2008</b>	<b>Q4 2008</b>	<b>Q1 2009</b>	<b>Q2 2009</b>	<b>Q3 2009</b>	<b>Q4 2009</b>
Contract 1				650,000						
<b>Cumulated</b>				<b>650,000</b>						
<b>Disbursed</b>										
Contract 1				390,000	130,000		130,000			
<b>Cumulated</b>				<b>390,000</b>	<b>520,000</b>	<b>520,000</b>	<b>650,000</b>	<b>650,000</b>	<b>650,000</b>	<b>650,000</b>

<b>Contracted</b>	<b>Q1 2010</b>	<b>Q2 2010</b>	<b>Q3 2010</b>	<b>Q4 2010</b>	<b>Q1 2011</b>	<b>Q2 2011</b>	<b>Q3 2011</b>	<b>Q4 2011</b>
Contract 1.1								
<b>Cumulated</b>								
<b>Disbursed</b>								
Contract 1.1								
<b>Cumulated</b>	<b>650,000</b>							

### **Annex III: Reference to laws, regulations and strategic documents:**

- Nuclear Safety and Radiation Protection action of the multi-country MIPD programme;
- Euratom Council Directive 96/29;
- The Joint Convention on the safety of spent fuel management and on the safety of radioactive waste management;
- The 1995 Law on radiation protection in **Albania**;
- 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 **Republic of Srpska of Bosnia & Herzegovina**;
- The Act on Protection Against Ionising Radiation 1999 and its 2003 amendment in **Croatia**;
- The Law on Protection against Ionizing Radiation and Radiation Safety (2002) in the **former Yugoslav Republic of Macedonia**;
- The draft Law on Radiation Protection and the Security of Radioactive Sources that will repeal Law 46/96 in **Montenegro**;
- The draft of the **Serbian** new Law on ionising radiation protection and on nuclear safety (2006) and existing **Serbian** Law on Protection against Ionising Radiation (1996);
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### **Annexe IV: 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 each of the beneficiary countries. It is thought that the cost of the information to be collected and analysed in each country should range within €40,000 to €120,000 depending on the size of the country. The preparation of the technical seminar that will conclude the project should be financed through incidental expenditure (about €70,000).

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