#### **COMMISSION DECISION**

#### C(2007)5493 of 16/11/2007

adopting part II of the horizontal programme on Nuclear Safety and Radiation Protection under the IPA -Transition Assistance and Institution Building Component for 2007,

THE COMMISSION OF THE EUROPEAN COMMUNITIES.

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1085/2006 of 17 July 2006 establishing an Instrument for Pre-Accession Assistance (IPA)<sup>1</sup>, and in particular Article 14(2)(a) thereof,

#### Whereas:

- (1) Regulation (EC) No 1085/2006 lays down the objectives and main principles for pre-accession assistance to candidate and potential candidate countries.
- (2) In accordance with Article 7 of Regulation (EC) No 1085/2006, the assistance should be provided through multi-annual or annual programmes, which can be established by country and by component, or, as appropriate, by group of countries or by theme. These programmes should be drawn up in accordance with the general policy framework referred to in Article 4 of Regulation (EC) No 1085/2006 and the relevant multi-annual indicative planning document referred to in Article 6 of that Regulation.
- (3) The Council established for all candidate and potential candidate countries an Accession Partnership or a European Partnership. The Commission has adopted on 29 May 2007 a multi-annual indicative planning document 2007/2009 which presents indicative allocations for the main priorities for pre-accession assistance to all countries concerned<sup>2</sup> and which comprises a programme on "Nuclear Safety and Radiation Protection".
- (4) Part II of the programme "Nuclear Safety and Radiation Protection" under the IPA Transition Assistance and Institution Building Component for 2007 ultimately aims at providing assistance for supporting nuclear regulatory bodies, improving current management schemes for sealed radioactive sources, medical radioactive waste, and naturally occurring radioactive materials, for the prevention of illicit trafficking of nuclear materials and radiation sources, and for a better monitoring of the radioactivity into the environment.
- (5) This decision meets the requirements of Article 90 of Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation No 1605/2002<sup>3</sup> (hereafter: "Implementing Rules")

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OJ L 210, 31.7.2006, p. 82.

C(2007)2205.

OJ L 357, 31.12.2002, p. 1 Regulation as last amended by Regulation (EC, Euratom) No 478/2007 (OJ L III, 28.04.2007, p. 13).

and constitutes thus a financing decision within the meaning of Article 75 of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities<sup>4</sup> (hereafter: "Financial Regulation");

(6) The measures provided for by this Decision are in accordance with the opinion of the IPA Committee,

#### HAS DECIDED AS FOLLOWS:

#### Article 1

Part II of the horizontal programme on Nuclear Safety and Radiation Protection under the IPA Transition Assistance and Institution Building Component for 2007, as set out in the Annex, is hereby adopted.

#### Article 2

The maximum amount of Community contribution shall be **EUR 2.56 million**, to be financed through Item 22.02.07.01 – regional and horizontal programmes of the General Budget of the European Communities for 2007.

Done at Brussels, [...]

For the Commission

*[...1* 

Member of the Commission

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OJ L 248, 16.9.2002, p.1. Regulation as amended by Regulation (EC, Euratom) No 1995/2006 (OJ L 390, 30.12.2006, p.1).

# ANNEX: PART II OF THE HORIZONTAL PROGRAMME ON NUCLEAR SAFETY AND RADIATION PROTECTION

#### 1. IDENTIFICATION

Beneficiaries	Albania, Bosnia and Herzegovina, Croatia, the former					
	Yugoslav Republic of Macedonia, Montenegro, and Serbia					
	including Kosovo (as defined by UNSCR 1244) <sup>1</sup>					
CRIS number	2007/019-301					
Year	2007					
Cost	€2.56 million					
Implementing Authority	The European Commission on behalf of the Beneficiary					
	countries <sup>2</sup> and the International Atomic Energy Agency					
	(IAEA) under Joint Management with the European					
	Commission.					
Final dates for contracting	30/11/2008					
Final dates for execution	30/11/2010					
Sector Code	23064					
Budget lines	22.02.07.01 – Regional and horizontal programmes					
Programming Task Manager	Unit D3 - Regional Programmes DG ELARG					
Implementation Task Manager	Unit D3 - Regional Programmes DG ELARG					

#### 2. PRIORITY AXES/ (MEASURES) / PROJECTS

## 2.a Priority axes

In the field of nuclear safety and radiation protection, the Multi-Beneficiary Multi-annual Indicative Planning Document (MIPD) addresses both regional and horizontal issues. Section 2.2.9 of the MIPD clearly mentions that:

- (1) 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;
- (2) these countries have the common feature of being vulnerable to illicit trafficking of nuclear materials and radiation sources;
- (3) the monitoring of radioactivity in the environment constitutes a significant radiological issue;
- (4) the national safety authorities in place that ought to be regulating nuclear safety and radiation protection are in most cases rather weak in terms of both personnel and level of expertise:
- (5) support can be provided through <u>multi beneficiary projects</u>;

In this context, this Financing proposal focuses on a set of six regional projects that are covering the MIPD priorities i.e.

- Assessment of the regulatory infrastructure in the field of nuclear safety and radiation protection;
- Assessment of needs and proposed actions to strengthen the safety and security of sealed radioactive sources;

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Hereafter referred to as Kosovo

<sup>&</sup>lt;sup>2</sup> "Beneficiary countries" includes Kosovo in the whole document

- Assistance to enhance the beneficiaries capabilities to developing regulations on Naturally Occurring Radioactive Materials (NORM) and Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM);
- Management of medical radioactive waste;
- Assessment of needs and proposed activities to strengthen capabilities for combating illicit trafficking in nuclear and other radioactive materials;
- Assessment of the needs and proposed actions in order to perform the monitoring of the radioactivity into the environment.

# 2. b Description of projects grouped per priority axis

#### General context

It is important to underline that most of the Western Balkan countries have not yet established any national strategy on nuclear and radiological issues. Therefore for most of them there is no action plan yet determined in order to align their legislation and regulations in this particular domain to the Community acquis and to implement management practices that are in line with the best EU practices, international instruments, standards and recommendations. For this reason it was deemed worthwhile to precede any significant IPA technical assistance and investment support with regional exploratory studies aiming to define in more detail possible needs.

These regional projects have been defined on the basis of several programming missions organised in the beneficiary countries, on discussions with a number of responsible persons in charge of nuclear activities in these countries, and on exchange of information with the International Atomic Energy Agency (IAEA). The main outcome of all these studies will be the identification of possible projects that would be worth being supported by the IPA programme during the next years.

The programme will be closely coordinated with the IAEA since several projects are extending and developing activities already funded by this agency. For two projects, it is even proposed to implement them in joint management with the IAEA.

The implementation of regional projects is justified on account of the economies of scale to be attained. Most Western Balkan countries are resulting from the splitting of the former Yugoslav republic and thereby have the same legislative background in the nuclear area. In addition, with the exception of Serbia, most radiological issues existing in the Western Balkan countries are very similar.

The programme will also be coordinated with the other financing instruments that are addressing nuclear issues (i.e. the Instrument for Nuclear Safety Cooperation and the Stability Instrument).

### Description of the projects

<u>Project no 1</u>: "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, and Serbia including Kosovo" comprises the following activities:

- Description and analysis of the current legislative background that is underpinning the establishment of regulatory bodies in each of the six beneficiary countries;
- Description and analysis of the current mandate, organisation, structure, quality management system, staffing, technical capacity, inspection procedures, and funding mechanism of the regulatory bodies in place in each of the beneficiary countries;

- Analysis of the adequation of the current structure, organisation and technical capacity of the regulatory bodies against the radiological issues posed in the country and the transposition of the EURATOM Directives;
  - Identification of the areas where enhancement of the capacity of the regulatory bodies would be desirable

A service contract for an amount of  $\bigcirc 00.000$  will be concluded following a tender that will be launched in Q1 2008.

<u>Project no 2:</u> "Assessment of needs and proposed actions to strengthen the safety and security of sealed radioactive sources in Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Montenegro, and Serbia including Kosovo" is structured in the following way:

- Analysis of the currently available documentation on the safety and security aspects of the regulatory control and the management of sealed radioactive sources in the six IPA eligible countries possibly supported by some expert missions on the spot;
- Analysis of the regulatory framework in force in the six IPA eligible countries with emphasis on progress made in the recent years;
- Analysis of the current management practices of sealed radioactive sources in each of the beneficiary countries;
- Preparation of possible future technical assistance and investment projects.

Taking into account the important documentation already accumulated by the IAEA on that specific issue within the framework of the EU/IAEA Joint Action, it was deemed appropriate to implement the project in joint management with the IAEA.

Therefore, a contribution agreement for an amount of €260,000 will be concluded with the IAEA in Q4 2007 for the implementation of this project in accordance with the terms of the Financial and Administrative Framework Agreement (FAFA) between the European Community and the United Nations, signed on 29 April 2003, to which the IAEA has adhered on 17 September 2004.

<u>Project no 3</u>:" Assistance to Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Montenegro, and Serbia including Kosovo to enhance their capabilities to developing regulations on Naturally Occurring Radioactive Materials (NORM) and Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM) to enhance their capabilities to developing regulations on Naturally Occurring Radioactive Materials (NORM) and Technologically Enhanced Naturally Occurring Radioactive Materials (TENORM)" should be implemented through the following activities:

- Establishment of a methodology for the acquisition of coherent and comparable data on management of NORM and TENORM in the beneficiary countries;
- Data collection and analysis;
- Identification of main regulatory differences and management practices between these countries;
- Comparison with regulations and management practices in several EU Member States;
- Preparation and practical organisation of a <u>technical seminar</u> where recommendations should be proposed.

A service contract for an amount of €00.000 will be concluded following a tender that will be launched in Q4 2007.

<u>Project no 4</u>:" Management of medical radioactive waste in Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro, and Serbia including Kosovo" is actually an extension to the other candidate and potential candidate countries of the Phare funded study that was concluded in June 2007 and which focussed on the situation existing in Bulgaria, Croatia and Romania. The project comprises the following tasks:

- Establishment of a methodology for the acquisition of coherent and comparable data on management of radioactive waste in medical establishments in the beneficiary countries;
- Data collection and analysis;
- Identification of main regulatory differences and management practices between these countries:
- Preparation and practical organisation of a <u>technical seminar</u>.

The total duration of the project is estimated to 12 months.

A service contract for an amount of €50.000 will be concluded following a tender that will be launched in Q1 2008.

<u>Project no 5</u>: "Assessment of needs and proposed activities to strengthen capabilities for combating illicit trafficking in nuclear and other radioactive materials in Albania, Bosnia & Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro and Serbia including Kosovo" is subdivided in five tasks:

- Analysis of the current legislative and regulatory framework in force in each of the seven beneficiary countries that is covering illicit trafficking in nuclear and other radioactive materials, including planned legislation for the near future;
- Analysis of the status (in operation, under repair, worn out) of the detection devices that have been installed to protect the border crossing points (airports, harbours, railway stations and roads) for the detection of possible illicit trafficking in nuclear and other radioactive materials:
- Analysis of technical specifications and characteristics of the different detection devices that are currently in place;
- Analysis of the possible needs of the beneficiary countries in terms of transportable and mobile monitors;
- Preparation of possible future technical assistance and investment projects including determination of the technical performance of the radiation control systems to be possibly installed and/or maintained in good operation in the six countries and the corresponding cost.

Taking into account the important documentation already accumulated by the IAEA on that specific issue within the framework of the EU/IAEA Joint Action, and the confidential character of the information, implementation of the project should be carried out in joint management with the IAEA.

Therefore, a contribution agreement for an amount of €250.000 will be concluded in Q4 2007 with the IAEA for the implementation of this project in accordance with the terms of the Financial and Administrative Framework Agreement (FAFA) between the European Community and the United Nations, signed on 29 April 2003, to which the IAEA has adhered on 17 September 2004.

<u>Project no 6</u>:"Assessment of the needs and proposed actions in order to perform the monitoring of the radioactivity into the environment in Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Montenegro, and Serbia including Kosovo" aims at investigating four main topics:

- Analysis of the regulatory framework in force in the beneficiary countries;
- Analysis of the current national monitoring and sampling programmes in each of the beneficiary countries;
- Assessment of the equipment of the laboratories involved in the monitoring programmes, procedures for sampling and measurements, implementation of possible on- or off-line automatic monitoring systems;
- Preparation of possible future technical assistance and investment projects.

A service contract for an amount of  $\le 300.000$  will be concluded following a tender that will be launched in Q4 2007.

# 2. c Overview of past and on going assistance including lesson learned and donor coordination

Assistance to nuclear regulatory bodies was the subject of many Phare-funded projects over the period 2001-2006. This assistance was dealing with the enhancement of the capacity of the regulatory bodies in a large variety of domains. It was given taking into consideration advices from the regulatory bodies of EU Member States via the Regulatory Authority Management Group (RAMG). This support was highly appreciated by the beneficiary countries and gave rise to presentations in international conferences<sup>3</sup>. The only problem that was encountered is related to the so-called "new rules for contracts in the field of nuclear safety" that were adopted by the Commission in September 2000 and that opened the possibility of concluding direct treaties with the technical support organisations in charge of regulatory matters in EU Member States. Since 2004, such practices have in fact disappeared and since then technical support organisations from EU Member States involved in regulatory assistance are selected on the basis of open tendering. It is worth mentioning that assistance to regulatory bodies proved to be the most effective whenever it is provided together with a strong involvement of the beneficiary organisations in the work to be performed. The IAEA is supporting some projects in this specific area, therefore a coordination mechanism should be established to develop synergies between both international programmes.

In the field of management of sealed radioactive sources, the general approach consisting of carrying out a regional exploratory study before supporting national projects was the one that was successfully followed for the Central Europe and Eastern Countries over the period 1999-2006. Actually most of the Phare projects dealing with regulatory aspects or improvement of management practices for sealed radioactive sources resulted from the recommendations of the regional exploratory study. However taking into account the important activities conducted by the IAEA in a recent past within the framework of the EU/IAEA Joint Action in the Western Balkan Countries<sup>4</sup>, it is considered worthwhile to conclude a contribution agreement with this organisation. Otherwise, there is an important risk of duplication of the work carried by the IAEA that was at least partly funded by the EU.

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Eurosafe conference, Paris, 2003

Council Joint Action 2004/495/CFSP of 17 May 2004 on support for IAEA activities under its Nuclear Security Programme and in the framework of the implementation of the EU Strategy against Proliferation of WMD

Management of medical radioactive waste generated in hospitals (Bulgaria, Croatia and Romania) has recently been the subject of a technical seminar organised by the Commission services. This notably revealed that in a number of medical establishments, even in some rather old EU Member States, there is no demonstrated compliance of the discharges of radioactive effluents into the environment with the national regulations. This situation would result from a lack of funding and technical expertise in the hospitals operating nuclear medicine services. It is very likely that the situation is similar in the six beneficiary countries concerned by the related project. An important recommendation of this project might be the delivery of appropriate measuring equipment and organisation of training courses in the most important hospitals of the beneficiary countries.

Prevention of illicit trafficking of nuclear materials has recently been the subject of technical assistance and investment projects in Bulgaria, Romania, and Croatia as well as in the former Yugoslav Republic of Macedonia a few years ago via the Phare programmes. The main lesson is that determination of the right technical specifications of the equipment to be purchased (e.g. stationary portal monitors) is of paramount importance for the success of the project. Another lesson is that a close coordination between all the national services that will use this equipment (police, customs, and regulatory body) is required. At the Commission level, coordination should also be established with the other financing instruments and programmes conducted by DG RELEX, DG AIDCO, and the JRC-(e.g. TACIS and INSC) that are supporting prevention and combat against illicit trafficking of nuclear materials and radiation sources in other countries. Due to the confidential character the information collected by the IAEA on that specific issue in the Western Balkan Countries within the framework of the EU/IAEA Joint Action abovementioned, it was deemed worthwhile to entrust the IAEA with the implementation of the project.

Management of naturally occurring radioactive materials and technologically enhanced naturally occurring radioactive materials is becoming a more and more important radiological issue. Phare projects are just starting on that specific domain in Romania and Bulgaria. Taking into account the existence of projects supported by the IAEA, coordination with this organisation appears necessary. Involvement of DG TREN - that is preparing recommendations on the management of such radioactive waste type - is highly desirable.

Finally monitoring of the radioactivity in the environment is a rather new subject for EU external technical assistance in candidate countries to EU accession. During the last period only one Phare -funded project was supported in this particular domain in Lithuania. This project mainly consisted of equipping a laboratory for environmental monitoring. As for all supply projects, determination of the right technical specifications of the equipment to be purchased plays an important part in the success of the project. Coordination with DG TREN that is in charge of the verification of the provisions taken by EU Member States for environmental monitoring of the radioactivity (article 35 of the Euratom Treaty) is a prerequisite.

#### 2. d Horizontal issues

The implementation of projects 1 to 6 will contribute to significantly improve the protection of man and the environment from ionising radiation in the Western Balkan countries. They will also contribute to reinforce preventive and combat actions against nuclear terrorism and illicit trafficking of nuclear materials and radiation sources. As a general rule enhancement of the capacity of nuclear safety authorities can only have a positive impact on the monitoring of the radioactivity and the control radioactive materials in the whole Western Balkan countries.

# 2. e Conditions

The implementation of project No 1 under this programme is subject to the following prerequisite:

• National regulatory bodies in the field of nuclear safety and radiation protection have been set up by law in Montenegro and Serbia.

# 2. f Benchmarks

	N		N+1 (cumulative)		N+2 (cumulative)	
	EU	NF*	EU	NF*	EU	NF*
Contribution agreement with the IAEA to be concluded in December 2007 for project 2	€0.26 M		€0.26 M		€0.26 M	
Contribution agreement with the IAEA to be concluded in December 2007 for project 5	€0.25 M		€0.25 M		€0.25 M	
Contracting Rate(%)			100			
Number of tenders launched for projects 1, 3, 4 and 6	2		4			
Contracting Rate(%)			100			

# 3. BUDGET (amounts in €)

3.1. Indicative budget table

	EU – IPA assistance			Total Co- financing of Project (indicative)	Total (IPA plus Co- financing)
	Institution Building	Investment	Total (IB and INV)		
Project 1	500,000		500,000		500,000
Project 2	260,000		260,000		260,000
Project 3	600,000		600,000		600,000
Project 4	650,000		650,000		650,000
Project 5	250,000		250,000		250,000
Project 6	300,000		300,000		300,000
TOTAL	2,560,000		2,560,000		2,560,000

# 3.2 Principle of Co-Financing applying to the projects funded under the programme

All these projects that do not comprise any work or supply component, will be entirely supported by the European Community (100 %).

#### 4. IMPLEMENTATION ARRANGEMENTS

## 4.1 Method of implementation

For projects 1, 3, 4 and 6 the programme will be implemented on a centralised basis by the European Commission in accordance with Article 53a of the Financial Regulation<sup>5</sup> and the corresponding provisions of the Implementing Rules<sup>6</sup>.

For projects 2 and 5, the programme will be implemented by the European Commission by joint management with the International Atomic Energy Agency following Article 53.d of the Financial Regulation and the corresponding provisions of the Implementing Rules. To this end, the Commission and the IAEA will conclude two Contribution Agreements, in accordance with the FAFA.

# 4.2 General rules for procurement and grant award procedures

For projects **1**, **3**, **4** and **6** procurement shall follow the provisions of Part Two, Title IV of the Financial Regulation and Part Two, Title III, Chapter 3 of its Implementing Rules as well as the rules and procedures for service, supply and works contracts financed from the general budget of the European Communities for the purposes of cooperation with third countries adopted by the Commission on 24 May 2007 (C (2007)2034).

The Commission shall also use the procedural guidelines and standard templates and models facilitating the application of the above rules provided for in the "<u>Practical Guide to contract procedures for EC external actions</u>" ("Practical Guide") as published on the EuropeAid website at the date of the initiation of the procurement or grant award procedure.

For projects 2 and 5, the general rules for procurement and grant award procedures shall be defined in the Contribution Agreement between the Commission and the IAEA implementing such programme/activity.

#### 5. MONITORING AND EVALUATION

# 5.1 Monitoring

The Commission may undertake any actions it deems necessary to monitor the programmes concerned and for the projects under joint management with IAEA these actions may be carried out jointly with the IAEA.

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<sup>&</sup>lt;sup>5</sup> OJ L 248, 16.9.2002, p.1. Regulation as amended by Regulation (EC, Euratom) No 1995/2006 (OJ L 390, 30.12.2006, p.1).

OJ L 357, 31.12.2002, p. 1 Regulation as last amended by Regulation (EC, Euratom) No 478/2007 (OJ L 111, 28.04.2007, p. 13).

http://ec.europa.eu/europeaid/work/procedures/implementation/practical guide/index en.htm

#### 5.2 Evaluation

Programmes shall be subject to *ex ante* evaluations, as well as interim and, where relevant, *ex post* evaluations in accordance with Articles 57 and 82 of the IPA Implementing Rules<sup>8</sup>, with the aim of improving the quality, effectiveness and consistency of the assistance from Community funds and the strategy and implementation of the programmes.

The results of *ex ante* and interim evaluation shall be taken into account in the programming and implementation cycle.

The Commission may also carry out strategic evaluations.

### 6. AUDIT, FINANCIAL CONTROL AND ANTI-FRAUD MEASURES

The accounts and operations of all parties involved in the implementation of this programme, as well as all contracts and agreements implementing this programme, are subject to, on the one hand, the supervision and financial control by the Commission (including the European Anti-Fraud Office), which may carry out checks at its discretion, either by itself or through an outside auditor and, on the other hand, audits by the European Court of Auditors. This includes measures such as ex-ante verification of tendering and contracting carried out by the Delegation in the Beneficiary Country.

In order to ensure the efficient protection of the financial interests of the Community, the Commission (including the European Anti-Fraud Office) may conduct on-the-spot checks and inspections in accordance with the procedures foreseen in Council Regulation (EC, Euratom) 2185/96<sup>9</sup>.

The controls and audits described above are applicable to all contractors, subcontractors and grant beneficiaries who have received Community funds.

#### 7. LIMITED CHANGES

Limited changes in the implementation of this programme affecting essential elements listed under Article 90 of the Implementing Rules to the Financial Regulation, which are of an indicative nature <sup>10</sup>, may be undertaken by the authorising officer by delegation (AOD), or by the authorising officer by sub-delegation (AOSD), in line with the delegation of powers conferred upon him by the AOD, in accordance with the principles of sound financial management without an amending financing decision being necessary.

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<sup>8</sup> Commission Regulation (EC) No 718/2007 of 12 June 2007 (OJ L 170, 29.6.2007, p. 1).

<sup>9</sup> OJ L 292; 15.11.1996; p. 2

These essential elements of an indicative nature are, for grants, the indicative amount of the call for proposals and, for procurement, the indicative number and type of contracts envisaged and the indicative time frame for launching the procurement procedures.