

**Project Fiche No. 1**

**Further steps to approximate the Albanian legislation and regulations in accordance with the *EU acquis* in the field of radiation protection, nuclear safety and security**

**1. Basic information**

**1.1 CRIS Number:** 2010/022-503

**1.2 Title:** Further steps to approximate the Albanian legislation and regulations in accordance with the *EU acquis* in the field of radiation protection, nuclear safety and security

**1.3 ELARG Statistical code:** 03.64 - Nuclear Safety

**1.4 Location:** Tirana - Albania

**Implementing arrangements:**

**1.5 Contracting Authority:**

The European Union represented by the European Commission for and on behalf of Albania.

**1.6 Implementing Agency:**

Not applicable.

**1.7 Beneficiaries:**

Radiation Protection Commission and Radiation Protection Office, in Albania

**Financing**

**1.8 Overall cost (VAT excluded)<sup>1</sup>:** EUR 220 000

**1.9 EU contribution:** EUR 220 000

**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:** 1 year following the end date for execution of contracts

---

<sup>1</sup> The total cost of the project should be net of VAT and/or other taxes. Should this not be the case, the amount of VAT and the reasons why it should be considered eligible should be clearly indicated

## **2. Overall Objective**

### **2.1 Overall Objective:**

To decrease exposure of ionising radiation in all relevant sectors in line with the *EU acquis* in the field of radiation protection, nuclear safety and security.

### **2.2 Project purpose:**

To perform further steps forward to the approximation of the Albanian legislation and regulations with the *EU acquis* through three specific activities:

- Completion of the activities concerning the full approximation of the Albanian legislation and regulations with the *EU acquis* that were implemented in a previous IPA-funded project;
- Reviewing of procedures for the application of regulations in order to be in full compliance with the *EU acquis*;
- Establishment of quality control (QC) standards and procedures for X-ray machines working on the territory of Albania.

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

The sectoral policies of the European/Accession Partnerships with Albania in the field of environment mention the strengthening of the administrative capacity and alignment to the *acquis*. The 2007 and 2008 Progress Report of the European Commission on Albania stated that the situation in the field of nuclear safety and radiation requires improvement in terms of coordination and organisation of the activities.

### **2.4 Link with MIPD**

The IPA Multi-beneficiary Multi-annual Indicative Planning Document (MIPD) 2009-2011<sup>2</sup>, *section 2.3.3.11 - Nuclear Safety and Radiation Protection*, mentions that "All IPA beneficiaries are facing radiological issues that are connected with the use of radionuclides for industrial and medical applications. Moreover, management of radioactive waste in hospitals may require investments and training of the personnel". Therefore, this project proposal concerns firstly the reduction of doses received by patients and secondly, the occupational exposures in medical centres and industrial companies, in order to be fully in line with the Multi-Beneficiary MIPD activities.

### **2.5 Link with National Development Plan**

Not applicable.

### **2.6 Link with national / sectoral investment plans**

Not applicable.

---

<sup>2</sup> C(2009)4518 of 16.06.2009.

### 3. Description of project

#### 3.1 Background and justification:

The approximation of the Albanian legislation and regulations with the *EU acquis* - in particular in the field of radiation protection, nuclear safety and security - is one of the prerequisites for Albania to accede to the European Union. As demonstrated in several assessment studies funded by the IPA horizontal programme on nuclear safety and radiation protection, this is not yet the case.

Although the regulatory framework in this domain looks rather well advanced, since the additional regulations in need cover merely four topics, namely:

- Monitoring of the radioactivity into the environment;
- Management of Naturally Occurring Radioactive Materials and Technologically Enhanced Naturally Occurring Radioactive Materials;
- Public information;
- Protection of aircrew from ionising radiation;

the compliance with the *EU acquis* of the eleven existing regulations/guidance in the field of radiation protection that have been laid down by the Radiation Protection Commission of Albania over the last years, has still to be checked, assessed and whenever necessary to be amended in order to be in full compliance with the *EU acquis*. These regulations are as follows:

- Regulation "On safe handling with ionizing radiation sources" Nr. 3918 / 5, dated the 3/11/2004;
- Regulations for "Licensing and inspection of activities with sources of ionizing radiation" No.10, dated the 07 January 2010 (Council of Ministers);
- Regulation "On the safe transport of radioactive materials" No. 3918/1, dated the 3/11/2004;
- Regulation "On the treatment of radioactive waste" Nr. 08 dated the 07 January 2010;
- Regulation on "Categorization of radioactive sources in the Republic of Albania" No. 09 dated the 07 January 2010;
- Regulation on "Control of workers professionally exposed" No. 2269/2, dated the 19/06/2007;
- Regulation on "Control of public exposure" 2269/3 dated the 19.06.2007;
- Regulation on "Control of Medical exposures "2269/1 dated the 19.06.2007;
- Regulation on "Physical protection of radioactive materials" 2518 dated the 12.06.2006;
- Guidance on import / export of radioactive materials in Republic of Albania No.4756/1, dated the 21/12/2006
- Regulation on "Limit for concentration levels of radon in buildings, radionuclides in food and construction materials "No. 804 /1, dated the 15/03/2005.

It is expected that via the 2008 IPA regional project aimed at enhancing the technical capacity of nuclear regulatory bodies in the Western Balkans, the assessment of the degree of transposition of the *EU acquis* in the field of radiation protection, nuclear safety and security into the Albanian national legislation and regulations will be

performed so that amendments to the regulations in force can be proposed at least partially.

Therefore, the first aim of this additional project on regulatory assistance aims at completing this transposition through the drafting of additional regulations/guidances that are in full compliance with the *acquis*.

The second aim of the project constitutes a logical continuation of the transposition of the *EU acquis* into the Albanian regulations, and consists in the reviewing and the development of administrative procedures that will derive from the amended regulations. These procedures will cover authorisation, inspection and enforcement activities that must be performed by the Radiation Protection Office.

The third aim is more specific and concerns the implementation of one of the recommendations of the IPA-funded study on the assessment of the nuclear regulatory infrastructure of the Western Balkans<sup>3</sup>, and the compliance of the Albanian regulations with the provisions of Article 8 of the EURATOM Council Directive 97/43 i.e. the need to establish procedures for the QC (Quality Control) of the X-ray machines that are generating ionising radiation.

It is important to underline that at present in Albania, none of the X-ray machines is regularly controlled by appropriate recognised experts or companies since there is no regulations on how to perform the QC of such a kind of equipment.

To a certain extent this activity is also in line with the development of procedures for the application of the following regulations:

- Regulation "On safe handling with ionizing radiation sources" Nr. 3918 / 5, dated the 3/11/2004;
- Regulations for "Licensing and inspection of activities with sources of ionizing radiation" No.10, dated the 07 January 2010 (Council of Ministers);
- Regulation on "Control of Medical exposures "2269/1 dated the 19.06.2007;

However, this activity goes further since it also covers the creation of a national inventory for the technical parameters of X-ray machines all over the territory of Albania. Some of these parameters are the following: the establishment of national standards on QC, the definition of QC tests, the frequency of the tests and the identification of companies that could become recognised organisations for the performance of QC tests. Finally, this activity would comprise training courses for the personnel of the Radiation Protection Office, the users of X-ray machines and the recognised experts or companies in charge of QC.

---

<sup>3</sup> Task 6 report: Action Plans for Improvement of Regulatory Infrastructure on Nuclear/Radiation Issues, carried out by the consortium Enconet/Slovenian Nuclear Safety Administration (December 2009)

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

This project will contribute to the reduction of doses received by patients and the occupational exposure in several diagnostic departments of medical centres, hospitals, and dentistry in Albania.

In order to become sustainable this project should also comprise a training component of the personnel that is operating ionising radiation equipments.

This project has also a cross-border impact in the sense that compliance of the Albanian regulations on the physical protection of radioactive and nuclear materials with the *acquis* and the international conventions to which the European Union is a party, may decrease the risk of illicit trafficking of nuclear materials in the Western Balkans.

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

#### Results in relation with activity 1: Transposition of the *EU acquis*

- At least four additional regulations in the field of radiation protection, nuclear safety and security are fully aligned to the *EU acquis* in the field of radiation protection;
- The personnel of the Radiation Protection Office in Albania have become familiar with the *EU acquis*.

#### Results in relation with activity 2: Development of procedures

- Procedures for the application of the eleven regulations/guidance in the field of radiation protection have been reviewed, analysed and developed in accordance with the amendments proposed in the foregoing step (transposition of the *acquis*);
- The personnel of the Radiation Protection Office in Albania have become familiar with the development of procedures covering authorisation, inspection and enforcement.

#### Results in relation with activity 3: Quality Control of X-ray machines

1. A comprehensive list of the technical parameters of the X-ray machines for radiography, fluoroscopy, computerised tomography, digital panoramic systems, and mammography operating on the territory of Albania has been established;
2. Procedures for QC tests have been established;
3. Potential experts or companies that could potentially performed QC tests have been identified;
4. All Albanian experts involved in the development and application of QC tests have attended appropriate training courses;
5. A testing campaign of X-ray machines has been performed on at least 6 sites.

Indicators:

1. The progress report for accession to the EU should highlight in 2013 the fact that the Albanian legislation and regulations are fully in line with the *EU acquis* in the radiation protection, nuclear safety and security areas;
2. Attendance certificates for the Albanian experts that will participate in the training courses on QC of X-ray machines

**3.4 Activities:**

Activity 1: Transposition of the *EU acquis*

The contractor will complete the activities on the transposition of the EU acquis in the field of radiation protection into the Albanian regulations that were partially implemented within the framework of the 2008 IPA-funded project on enhancing the technical capacity of nuclear regulatory bodies in the Western Balkans. This will consist of analysing the results of the related project on the degree of transposition and - following a similar approach - complete the drafting of amended regulations that must become fully in line with the *EU acquis* in the field of radiation protection. This activity has to be performed jointly with the members of the Radiation Protection Office and any modification to be brought to the existing regulations should be clearly explained to the Albanian partners as part of the know-how transfer.

It is expected, at this stage, that the transposition to be performed will cover at least four regulations, in order to have all Albanian regulations in accordance with the EU acquis.

Activity 2: Development of procedures

Based on the results of the foregoing activity and by taking into account the results of the regional IPA-funded project already mentioned, the contractor will develop together with the personnel of the Radiation Protection Office, appropriate procedures of application for the eleven amended regulations/guidances that will cover authorisation, inspection and enforcement.

Activity 3: Quality Control of X-ray machines

This activity will consist of the following tasks:

- Establishment of an inventory of X-ray machines being used in the medical sector of Albania.

This task has to be performed jointly with the Radiation Protection Office as well as with the main Albanian medical establishments, i.e.:

- ❖ University Hospital Centre “Mother Tereza”, Tirana,
- ❖ Hygeia Hospital, Tirana
- ❖ Regional Hospital, Durres
- ❖ Regional Hospital, Shkodra
- ❖ Regional Hospital, Korça
- ❖ Regional Hospital, Vlora

It should cover the following applications of X-ray machines: radiography, fluoroscopy, computerised tomography, digital panoramic systems, and mammography.

- Establishment of procedures for QC tests

The Contractor will have first to review the existing QC tests being applied in several EU Member States and on this basis to propose procedures for QC tests to the Radiation protection Office that will cover authorisation for using X-ray machines, their inspection and finally the enforcement of the regulations in the case there are not fully respected by the users.

- Identification of potential experts or organisations in charge of QC tests

This task will consist of identifying in the Albanian society those individuals or companies which could perform the QC tests in medical establishments, by taking into account their professional background (physicists should be preferably recruited for that purpose) and ability to become recognised experts or companies after having followed training courses to be organised by the contractor.

The identification of the potential experts will be performed in close collaboration with the Radiation protection Office.

- Organisation of training courses

The contractor will have to organise appropriate training courses either in Tirana or in regional centres in order to train the selected group of potential experts identified earlier. These courses are not expected to concern more than 30 people.

- Testing of the QC procedures

In close collaboration with the concerned medical establishments on at least six different sites, the contractor will test the ability of the trainees to perform QC tests through on-the-job training.

### **3.5 Conditionality and sequencing**

Activities no 1, 2 and 3 will be implemented one after the other in a logical manner.

### **3.6 Linked activities**

The implementation of this project should take into account the results of two IPA-funded projects, namely:

- A project on enhancing the technical capacity of nuclear regulatory bodies in the Western Balkans that was programmed in 2008 and that should start in 2010;
- A project on upgrading of radiation protection and safety monitoring that was programmed in 2009 and that should start in 2010.

### 3.7 Lessons learned

One could come to the result that Albania has the capacity to absorb the technical assistance provided by several Western contractors specialised in various nuclear areas. This can be justified if one takes into consideration the performance and the contributions of the Albanian nuclear experts of the Radiation Protection Office in Tirana, with regard to the implementation of six assessment studies on main radiological issues (currently existing in the Western Balkans and in particular in Albania) funded by IPA in 2008 and 2009

### 4. Indicative Budget (amounts in EUR)

			SOURCES OF FUNDING									
			TOTAL EXP.RE	IPA EU CONTRIBUTION		NATIONAL CONTRIBUTION					PRIVATE CONTRIBUTION	
ACTIVITIES	IB (1)	INV (1)	EUR (a)=(b)+(c) (d)	EUR (b)	%(2)	Total EUR (c)=(x) +(y)+(z)	% (2)	Central EUR (x)	Regional/ Local EUR (y)	IFIs EUR (z)	EUR (d)	% (2)
Activity 1	x		60 000	60 000	100							-
												-
Activity 2	x		100 000	100 000	100							-
Activity 3	x		60 000	60 000	100							
TOTAL IB			220 000	220 000	100							
TOTAL INV												
<b>TOTAL PROJECT</b>			<b>220 000</b>	<b>220 000</b>	<b>100</b>							

Amounts net of VAT

- (1) In the Activity row use "X" to identify whether IB or INV
- (2) Expressed in % of the **Total** Expenditure (column (a))

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

Contracts	Start of Tendering	Signature of Contract	Project Completion
Contract 1-Service	Q3 2011	Q1 2012	Q3 2013

## **6. Cross cutting issues**

### **6.1 Equal Opportunity**

The project will benefit both women and men through improvements in radiation protection in the medical sector and the industry. On all activities, both men and women will have equal opportunities to compete for contracts and to work on any related activities.

### **6.2 Environment**

The achievement of full compliance of the Albanian legislation/regulations with the Community acquis will have a positive impact on the protection of the environment since all discharges of radioactive waste will be under control. Under these circumstances the risk of environmental pollution and the risk of public exposure will be significantly diminished.

### **6.1 Minorities**

Considering that the project will contribute to the overall development of the society through better use of devices generating ionised radiation, it is expected that access of disabled and minorities groups (including Roma) to medical services or to industrial activities would be improved.

**ANNEXES**

- I- Logical framework matrix in standard format
- II- Amounts (in EUR) contracted and disbursed per quarter over the full duration of the project
- III- Description of Institutional Framework
- IV - Reference to laws, regulations and strategic documents:
- V- Details per EU funded contract (where applicable)

2010 IPA Horizontal Programme on Nuclear Safety and Radiation Protection  
PF1 – Albania - Final

**ANNEX I: Logical framework matrix in standard format**

<b>LOG FRAME PLANNING MATRIX FOR Project Fiche</b>	Programme name and number: 2010/022-503 2010 IPA Horizontal Programme on Nuclear Safety and Radiation Protection	
Further steps to approximate the Albanian legislation and regulations in accordance with the <i>EU acquis</i> in the field of radiation protection, nuclear safety and security	Contracting period expires: 2 years following the date of conclusion of the financing agreement	Disbursement period expires : 1 year following the end date for execution of contracts
	Total budget : EUR 220 000	IPA budget: EUR 220 000

Overall objective	Objectively verifiable indicators	Sources of Verification	
To decrease exposure of ionising radiation in all relevant sectors in line with the <i>EU acquis</i> in the field of radiation protection, nuclear safety and security.			
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
To perform further steps forward to the approximation of the Albanian legislation and regulations with the <i>EU acquis</i> through three specific activities: •Completion of the activities concerning the full approximation of the Albanian legislation and regulations with the <i>EU acquis</i> that were implemented in a previous IPA-funded project; •Reviewing of procedures for the application of regulations in order to be in full compliance with the <i>EU acquis</i> ; •Establishment of quality control (QC) standards and procedures for X-ray machines working on the territory of Albania.	Procurement Procedure  Full compliance of the Albanian legislation and regulations with the EU <i>acquis</i> in the radiation protection field.	Medical centres and industrial companies using X-Ray machines  Radiation Protection Commission – RPC,  European Commission HQs  Progress reports	
Results	Objectively verifiable indicators	Sources of Verification	Assumptions
<b>Results in relation with activity 1: Transposition of the EU acquis.</b>  1. At least four additional regulations in the field of radiation protection, nuclear safety and security are fully aligned to the <i>EU acquis</i> in the field of radiation protection;  2. The personnel of the Radiation Protection Office in Albania has become familiar with the <i>EU acquis</i> .	Full compliance with the <i>acquis</i> .  No more regulatory assistance requested in the field of radiation protection	Visit of the European Commission HQs  Progress Report  Reports from EU experts in charge of organising training courses.	Approval of the regulations by RPC.  Staff of RPO shall be extended.
<b>Results in relation with activity 2: Development of procedures.</b>  1. Procedures for the application of the eleven regulations/guidance in the field of radiation protection have been reviewed, analysed and developed in accordance with the amendments proposed in the foregoing step (transposition of the <i>acquis</i> );  2. The personnel of the Radiation Protection Office in Albania has become familiar with the development of procedures covering authorisation, inspection and enforcement.	Procedures to implement the <i>acquis</i> in place.  No more regulatory assistance requested in the field of procedures for implementing regulations.	Progress report  Reports from EU experts in charge of organising training courses.	Approval of the procedures by the RPC and the RPO.  Staff of RPO shall be extended.
<b>Results in relation with activity 3: Quality Control of X-ray machines.</b>  1. A comprehensive list of the technical parameters of the X-ray machines for radiography,		Database can be consulted in the RPO premises.	Subject to good communication between the users of X-ray machines and the RPO.

**2010 IPA Horizontal Programme on Nuclear Safety and Radiation Protection  
PF1 – Albania - Final**

<p>fluoroscopy, computerised tomography, digital panoramic systems, and mammography operating on the territory of Albania has been established;</p> <p>2.Procedures for QC tests have been established;</p> <p>3.Potential experts or companies that could potentially perform QC tests have been identified;</p> <p>4.All Albanian experts involved in the development and application of QC tests have attended appropriate training courses;</p> <p>5. A testing campaign of X-ray machines has been performed on at least 6 sites.</p>	<p>QC tests subject to comparison with existing QC tests used by Member States.</p> <p>CV's of physicists and/or demonstration of capabilities to follow relevant training courses.</p> <p>Attendance certificates.</p> <p>Recalibration of the X-ray machines requested.</p>	<p>Medical centres and industrial companies, RPC.</p> <p>Procedures and relevant reports for QC tests validated by RPO.</p> <p>Database can be consulted in the RPO premises.</p> <p>Reports from EU experts in charge of organising training courses.</p> <p>Reports to be produced by the experts and/or the specialised companies together with the Radiation Protection Office, the University Hospital Centre "Mother Tereza", the Hygeia Hospital and three Regional Hospitals.</p>	<p>Approval of QC tests by RPC and RPO.</p> <p>Approval of the list by RPO.</p> <p>Availability of physicists and/or specialised companies.</p> <p>Availability of sufficient number of trainees.</p> <p>X-ray machines must be operational.</p>
<b>Activities</b>	<b>Means</b>	<b>Costs</b>	<b>Assumptions</b>
<p>Activity 1: Transposition of the Community acquis.</p> <p>Activity 2: Development of procedures.</p> <p>Activity 3: Quality Control of X-ray machines.</p>	<p>Technical assistance – service contract</p>	<p>EUR 220 000</p>	

**ANNEX II: Amounts (EUR) contracted and disbursed per quarter over the full duration of the project**

Contracted	Q1 2012	Q2 2012	Q3 2013	Q4 2012	Q1 2013	Q2 2013	Q3 2013
Contract 1 - Service	220 000						
Cumulated	220 000	220 000	220 000	220 000	220 000	220 000	220 000
Disbursed	Q1 2012	Q2 2012	Q3 2012	Q4 2012	Q1 2013	Q2 2013	Q3 2013
Contract 1 - Service	140 000			70 000			10 000
Cumulated	140 000	140 000	140 000	210 000	210 000	210 000	220 000

**Annex III: Description of Institutional Framework**

In Albania the regulatory body in the area of nuclear safety and radiation protection is the Commission for Radiation Protection (CRP). The Office of Radiation Protection (ORP) is a permanent organization, which acts as the executive body for CRP.

The Commission for Radiation Protection consists of seven members, which are appointed by the Prime Minister. The chair of CRP is the Minister of Health. They are the decision making body and their working mode are regular (or extraordinary) sessions or meetings. The executive part is the Office of Radiation Protection, which implements the decisions of CRP as well as it prepare proposals and materials for CRP sessions.

The ORP has regularly employed staff, which are, in terms of infrastructure (housing, transport – i.e. vehicles) and budget, dependent on the Institute of Public Health. So far the working arrangements and relations between the ORP and Institute of Public Health were good, but on a long term this situation needs a consideration because it may question the independence status of the ORP.

The responsibilities are the following:

- CRP: prepares regulations, guides and codes of practices for radiation protection and nuclear safety; oversees the enforcement of the provisions related with radiation protection; issues the licences; makes the recommendations and proposals for the improvement of the radiation protection legislation; co-operates with national and international organisations on radiation protection issues; determines the structure of the ORP; co-operates with State Labour Inspectorate;
- ORP: performs the inspection; performs radiation measurements and evaluates them; prepares the documentation for issuance, suspension and withdrawal of licences and presents them to the CRP for approval; prepares the materials for the CRP meetings; keeps national inventory of sources. With regard to cross-cutting responsibilities, the areas such as physical protection and emergency preparedness are within the Ministry of Interior and ORP assumes the advisory role. The Department of Emergencies was established in the Ministry of Interior. The ORP also cooperates with the General Customs Directorate in the area of import and export of radioactive substances. This is regulated by the Decision of the council of ministers on control of import export of radioactive material (2008). The Albanian General Customs Directorate has the responsibility to prevent the import and export of unlicensed goods, investigating offences, and taking appropriate actions, including prosecution of offenders.

**Annex IV: Reference to laws, regulations and strategic documents:**

- Nuclear Safety and Radiation Protection action of the Multi-beneficiary MIPD 2009-2011.
- The Law on Radiation Protection from Ionizing Radiation.
- The Regulation approved by Radiation Protection Commission in Albania.

**Annex V: Details per EU funded contract**

Contract 1: A service contract for an amount of EUR 220 000 will be concluded following a tender that will be launched in the third quarter of 2011. The contractor is expected to fulfil all the activities with the support of the local companies and/or relevant organizations established in Albania.

On account of the specific objectives of the project and the specificity of the service to be provided, participation is open to all Nuclear Regulatory bodies of the EU Member-States participating either individually or in a grouping (consortium).

Technical Safety Organisations established in EU Member-States can be part of consortia together with the above regulatory bodies.

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