

Standard Summary Project Fiche**1. Identification**

Project Title	Further enhancement of the technical capacity of nuclear regulatory bodies in Albania, the former Yugoslav Republic of Macedonia, Serbia, as well as Kosovo ¹
Cris Decision number	2011/023-384
Project no.	2
MIPD Sector Code	5. Energy (Multi-Beneficiary MIPD – 5.Transport and Energy Infrastructure, including nuclear safety)
ELARG Statistical code	03.64 - Nuclear Safety
DAC Sector code	23064
Total cost (VAT excluded)²	EUR 2 300 000
EU contribution	EUR 2 300 000
EU Delegation in charge/Responsible Unit	Unit D3 - Regional Programmes DG Enlargement
Management mode	Centralised
Implementing modality	Project
Project implementation type	Bilateral
Zone Benefiting from the action/Beneficiaries	Albania, the former Yugoslav Republic of Macedonia, Serbia, as well as Kosovo
Final date for contracting	3 years following the date of conclusion of the financing agreements
Final date for execution of contracts	2 years following the end date for contracting
Final date for disbursement	1 year following the end date for execution of contracts

¹ under UNSCR 1244/1999.

² The total project cost should be net of VAT and/or of other taxes. Should this not be the case, clearly indicate the amount of VAT and the reasons why it is considered eligible.

2. Overall Objective and Project Purpose

2.1 Overall Objective:

To contribute to improve radiation protection, nuclear safety and security in Albania, the former Yugoslav Republic of Macedonia, Serbia, as well as Kosovo through the reinforcement of the technical capacity of their nuclear regulatory agencies.

2.2 Project purpose:

To further contribute to the transposition of the *acquis* in the field of nuclear safety and radiation protection, and to align the functioning of nuclear regulatory agencies in Albania, the former Yugoslav Republic of Macedonia, Serbia, as well as Kosovo with their sister organisations in the EU.

2.3 Link with AP/NPAA/EP/SAA:

- The sectoral policies of the European/Accession Partnerships with Albania (2006/54/EC), the former Yugoslav Republic of Macedonia (2006/57/EC), Serbia (2006/56/EC), as well as Kosovo (2006/56/EC) mention the strengthening of the administrative capacity, and alignment of the legislation with the *acquis*.
- Article 107 of the SAA (22 May 2006) between the European Union and Albania specifically refers to the European Union *acquis* in the field of nuclear safety.
- Article 103 of the SAA (26 March 2001) with the former Yugoslav Republic of Macedonia asks for a reinforcement of nuclear safety.
- The Commission Opinion on Albania's application for membership of the European Union issued in 2010 stipulates that "the regulatory authority is weak and will require substantial financial and human resources to build up its capacity to establish implement and effectively enforce legislation in line with international standards and the Euratom *acquis*, including the 2009 Nuclear Safety Directive. The arrangements for informing the public are incomplete. The environmental radiation monitoring programme needs to be put into action. Finally, measures will be required to guarantee the financial independence of the regulatory authority from the Ministry of Health".
- The former Yugoslav Republic of Macedonia 2010 progress report underlines that "the Radiation Safety Directorate (RSD) issued several implementing regulations. However, their compliance with the EU *acquis* still needs to be checked. The administrative capacity of the RSD is acceptable, although additional staff is needed to enable the RSD to fulfil all its tasks. Licensing of the storage facility for radioactive waste is a key issue for guaranteeing safe management of radioactive waste in the country. This should be carried out in full compliance with the *acquis* concerning assessment of the environmental impact. Criteria for defining a technical support organisation should be established in order to enable the RSD to receive technical assistance, not least in the field of safety assessment of complex facilities. A national emergency plan has to be developed. Training in the field of radiation protection should be organised. The financial independence of the directorate is still not secured."
- The Serbia 2010 progress report specifies that "legislation and working procedures in the nuclear area need be revised in order to comply with the EU *acquis*. Working procedures, appropriate staffing and technical means have to be established to enable the nuclear regulatory agency (SRPNA) to work properly. Responsibility for inspection and the operating budget for the Agency need to be clearly defined.

- The Kosovo 2010 progress report mentions that "in the area of nuclear safety and radiation protection, the Law on protection from non-ionising radiation, ionising radiation and nuclear security was adopted in February. It provides for establishment of a radiation protection agency by the Ministry of Environment and Spatial Planning. This has not yet happened. In addition, the law is of a very general nature: transposition of the EU nuclear safety and radiation protection *acquis* into national legislation and regulations in the nuclear field has therefore not yet started.

2.4 Link with MIPD

The IPA Multi-Beneficiary Multi-annual Indicative Planning Document (MIPD) for the years 2011 - 2013³ states that:

“Sector Objectives for EU support over next three years

As for nuclear safety and radiation protection, IPA Multi-beneficiary assistance will aim at strengthening the capacities of national regulatory authorities dealing with nuclear safety and radiation protection, thus decreasing the radiological risks for the public associated with radioactive materials and waste as well as the use of devices generating ionising radiation.

Indicators

As for nuclear safety, support in this area will result in the full transposition of the relevant EU *acquis* into the national legislations of all Beneficiaries. In addition, conditions will be in place allowing for the appropriate handling and storage of radioactive material and waste.

In order to meet the sector objectives outlined above, actions foreseen under this sector will aim at achieving the following:

- Technical capacity of the national regulatory agencies enhanced to comply with EU *acquis* and regulations on nuclear safety and radiation protection.”

In addition, the IPA Multi-beneficiary Multi-annual indicative Planning Document (MIPD) 2009-2011⁴, section 2.3.3.11 - Nuclear Safety and Radiation Protection, includes among its main objectives “enhance the technical competence and administrative capacity of the national radiation safety authorities and other relevant public organisation”.

This regional project that will aim at enhancing the technical capacity of the regulatory bodies of the Beneficiaries in the field of nuclear safety and radiation protection is therefore fully compliant with the MIPD’s objectives.

3. Description of project

3.1 Background and justification:

Beneficiaries are obliged to transpose eventually into their national legislation and regulations the EURATOM Directives which in particular comprise requirements concerning the use of radionuclides for a number of applications in the medical sector and the industry. This presupposes that regulatory bodies are operational in each of the Beneficiaries.

The assessment of the regulatory infrastructure of the Beneficiaries was performed in 2009/2010 via the 2007 IPA-funded project entitled "Assessment of the Regulatory Infrastructure in the field of Nuclear Safety and Radiation Protection in Albania, Bosnia and Herzegovina, Croatia,

³ C(2011)4179, of 20.06.2011.

⁴ C(2011)4518, of 16.06.2009.

the former Yugoslav Republic of Macedonia, Montenegro, Serbia as well as Kosovo". This project comprises a gap analysis that highlights and costs regulatory aspects that need to be improved in the short- and medium-term. The conclusions of this project constitute the basis of the current project-fiche. These are detailed hereafter for each beneficiary country.

The assessment of the degree of transposition of the EU *acquis* into the national legislation and regulations of Albania, the former Yugoslav Republic of Macedonia, Serbia, as well as Kosovo is being subject to the 2008 IPA regional project on "Enhancement of the technical capacity of nuclear regulatory bodies in Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Montenegro, Serbia as well as Kosovo". This project is being implemented in joint management with the International Atomic Energy Agency. It should be completed in early 2013. It is not expected that through this project 100% of the EU *acquis* will be transposed. Further support seems to be necessary.

The situation of the regulatory bodies in the Beneficiaries can be outlined as follows:

Albania

The Radiation Protection Commission (RPC) is the main regulatory body. It notably approves regulations, guides and codes of practices, proceeds with the enforcement of the provisions related with radiation protection, and issues licences for users of radionuclides. The RPC also defines the structure of its executive office that is named Radiation Protection Office (RPO). Fifteen non-permanent members belonging to several organisations are working for the RPC. The Minister of Health chairs the RPC. The secretary of the RPC is the chairman of the RPO.

The RPO is in charge of a number of technical issues (establishment of inventories of sealed radioactive sources, dosimetry control, drafting of new laws and regulations, inspections, etc). Albania is rather well advanced in the transposition of the EU *acquis* into the national legislation and regulations, however external assistance appears to be necessary in a number of specific domains.

These are highlighted in the 2007 IPA-funded project entitled "Assessment of the Regulatory Infrastructure in the field of Nuclear Safety and Radiation Protection in Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Montenegro, Serbia as well as Kosovo" (gap analysis report) i.e.

- Upgrading the Quality Management System in line with international practices (medium priority);
- Preparation of procedures for licensing of installations, e.g. radioactive waste storage facility (high priority);
- Development of procedures for customs to deal with packages containing radioactive material (high priority);
- Responsibilities and decision making process during emergencies (medium priority);
- Development of missing regulations (high priority)

The aim of this project is to cope with these priorities.

The former Yugoslav Republic of Macedonia

The Radiation Safety Directorate (RSD) - which is the nuclear regulator - was established on 5th May 2005 as a result of the Law on Protection against Ionising Radiation and Radiation Safety adopted in 2002. The RSD is directly responsible to the government. The main tasks of the RSD are to prepare relevant legislation and regulations, to authorise activities involving the use of radionuclides and to proceed with inspections.

Considerable regulatory activities have been performed in the former Yugoslav Republic of Macedonia during the last four years. It is very likely that most part of the EU *acquis* has already been transposed into the former Yugoslav Republic of Macedonia legislation and regulations.

The Stip nuclear medicine institute - located in the eastern part of the former Yugoslav Republic of Macedonia - will make use of SPECT-CT equipment. This equipment together with a cyclotron for the production of radionuclides should be operational by the end of 2012. To this end, regulatory support is needed (including the acquisition of some equipment for checking) in order for this facility to be licensed in time. In addition, the establishment of Quality Assurance/Quality Control (QA/QC) measures for devices generating ionising radiation in hospitals constitutes an important radiological issue. Therefore external support has been asked in order to cover both topics.

It should be pointed out that both topics (licensing of facilities generating ionising radiation) and reduction of medical exposure in line with the Euratom Council Directive 97/43 (establishment of QA/QC measures) have been assessed as high priorities in the 2007 IPA-funded project entitled "Assessment of the Regulatory Infrastructure in the field of Nuclear Safety and Radiation Protection in Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Montenegro, Serbia as well as Kosovo" (gap analysis report).

Serbia

The Serbian Radiation Protection and Nuclear Safety Agency (SRPNA) is the regulatory body for Serbia since July 2010. In terms of staffing, fifteen persons are currently working in the Agency and three more should be appointed by the end of the year. A system of fees to be paid by licensees has been established. However the additional resources to be provided every three or five years will not significantly impact on the operating annual budget of the Agency which is still too low to fulfil all its commitments for the year 2011.

So far the SRPNA has produced twelve regulations that are covering different aspects of radiation protection and nuclear safety. Twelve additional ones are planned to be adopted by December 2011. Their degree of compliance with the EU *acquis* should be checked through the 2008 IPA regional project on regulatory assistance that has started as of 20 March 2011. The goal is to have a regulatory framework in the nuclear field in full compliance with the EU *acquis* ready by the end of 2013.

The 2007 IPA-funded project entitled "Assessment of the Regulatory Infrastructure in the field of Nuclear Safety and Radiation Protection in Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Montenegro, Serbia as well as Kosovo" (gap analysis report) highlighted a quite large number of topics for which external assistance would be required; these are amongst others:

- Development of a national strategy for radioactive waste and decommissioning (high priority);
- Development of regulations on the transport of radioactive material (high priority);

- Regulation on categorisation of sources addressing both safety and security issues, missing (high priority);
- Regulation on monitoring of scrap metal yards (medium priority);
- Preparation of implementing regulations (high priority);
- Definition of responsibilities for inspection (high priority);
- Transposition of the EU directives into the national legislation/regulations (high priority);
- Ratification of the remaining international Conventions and additional Safeguards protocol (medium priority);
- Establishment of the administrative and procedural basis including the development of Quality Management System (high priority);
- Development of necessary documents on conducting of licensing process, annual inspection programme, records template, documentation keeping rules (high priority);
- Training of the SRPNA staff (high priority);
- Establishment of regulation on categorisation of radiation sources (high priority).

Regulatory assistance provided under this project will address all of these topics. As a result of this assistance SRPNA should be in a position to operate in a similar way than its sister organisations in the EU Member States.

Kosovo

A new law on protection against non-ionised, ionised radiation and nuclear security has been promulgated by the Kosovar Parliament in 2009. This law entrusts the Ministry of Environment and Spatial Planning (MESP) to play the role of nuclear regulator, and thereby will formalise the role that this Ministry is playing now. MSEP is currently working on regulatory issues with a very limited number of experts and does not have the technical capacity to transpose the EU *acquis* into their legislation and regulations. However, the MSEP has just appointed the director of the Agency for Protection from Radiations of Kosovo (APRK) that is expected to become fully operational in early 2012..

APRK will therefore be next confronted with the drafting of new pieces of legislation and regulations in line with the EU *acquis*. Although support is expected to be provided through the 2008 IPA regional project already mentioned, the full transposition will require further support. Another important issue is the assessment of the APRK infrastructure which will certainly need improvement. It should be pointed out that regulatory support to APRK on radioactive waste management should start in beginning 2012 as part of the 2009 IPA-funded project that is entitled "Management of sealed radioactive sources, including radioactive lightning rods".

The 2007 IPA-funded project entitled "Assessment of the Regulatory Infrastructure in the field of Nuclear Safety and Radiation Protection in Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Montenegro, Serbia as well as Kosovo" (gap analysis report) identified a number of high priority domains for which external regulatory assistance should be allocated, namely:

- Preparation of the administrative structure for APRK (organisational chart, staffing, job description, internal rules and procedures, etc)
- Development of regulations in full compliance with the EU acquis;
- Providing equipment for the assessment of occupational exposure.

This project intends to provide regulatory assistance in each of these high priority domains.

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

This project will enable the Beneficiaries to have regulatory bodies in the nuclear field capable of better control radiological issues on their territories, i.e. management of institutional radioactive waste, prevention and combat of illicit trafficking of nuclear materials and radiation sources, management of naturally occurring radionuclides in materials (NORM), possible radioactive contamination of the environment, installation of early warning systems and emergency preparedness, and control of medical exposure of patients and workers. It may also impact on the content of the roadmaps for external technical assistance projects that should be implemented within the framework of the nuclear safety and radiation protection action of the IPA regional programme over the period 2013 - 2015. Operation of efficient regulatory bodies in each of the Beneficiaries is a key-issue for radiation safety. This may significantly reduce the risk of cross-border radioactive contamination of the environment most notably by airborne dispersion and shared waterways.

3.3 Results and measurable indicators:

In Albania

Results:

- New procedure for the licensing of nuclear installations in place;
- Guidelines concerning inspection of transport means containing radioactive materials by the Customs, established;
- A Technical Support Organisation to the Radiation Protection Office has been established;
- Response plans in case of radiological emergencies reviewed and updated;
- Breakdown of responsibilities between all actors involved in emergency plans checked and improved;
- Guidance documents for implementing regulations, reviewed and updated;
- Quality Management System of the Radiation Protection Office in place.

Indicators:

- Certification by the EU regulators that the Radiation Protection Office operates in a similar way to its sister EU regulatory bodies;
- Import/Export of goods containing radioactive materials can proceed at the border crossing points;
- Improved regulatory activities of the Radiation Protection Office thanks to the support given by an accredited TSO;
- Emergency plan finalised and emergency exercise tested .

In the former Yugoslav Republic of Macedonia

Results:

- Established complete Quality Assurance programmes, including Quality Control measures and patient dose assessment in the field of diagnostic and interventional radiology (e.g.

- radiography, fluoroscopy, computerised tomography, digital panoramic systems, and mammography whenever applicable) for all the medical establishments;
- Supplied and installed equipment for complete Quality Assurance programme;
 - Operators of the equipment trained;
 - Established written protocols for diagnostic and interventional radiology;
 - All relevant personnel involved in diagnostic and interventional radiology in protocol application trained;
 - Checked and possibly upgraded national regulations for cyclotron radionuclide production and PET/CT;
 - Established licensing and inspection procedures for radionuclide production by a cyclotron and the PET/CT facility;
 - Trained staff for licensing and inspection of cyclotron radionuclide production and PET/CT;
 - Technical specifications for equipment for inspection of the cyclotron and PET/CT facilities determined;
 - Equipment for inspection of the cyclotron and PET/CT facilities, purchased and installed.

Indicators:

- Operation of the Radiation Safety Directorate in line with EU regulatory bodies as certified by EU regulators;
- Existing national requirements for cyclotron radionuclide productions and PET/CT;
- Existing written protocols for licensing and inspection of PET/CT facility and cyclotron radionuclide production;
- PET/CT facility licensed and operational;
- Certificate of attendance in appropriate seminars;
- Equipment installed.

In Serbia

Results:

- National strategy for radioactive waste management and decommissioning of research reactor established;
- Transposition of the EU *acquis* into the national legislation/regulations completed;
- Implementing regulations and guides books in line with the EU *acquis* established;
- SRPNA staff in charge of drafting regulations and guides properly trained;
- Revision of the Law on Ionising Radiation Protection and Nuclear Safety, drafted;
- Specific regulations on the recovery of orphan sources and monitoring of scrap yards, established;
- Regulatory conditions to ratify International conventions, protocols and agreements related to radiation protection and nuclear safety, identified;
- Quality Management System of the regulatory body in place;
- New infrastructure and internal distribution of responsibilities of SRPNA proposed.

Indicators:

- The progress report for accession of Serbia to the EU should highlight the fact that the legislation and regulations in this country are fully in line with the EU *acquis* in the field of radiation protection, radiation safety, nuclear safety and security;
- Decommissioning of the RA research reactor starts as a result of the adoption of a decommissioning plan
- Options for the disposal of radioactive waste are defined.
- New Law on nuclear safety and radiation protection drafted and approved;
- No more orphan sources found in scrap yards;
- International Conventions, protocols and agreements ready for ratification;

- Operation of the SRPNA is in line with EU regulatory bodies as certified by EU regulators.

In Kosovo

Results:

- Structure of the new regulatory body assessed;
- Transposition of the EU *acquis* into the national legislation and regulations completed;
- Implementing regulations and guides books in line with the EU *acquis* established;
- Revision of the Law on protection against non-ionised, ionised radiation and nuclear security, drafted;
- Technical specifications for equipment for inspection determined;
- Equipment for inspection purchased and installed.

Indicators:

- New structure and operating procedure proposed for APRK;
- Full compliance of the Kosovo legislation and regulations with the EU *acquis* in the field of radiation protection and nuclear safety as certified by EU regulators;
- Law on protection against non-ionised, ionised radiation and nuclear security, amended;
- APRK performs inspection thanks to the equipment delivered.

3.4 Activities:

In Albania

- Establishment of a procedure to license the national storage facility for radioactive waste currently managed by the Centre for Applied Nuclear Physics in Tirana;
- Development of procedures for Customs to deal with packages containing radioactive material, including training;
- Definition of the criteria to establish Technical Support Organisations to the Radiation Protection Office as well as their tasks to be assigned to them. This should include the identification of the needs in terms of equipment and technical capacity;
- Definition of the responsibilities of all actors involved in case of radiation emergency and clarification of the decision making process;
- Reviewing of the guidance documents for implementing regulations in line with the EU *acquis* (this activity will complete the one programmed under the 2010 IPA horizontal programme on nuclear safety and radiation protection);
- Establishment of a Quality Management System for the Radiation Protection Office that is in line with the International Atomic Energy Agency/International Organization for Standardization (IAEA/ISO) format or any other appropriate system.

In the former Yugoslav Republic of Macedonia

- Reviewing of the existing QA/QC procedures for diagnostic and interventional radiology (e.g. radiography, fluoroscopy, computerised tomography, digital panoramic systems, and mammography whenever applicable) and establishment of improved QA/QC procedures in line with national legislation, international standards and best EU practices;
- Assessment of the needed equipment to implement improved QA/QC procedures and determination of the related technical specifications;
- Training of the operators of the equipment related to QA/QC procedures;
- Based on the improved QA/QC procedures, establishment of optimized protocols for diagnostic and interventional radiology;
- Training of the personnel involved in diagnostic and interventional radiology in protocol application;
- Assistance to RSD to check existing regulations for operating a cyclotron for radionuclide

- production and the PET-CT facility;
- Assistance to RSD in the establishment of the licensing and inspection procedures connected to the cyclotron and PET-CT facility;
- Training of the RSD inspectors in charge of checking both the cyclotron for radionuclide production and the PET-CT facility;
- Determination of the technical specifications for the equipment needed for inspection activities of both the cyclotron for radionuclide production and the PET-CT facility;
- Supply of the relevant equipment for both the implementation of QA/QC procedures and the inspection of the cyclotron and PET-CT facilities.

In Serbia

For drawing-up a national strategy for radioactive waste management and decommissioning of research reactor

- Establishment of radioactive waste categories based on their radioactivity level;
- Establishment of clearance and exemption levels for radioactive waste;
- Identification of options for the decommissioning of the RA nuclear research reactor, including the possible re-use of the building to accommodate a new reactor or cyclotron and the green-field option;
- Identification of the arisings of radioactive waste for each main decommissioning option and other radioactive waste coming from other generators in Serbia;
- Identification of management routes for radioactive graphite resulting from decommissioning options;
- Identification of potential treatment and conditioning processes for each radioactive waste type generated or to be generated in the future as a result of the decommissioning options and other radioactive waste coming from other generators in Serbia;
- Definition of an action plan related to the siting, licensing, construction and operation of a disposal facility for radioactive waste according the law in force, including variants whenever there are uncertainties;
- Identification of the different possible design options for the disposal facility;
- Development of a methodology (multi-attribute analysis) in order to assess each management route thus identified in terms of cost, occupational exposure, easiness of implementation, needs for training, licensing and public acceptance;
- Identification of optimised strategies for radioactive waste management and decommissioning;
- Establishment of a mechanism to finance the adopted strategy for radioactive waste management;
- Identification of the actors, and the interactions between them, who will be involved in the implementation of the radioactive waste management strategy (ministries, private companies, public organisations);
- Development of a public information programme.

For the completion of the transposition of the EU acquis into the Serbian legislation and regulations

- Assistance in analysing the current Law on Ionising Radiation Protection and Nuclear Safety for possible improvement;
- Assistance in completing the reviewing activities of all current regulations (which have started under the 2008 IPA-funded regional project on regulatory assistance) and in drafting new ones in order to have a regulatory framework fully in line with the EU *acquis*;
- Assistance in establishing guide books and implementing regulations;

- Assistance in establishing specific regulations for the recovery of orphan sources and the monitoring of scrap yards;
- Setting-up of a training programme for the SRPNA personnel not yet fully familiar with the drafting of regulations and implementing regulations;
- Identification of the regulatory provisions that should be established in order to facilitate the ratification of International Conventions, protocols and agreements on radiation protection and nuclear safety.
- Assistance in the definition and drafting of enforcement procedure;
- Assistance in the development of required protocols for issuing licenses for transportation of sealed sources and radioactive waste, for authorizing exempted material from regulatory control, for the clearance of suspected radioactive waste.

For regulatory organisation, infrastructure and functioning

- Establishment of a Quality Management System for the SRPNA that is in line with the IAEA/ISO format or any other appropriate system;
- Definition of an organisational chart including the distribution of responsibilities;
- Definition of the annual inspection programme to be implemented by the SRPNA;
- Establishment of procedures for inspection records;
- Definition of the documentation keeping rules.

In Kosovo

- Critical analysis of the current infrastructure of the Agency for Protection from Radiation of Kosovo in terms of mandate, staffing, operating budget, level of expertise, independence from users of radionuclides, relationship with other actors involved in medical and/or industrial applications of radionuclides in Kosovo.
- Assistance in completing the reviewing activities of all current regulations (which have started under the 2008 IPA-funded regional project on regulatory assistance) and in drafting new ones in order to have a regulatory framework fully in line with the EU acquis;
- Assistance in establishing guide books and implementing regulations;
- Assistance in analysing the current Law on protection against non-ionised, ionised radiation and nuclear security for possible improvement and revision;
- Determination of the technical specifications for the equipment needed for inspection activities.
- Supply of the relevant equipment for inspection activities of the new regulatory body.

3.5 Conditionality:

Kosovo must have an operating regulatory body in the nuclear area at the time of the launching of the tendering procedure for contracting.

3.6 Linked activities:

Already for several years, the IAEA has been supporting the establishment and development of nuclear regulatory bodies in the Western Balkans. However the most important project being implemented by the IAEA is the 2008 IPA-funded project - abovementioned in section 3.1 - that is dealing with the "Enhancement of the technical capacity of nuclear regulatory bodies in Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Montenegro, Serbia as well as Kosovo". Amongst the running IAEA national and regional projects, it is worth mentioning:

- The upgrading of radiotherapy facilities and introducing new radiotherapy techniques in the former Yugoslav Republic of Macedonia (MAK 6010);

- Introducing Positron Emission Tomography (PET) in clinical practice in the former Yugoslav Republic of Macedonia (MAK 6011);
- Strengthening national capabilities for radiological protection of workers and occupational exposure in the region (RER2007012);
- Strengthening safety assessment capabilities in the region (RER2007007);
- Effectiveness of regulatory authorities and advanced training in nuclear safety in the region (RER2007040).

In addition there are a number of IAEA projects that are already planned for support in 2012/2013 and that are related to this regulatory assistance project, e.g.

- Support for the safe implementation of advanced techniques in radiotherapy and nuclear medicine (ALB 2010005)
- Establishment of nuclear medicine in the Eastern part of the former Yugoslav Republic of Macedonia (MAK 2010001);

3.7 Lessons learned

From past IPA-funded projects on regulatory assistance that were implemented over the period 2008 - 2011, the main lesson to be drawn is that absorption capacity of the regulatory bodies may be critical in Kosovo. In the other concerned Beneficiaries, all the regulatory bodies have been recently staffed and their internal structure seems capable of absorbing further technical assistance.

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		2 100 000	2 100 000	100	-	-	-	-	-	-	-
Contract 1 – Service contract (Technical Assistance)	x		2 100 000	2 100 000	100	-	-	-	-	-	-	-
Activity 2		x	200 000	200 000	100	-	-	-	-	-	-	-
Contract 2 – Supply contract (Equipment)		x	200 000	200 000	100	-	-	-	-	-	-	-
TOTAL IB			2 100 000	2 100 000	100	-	-	-	-	-	-	-
TOTAL INV			200 000	200 000	100	-	-	-	-	-	-	-
TOTAL PROJECT			2 300 000	2 300 000	100	-	-	-	-	-	-	-

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	Contract signature	Project Completion
Contract 1 - Service	2Q 2013	4Q 2013	4Q 2015
Contract 2 - Supply	4Q 2013	1Q 2014	4Q 2014

6. Cross cutting issues

6.1 Equal Opportunity

The project will benefit both women and men through improvements in environmental protection and safety. 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

There are substantial environmental gains to the Beneficiaries by accomplishment of this project since a better control of the use of radionuclides may have a favourable impact on the protection of the environment.

6.3 Minorities

On all activities, minorities will have equal opportunities to compete for contracts and to work on any related activities.

ANNEXES

- I- Log frame in Standard Format
- II- Amounts contracted and disbursed per quarter over the full duration of the project
- III- Description of Institutional Framework
- IV - Related laws, regulations and strategic documents
- V- Details per EU funded contract

ANNEX I: Logical framework matrix in standard format

LOGFRAME PLANNING MATRIX FOR Project Fiche	Programme name and number –	2011 IPA Horizontal Programme on Nuclear Safety and Radiation Protection (2011/023-384)
Further enhancement of the technical capacity of nuclear regulatory bodies in Albania, the former Yugoslav Republic of Macedonia, Serbia, as well as Kosovo .	Contracting period expires – 3 years following the date of the conclusion of the financing agreements	Disbursement period expires – 1 year following the end date for execution of contracts
	Total budget EUR 2 300 000	IPA budget: EUR 2 300 000

Overall objective	Objectively verifiable indicators	Sources of Verification	
To contribute to improve radiation protection, nuclear safety and security in Albania, the former Yugoslav Republic of Macedonia, Serbia, as well as Kosovo through the reinforcement of the technical capacity of their nuclear regulatory agencies.	Demonstrated improvement in beneficiaries in establishing nuclear and radiation safety legislation and regulations and implementing those regulations through a regulatory body that demonstrates competence through licensee oversight, inspection and enforcement.	New or revised regulations; international conventions signed; final project report for each participating country identifying the achievements.	
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
To further contribute to the transposition of the acquis in the field of nuclear safety and radiation protection, and to align the functioning of nuclear regulatory agencies in Albania, the former Yugoslav Republic of Macedonia, Serbia, as well as Kosovo with their sister organisations in the EU.	Successful transposition of technical capacity as demonstrated through new or improved regulations which incorporate international standards and Euratom Council Directives, as well as international conventions to which the European Union is a signatory.	New or revised regulations; international conventions signed; final project report for each participating country identifying the achievements.	Initiation of any activity in Kosovo is dependent on meeting the precondition of having a regulatory body in place in the nuclear area.
Results	Objectively verifiable indicators	Sources of Verification	Assumptions
<p><i>In Albania</i></p> <ul style="list-style-type: none"> • New procedure for the licensing of nuclear installations in place; • Guidelines concerning inspection of transport means containing radioactive materials by the Customs, established; • • A Technical Support Organisation to the Radiation Protection Office has been established; • Response plans in case of radiological emergencies reviewed and updated; • Breakdown of responsibilities between all actors involved in emergency plans checked and improved; • Guidance documents for implementing regulations, reviewed and updated; • Quality Management System of the Radiation Protection Office in place. <p><i>In the former Yugoslav Republic of Macedonia</i></p> <ul style="list-style-type: none"> • Established complete Quality Assurance programmes, including Quality Control measures and patient dose assessment in the field of diagnostic and interventional radiology (e.g. radiography, fluoroscopy , computerised tomography, digital panoramic systems, and mammography whenever applicable) for all the medical establishments; • Supplied and installed equipment for complete Quality Assurance programme; • Operators of the equipment trained; • Established written protocols for diagnostic and interventional radiology; • All relevant personnel involved in diagnostic and 	<p>Operation of the Radiation Protection Office is in line with EU regulatory bodies</p> <p>Operation of the Radiation Safety Directorate in line with EU regulatory bodies</p>	A final project report to which at least one EU nuclear regulator has contributed	

<p>interventional radiology in protocol application trained;</p> <ul style="list-style-type: none"> • Checked and possibly upgraded national regulations for cyclotron radionuclide production and PET/CT; • Established licensing and inspection procedures for radionuclide production by a cyclotron and the PET/CT facility; • Trained staff for licensing and inspection of cyclotron radionuclide production and PET/CT; • Technical specifications for equipment for inspection of the cyclotron and PET/CT facilities determined; • Equipment for inspection of the cyclotron and PET/CT facilities, purchased and installed. <p><i>In Serbia</i></p> <ul style="list-style-type: none"> • National strategy for radioactive waste management and research reactor established; • Transposition of the EU acquis into the national legislation/regulations completed; • Implementing regulations and guides books in line with the EU acquis established; • SRPNA staff for drafting regulations and guides properly trained; • Revision of the Law on Ionising Radiation Protection and Nuclear Safety, drafted; • Specific regulations on the recovery of orphan sources and monitoring of scrap yards, established; • Regulatory conditions to ratify International conventions protocols and agreements related to radiation protection and nuclear safety, identified; • Quality Management System of the regulatory body in place; • New infrastructure and internal distribution of responsibilities of SRPNA proposed. <p><i>In Kosovo</i></p> <ul style="list-style-type: none"> • Structure of the new regulatory body assessed; • Transposition of the EU acquis into the national legislation and regulations completed. • Implementing regulations and guides books in line with the EU acquis established; • Revision of the Law on protection against non-ionised, ionised radiation and nuclear security , drafted; • Technical specifications for equipment for inspection determined; • Equipment for inspection purchased and installed. 	<p>Established national requirements for cyclotron radionuclide productions and PET/CT; Established written protocols for licensing and inspection of PET/CT facility and cyclotron radionuclide production;</p> <p>Certificate of attendance in appropriate seminars</p> <p>Call for tenders launched</p> <p>Full compliance of the legislation and regulations with the EU acquis in the field of radiation protection and nuclear safety</p> <p>New Law on nuclear safety and radiation protection drafted and approved</p> <p>No more orphan sources found in scrap yards</p> <p>International Conventions, protocols and agreements ready for ratification</p> <p>Operation of the SRPNA in line with EU regulatory bodies</p> <p>New structure and operating procedure proposed</p> <p>Full compliance of the Kosovo legislation and regulations with the EU acquis in the field of radiation protection and nuclear safety</p> <p>Call for tenders launched</p>	<p>Monitoring equipment can be visualised and checked upon request</p> <p>Monitoring equipment can be visualised and checked upon request</p>	<p>Kosovo has a regulatory body in the nuclear area already established by law at the time of the launching of the tendering procedure for contracting. All the other regulatory bodies have enough staff to absorb all technical assistance activities</p>
Activities	Means	Costs	Assumptions
For Albania			
<ul style="list-style-type: none"> • Establishment of a procedure to license the national storage facility for radioactive waste currently managed by the Centre for Applied Nuclear Physics in Tirana; • Development of procedures for Customs to deal with packages containing radioactive material, including training; • Definition of the criteria to establish Technical Support Organisations to the Radiation Protection Office as well as their tasks to be assigned to them. This should include the identification of the needs in terms of equipment and technical capacity; • Definition of the responsibilities of all actors involved in 	<p>Part of the overall technical assistance contract</p>	<p>EUR 250 000</p>	

<ul style="list-style-type: none"> case of radiation emergency and clarification of the decision making process; Reviewing of the guidance documents for implementing regulations in line with the EU <i>acquis</i> (this activity will complete the one programmed under the 2010 IPA horizontal programme on nuclear safety and radiation protection); Establishment of a Quality Management System for the Radiation Protection Office that is in line with the IAEA/ISO format or any other appropriate system. 			
For the former Yugoslav Republic of Macedonia			
<ul style="list-style-type: none"> Reviewing of the existing QA/QC procedures for diagnostic and interventional radiology (e.g. radiography, fluoroscopy, computerised tomography, digital panoramic systems, and mammography whenever applicable) and establishment of improved QA/QC procedures in line with national legislation, international standards and best EU practices; Assessment of the needed equipment to implement improved QA/QC procedures and determination of the related technical specifications; Training of the operators of the equipment related to QA/QC procedures; Based on the improved QA/QC procedures, establishment of optimized protocols for diagnostic and interventional radiology; Training of the personnel involved in diagnostic and interventional radiology in protocol application; Assistance to RSD to develop new regulations for operating a cyclotron for radionuclide production and the PET-CT facility; Assistance to RSD in the establishment of the licensing and inspection procedures connected to the cyclotron and PET-CT facility; Training of the RSD inspectors in charge of checking both the cyclotron for radionuclide production and the PET-CT facility; Determination of the technical specifications for the equipment needed for inspection activities of both the cyclotron for radionuclide production and the PET-CT facility; Supply of the relevant equipment for both the implementation of QA/QC procedures and the inspection of the cyclotron and PET-CT facilities; 	Part of the overall technical assistance contract	EUR 350 000	
	Part of the overall supply contract	EUR 150 000	
For Serbia			
<p><u><i>For drawing-up a national strategy for radioactive waste management and decommissioning of research reactor</i></u></p> <ul style="list-style-type: none"> Establishment of radioactive waste categories based on their radioactivity level; Establishment of clearance and exemption levels for radioactive waste; Identification of options for the decommissioning of the RA nuclear research reactor, including the possible re-use of the building to accommodate a new reactor or cyclotron and the green-field option; Identification of the arisings of radioactive waste for each main decommissioning option and other radioactive waste coming from other generators in Serbia; Identification of management routes for radioactive graphite resulting from decommissioning options; Identification of potential treatment and conditioning processes for each radioactive waste type generated or to be generated in the future as a result of the decommissioning options and other radioactive waste 	Part of the overall technical assistance contract	EUR 800 000	

<p>coming from other generators in Serbia;</p> <ul style="list-style-type: none"> • Definition of an action plan related to the siting, licensing, construction and operation of a disposal facility for radioactive waste according the law in force, including variants whenever there are uncertainties; • Identification of the different possible design options for the disposal facility; • Development of a methodology (multi-attribute analysis) in order to assess each management route thus identified in terms of cost, occupational exposure, easiness of implementation, needs for training, licensing and public acceptance. • Identification of optimised strategies for radioactive waste management; • Establishment of a mechanism to finance the adopted strategy for radioactive waste management; • Identification of the actors, and the interactions between them, who will be involved in the implementation of the radioactive waste management strategy (ministries, private companies, public organisations); • Development of a public information programme. 			
<p><i>For the completion of the transposition of the EU acquis into the Serbian legislation and regulations</i></p>			
<ul style="list-style-type: none"> • Assistance in analysing the current Law on Ionising Radiation Protection and Nuclear Safety for possible improvement; • Assistance in completing the reviewing activities of all current regulations (which have started under the 2008 IPA-funded regional project on regulatory assistance) and in drafting new ones in order to have a regulatory framework fully in line with the EU <i>acquis</i>; • Assistance in establishing guide books and implementing regulations; • Assistance in establishing specific regulations for the recovery of orphan sources and the monitoring of scrap yards; • Setting-up of a training programme for the SRPNA personnel not yet fully familiar with the drafting of regulations and implementing regulations; • Identification of the regulatory provisions that should be established in order to facilitate the ratification of International Conventions, protocols and agreements on radiation protection and nuclear safety; • Assistance in the definition and drafting of enforcement procedure; • Assistance in the development of required protocols for issuing licenses for transportation of sealed sources and radioactive waste, for authorizing exempted material from regulatory control, for the clearance of suspected radioactive waste. 	<p>Part of the overall technical assistance contract</p>	<p>EUR 250 000</p>	
<p><i>For regulatory organisation, infrastructure and functioning</i></p>			
<ul style="list-style-type: none"> • Establishment of a Quality Management System for the SRPNA that is in line with the IAEA/ISO format or any other appropriate system. • Definition of an organisational chart including the distribution of responsibilities; • Definition of the annual inspection programme to be implemented by the SRPNA; • Establishment of procedures for inspection records; • Definition of the documentation keeping rules. 	<p>Part of the overall technical assistance contract</p>	<p>EUR 250 000</p>	

For Kosovo			
<ul style="list-style-type: none"> • Critical analysis of the current infrastructure of the Agency for Protection from Radiation of Kosovo in terms of mandate, staffing, operating budget, level of expertise, independence from users of radionuclides, relationship with other actors involved in medical and/or industrial applications of radionuclides in Kosovo. • Assistance in completing the reviewing activities of all current regulations (which have started under the 2008 IPA-funded regional project on regulatory assistance) and in drafting new ones in order to have a regulatory framework fully in line with the EU acquis; • Assistance in establishing guide books and implementing regulations; • Assistance in analysing the current Law on protection against non-ionised, ionised radiation and nuclear security for possible improvement and revision; • Determination of the technical specifications for the equipment needed for inspection activities. • Supply of the relevant equipment for inspection activities of the new regulatory body. 	Part of the overall technical assistance contract	EUR 200 000	
	Part of the overall supply contract	EUR 50 000	

The activities to be performed may be modified according to the results of the 2008 IPA regional project on the enhancement of the technical capacity of the regulatory bodies of the Western Balkans that has started in March 2011.

ANNEX II: Amounts (in EUR) contracted and disbursed by quarter for the project

Contracted	Q4 2013	Q1 2014	Q2 2014	Q3 2014	Q4 2014	Q1 2015	Q2 2015	Q3 2015	Q4 2015
Contract 1 - Service (Technical assistance)	2 100 000								
Contract 2 - Supply		200 000							
Cumulated	2 300 000	2 300 000	2 300 000	2 300 000	2 300 000	2 300 000	2 300 000	2 300 000	2 300 000
Disbursed	Q4 2013	Q1 2014	Q2 2014	Q3 2014	Q4 2014	Q1 2015	Q2 2015	Q3 2015	Q4 2015
Contract 1 - Service (Technical assistance)	1 260 000				420 000				420 000
Contract 2 - Supply		120 000			80 000				
Cumulated	1 260 000	1 380 000	1 380 000	1 380 000	1 880 000	1 880 000	1 880 000	1 880 000	2 300 000

ANNEX III: Description of Institutional Framework

See section 3.1 (background and justification)

ANNEX IV: Related laws, regulations and strategic documents

- Nuclear Safety and Radiation Protection action of the Multi-Beneficiary Multi Annual Indicative Planning Document (MIPD), 2009-2011, and 2011-2013;
- 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** amended on 28 July 2008;
- The Law on Protection against Ionizing Radiation and Radiation Safety (2002 and amended 2007 and 2011) in the **former Yugoslav Republic of Macedonia**;
- The **Serbian** new Law on ionising radiation protection and on nuclear safety (2009).
- The Law on Protection against Non-Ionised, Ionised Radiation and Nuclear Security in **Kosovo** that was promulgated in 2010.

ANNEX V: Details per EU funded contract

This project will be implemented through one technical assistance contract (maximum EUR 2.1 million and one supply contract (maximum EUR 0.2 million), following call for tenders that will be launched in the second quarter of 2013 and in the fourth quarter of 2013, respectively.

Contracting will be performed according to the practical guide to contract procedures for EU external actions.

Considering the specific objectives of the project and the specificity of the service to be provided, participation in the related tendering procedure - that is dealing with the regulatory assistance part of the project - is only open to Nuclear Regulatory bodies of EU Member-States participating either individually or in a grouping (consortium).