



EUROPEAN COMMISSION

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Proposal for a

COUNCIL REGULATION

establishing a Community system for registration of carriers of radioactive materials

{SEC(2011) 1005 final}

{SEC(2011) 1006 final}

EXPLANATORY MEMORANDUM

1. JUSTIFICATION AND OBJECTIVE

At European level, carriers of radioactive materials are covered by transport legislation under the Treaty on the Functioning of the European Union (TFEU) and legislation on radiation-specific aspects including the health protection of workers and the general public under the Treaty establishing the European Atomic Energy Community (Euratom).

TFEU legislation has been simplified by Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods by combining all inland transport modes.

Council Directive 96/29/Euratom of 13 May 1996 lays down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. According to Article 30 of the Treaty, these basic standards mean:

- maximum permissible doses compatible with adequate safety;
- maximum permissible levels of exposure and contamination;
- the fundamental principles governing the health surveillance of workers.

In accordance with Article 33, Member States must lay down appropriate provisions to ensure compliance with the basic standards.

For the sake of protecting the health of workers and the general public and to better focus their work, Member States' authorities need to know which persons, organisations or undertakings to check on. To that end, Articles 3 and 4 of the Directive require Member States to submit certain practices involving a hazard from ionising radiation to a system of reporting (notification) and prior authorisation or to prohibit certain practices.

Directive 96/29/Euratom applies to all practices which involve a risk from ionising radiation emanating from an artificial source or from a natural radiation source, including transport.

Given the frequent cross-border nature of transport operations, a carrier may have to comply with reporting and authorisation procedures in several Member States. In addition, Member States have implemented these procedures in different ways, thereby adding to the complexity of transport operations.

Replacing these national reporting and authorisation procedures with a single registration system for conducting transport will therefore contribute to simplifying the procedure, reduce the administrative burden and do away with barriers to entry, while the high radiation protection levels reached will be maintained.

This Regulation replaces the reporting and authorisation systems in the Member States for the purpose of implementing Council Directive 96/29/Euratom with a single registration. The Regulation establishes a European System for Carrier Registration. Carriers should apply through a central web interface. These applications will be screened by the respective national competent authority, which will issue the registration if the applicant fulfils the basic safety standards. At the same time, the system affords the competent authorities a better overview of the carriers that are active in their country.

The Regulation adopts a graded approach by exempting carriers who transport exclusively 'excepted packages' from the need to register. On the other hand, the Regulation leaves it up to the Member States to add additional registration requirements for carriers of fissile and highly radioactive materials.

Other Community law and international rules regarding physical protection, safeguards, and third-party liability continue to apply. This is true, in particular, for Directive 2008/68/EC.

2. LEGAL BASIS

The provisions of this Regulation relate to the basic safety standards for the protection of the health of workers and the general public. Consequently, the legal basis is Chapter 3 of the Treaty establishing the European Atomic Energy Community, and, in particular, Articles 31 and 32 thereof.

3. SUBSIDIARITY AND PROPORTIONALITY

As recognised by the Court of Justice of the European Union in its case-law, the provisions of Chapter 3 of the Euratom Treaty on health and safety form a coherent whole conferring upon the Commission powers of some considerable scope in order to protect the population and the environment against risks of nuclear contamination¹.

Based on the Court's ruling in Case C-29/99, the existing basic safety standards, which are mainly at protecting the health of workers and the general public against the dangers arising from ionising radiations can be 'supplemented'. The proposed Regulation would supplement the basic safety standards provided for in Article 30 of the Euratom Treaty, which have been revised several times since the Treaty entered into force and more recently on 13 May 1996 (Directive 96/29 Euratom)².

In its ruling of 10 December 2002 in Case C-29/99, the Court favours a wide interpretation of the scope of Directive 96/29/Euratom, stating that 'it is not appropriate, in order to define the Community's competencies, to draw an artificial distinction between the protection of the health of the general public and the safety of sources of ionising radiation'. The Court recognises that under Articles 30 to 32 of the Euratom Treaty the Community possesses wide 'legislative competence to establish, for the purpose of health protection, a related authorisation system which must be applied by the Member States. Such a legislative act constitutes a measure supplementing the basic standards referred to in that article'. As the proposed Regulation falls under the scope of Directive 96/29/Euratom, the subsidiarity principle does not apply because of the exclusive nature of the Community's legislative powers under Chapter 3 of the Euratom Treaty.

4. BUDGETARY IMPLICATIONS

Developing the registration system, whose website will also include links to the competent authorities in Member States, will cost roughly €1 million in operational appropriations followed by annual running costs of €0.18 million. To oversee the development process existing human resources costing €0.7 million would be required followed by assistance costing €0.1 million annually.

For the purposes of the Advisory Committee established under this Regulation, no additional budgetary implications would be incurred if the Member States agreed to make use of the existing Standing Working Group on the safe transport of radioactive materials. The financing for covering meetings of the Committee (less than € 30.000 per year) will be provided through redeployment of existing resources. No additional costs above the allocation foreseen on the budget line will be incurred.

¹ C-187/87 (1988 ECR p.5013) and C-29/99 (2002 ECR p. I-11221)

² OJ L 159, 29.6.1996, p. 1.

While the impact assessment report accompanying this proposal refers to an optional website with additional information on the competent authorities in the Member States, only a page with basic information is to become part of the registration system so that no additional costs will be incurred.

Proposal for a

COUNCIL REGULATION

establishing a Community system for registration of carriers of radioactive materials

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular the second paragraph of Article 31 and Article 32 thereof,

Having regard to the proposal from the Commission, drawn up after obtaining the opinion of a group of persons appointed by the Scientific and Technical Committee,

Having regard to the opinion of the European Economic and Social Committee³,

Having regard to the opinion of the European Parliament⁴,

Whereas:

- (1) Article 33 of the Treaty requires Member States to lay down the appropriate provisions to ensure compliance with the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation.
- (2) The basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation are established by Council Directive 96/29/Euratom of 13 May 1996⁵. That Directive applies to all practices which involve a risk of ionising radiation emanating from an artificial or a natural radiation source, including transport.
- (3) In order to ensure compliance with the basic safety standards persons, organisations or undertakings are subject to regulatory control by the authorities of the Member States. For that purpose Directive 96/29/Euratom requires Member States to submit certain practices involving a hazard from ionising radiation to a system of reporting and prior authorisation or to prohibit certain practices.
- (4) Transport being the only practice of a frequent cross-border nature, carriers of radioactive materials may be required to comply with requirements related to reporting and authorisation systems in several Member States. This Regulation replaces those reporting and authorisation systems in the Member States with a single registration system valid across the European Atomic Energy Community (hereinafter the 'Community').
- (5) For carriers by air and sea, such registration and certification systems already exist. Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonization of technical requirements and administrative procedures in the field of civil aviation⁶ lays down that air carriers need a specific air operator certificate for the transportation of

³ OJ C 143, 22.5.2012, p. 110.

⁴ OJ , , , p. .

⁵ OJ L 159, 29.6.1996, p. 1.

⁶ OJ L 373, 31.12.1991, p. 4.

dangerous goods. For transports by sea, Directive 2002/59/EC of the European Parliament and of the Council of 27 June 2002 establishes a Community vessel traffic monitoring and information system⁷. The certificates issued by the civil aviation authorities and the reporting system for maritime vessels are deemed to satisfactorily implement the reporting and authorisation requirements of Directive 96/29/Euratom. Registration of air and sea carriers under this Regulation is therefore not necessary to enable Member States to ensure compliance with the basic safety standards in these transport modes.

- (6) Carriers of radioactive material are subject to a number of requirements of Union and Euratom legislation as well as international legal instruments. The International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material (TS-R-1) and the Modal Regulations for the Transport of Dangerous Goods continue to apply directly or are implemented by Member States under Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods⁸ for road, rail and inland waterway transport. The provisions of this Directive are, however, without prejudice to the application of other provisions in the fields of occupational safety and health and environmental protection.
- (7) In order to ensure uniform conditions for implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for the control by the Member States of the Commission's exercise of implementing powers.

HAS ADOPTED THIS REGULATION

Article 1

Subject matter and scope

- (1) This Regulation establishes a Community system for the registration of carriers of radioactive materials which facilitates the Member States' task of ensuring that the basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiations laid down in Directive 96/29/Euratom are complied with.
- (2) This Regulation shall apply to any carrier transporting radioactive materials within the Community, from third countries into the Community and from the Community into third countries. It shall not apply to carriers transporting radioactive materials by air and sea.

⁷ OJ L 208, 5.8.2002, p. 10.

⁸ OJ L 260, 30.9.2008, p. 13.

Article 2
Definitions

For the purposes of this Regulation

- (a) ‘carrier’ means any person, organisation or public undertaking conducting the carriage of radioactive material by any means of transport in the Community. This includes carriers for hire or reward and carriers on own account;
- (b) ‘competent authority’ means any authority designated by the Member State to carry out tasks provided for in this Regulation;
- (c) ‘transport’ means all transport operations from the place of origin to the place of destination, including loading, storage in transit and unloading of radioactive material;
- (d) ‘radioactive material’ means any material containing radionuclides where both the activity concentration and the total activity in the consignment exceed the values specified in paragraphs 402–407 of the IAEA Regulations for the Safe Transport of Radioactive Material, Safety Requirements No. TS-R-1, Vienna, 2009;
- (e) ‘high consequence dangerous goods - radioactive material’ means radioactive material which have the potential for misuse in a terrorist incident and which may, as a result, produce serious consequences such as mass casualties or mass destruction as defined in Appendix A.9. of the IAEA Nuclear Security Series No.9 ‘Security in the Transport of Radioactive Material’, Vienna, 2008;
- (f) ‘excepted package’ means any package in which the allowed radioactive content does not exceed the activity levels laid down in Table V of Section IV of the IAEA Regulations for the Safe Transport of Radioactive Material, Safety Requirements No. TS-R-1, Vienna, 2009, or one tenth of these limits for transport by post and which is labelled as UN No. 2908, 2909, 2910 or 2911;
- (g) ‘fissile material’ means uranium-233, uranium-235, plutonium-239 and plutonium-241 or any combination of these radionuclides.

Article 3
General provisions

1. Carriers of radioactive materials shall have a valid registration obtained in accordance with Article 5. The registration shall allow the carrier to conduct transport throughout the whole Union.
2. Individual transport operations shall be accompanied by a copy of the carrier’s registration certificate or by the licence or registration obtained in accordance with the applicable national procedure in the case of transport referred to in paragraph 3.
3. A holder of valid licences or registrations issued in accordance with Directive 96/29/Euratom for the handling of radioactive material or for the use of equipment containing radioactive material or sources may transport these materials or sources without registration under this Regulation if transportation is included in the licences or registrations for all Member States where the transport takes place.
4. National reporting and authorisation requirements that are additional to the requirements laid down by this Regulation may only apply to the carriers of the following materials:

- (a) fissile material, except for natural uranium or depleted uranium which has been irradiated in a thermal reactor only;
 - (b) high consequence dangerous goods - radioactive material.
5. A registration shall not be required for carriers transporting exclusively excepted packages.

Article 4

Electronic System for Carrier Registration (ESCReg)

1. Electronic System for Carrier Registration (ESCReg) shall be established and maintained by the Commission for the supervision and control of the transport of radioactive material. The Commission shall define the information to be included in the system, technical specifications and requirements for the ESCReg.
2. The ESCReg shall grant restricted and secure access to the competent authorities of the Member States, to registered carriers and to applicants, subject to the relevant provisions on personal data protection, as laid down by Directive 95/46/EC of the European Parliament and of the Council⁹. The competent authorities shall have access to all data available.
3. The Commission shall not be responsible for the content and the accuracy of information submitted through the ESCReg.

Article 5

Registration procedure

1. A carrier shall apply for registration through the ESCReg.
The applicant carrier shall submit the completed electronic application form set out in Annex I.
2. Upon completion and submission of the application form, the applicant shall receive an automatic acknowledgement of receipt, together with an application number.
3. If the applicant is established in one or more Member States, the competent authority of the Member State where the head office of the applicant is established shall process the application.
If the applicant is established in a third country, the competent authority of the Member State where the carrier intends to first enter the territory of the Union shall process the application.
The competent authority of the Member State which issues the first certificate of carrier registration shall issue also the new certificate in the event of modification of data in accordance with Article 6.
4. Within eight weeks of issuing the acknowledgement of receipt the competent authority shall issue a certificate of carrier registration if it considers the submitted information to be complete and in compliance with this Regulation, Directive 96/29/Euratom and Directive 2008/68/EC.

⁹ OJ L 281, 23.11.1995, p. 31.

5. The certificate of carrier registration shall contain the information set out in Annex II and shall be issued in the form of the standardized registration certificate through the ESCReg.

A copy of the certificate of carrier registration shall be provided automatically through the ESCReg to all the competent authorities of the Member States where the carrier intends to operate.

6. If the competent authority refuses to issue a certificate of carrier registration on the grounds that the application is not complete or not in compliance with the applicable requirements, it shall respond in writing to the applicant within eight weeks after issuing the acknowledgement of receipt. Prior to such refusal, the competent authority shall require that the applicant corrects or supplements the application within three weeks from the receipt of this request. The competent authority shall provide a statement of the reasons for refusal.

A copy of the refusal and statement of the reasons shall be provided automatically through the ESCReg to all the competent authorities of the Member States where the carrier intends to operate.

7. If the request for a certificate of carrier registration is refused, the applicant may lodge an appeal in accordance with the applicable national legal requirements.
8. A valid certificate of registration shall be recognized by all Member States.
9. The certificate of carrier registration shall be valid for a period of five years and may be renewed upon application by the carrier.

Article 6 *Modification of data*

1. The carrier shall be responsible for ensuring the continued accuracy of the data provided in the application form for Community carrier registration submitted to the ESCReg.
2. The carrier shall apply for a new certificate in the event of modification of the data contained in part A of the application form for Community carrier registration.

Article 7 *Compliance assurance*

1. If a carrier does not comply with the requirements of this Regulation the competent authority of the Member State where the non-compliance was discovered shall apply enforcement measures within the legal framework of that Member State, such as written notices, training and education measures, suspension, revocation or modification of the registration or prosecution, depending on the safety significance of the non-compliance and the record of compliance of the carrier.
2. The competent authority of the Member State where the non-compliance was discovered shall communicate to the carrier and to the competent authorities of the Member States where the carrier was planning to transport radioactive materials, information on enforcement action applied and a statement of reasons for application of that action. If the carrier does not comply with the enforcement action applied pursuant to paragraph 1, the competent authority of the Member State of establishment of the head office of the carrier or, if the carrier is established in a third

country, the competent authority of the Member State, where the carrier intended to first enter the territory of the Community shall revoke the registration.

3. The competent authority shall communicate to the carrier and to the other competent authorities concerned the revocation together with a statement of reasons.

Article 8

Competent authorities and national contact point

1. Member States shall designate a competent authority and a national contact point for the transport of radioactive materials.

Member States shall forward to the Commission not later than one month after the entry into force of this Regulation the name(s), address(es) and all necessary information for rapid communication with the competent authorities and with the national contact point for the transport of radioactive materials, as well as any subsequent change to such data.

The Commission shall communicate this information and any changes thereto to all competent authorities in the Community through the ESCReg.

2. The information on the national rules on radiation protection applicable to the transport of radioactive materials shall be easily accessible to carriers through the contact points.
3. Upon carriers' request the contact point and the competent authority of the respective Member State shall provide complete information on the requirements for the transport of radioactive materials on the territory of that Member State.

The information shall be easily accessible at a distance and by electronic means and kept up to date.

The contact points and the competent authorities shall respond as quickly as possible to any request for information and in cases where the request is faulty or unfounded, inform the applicant accordingly without delay.

Article 9

Cooperation between competent authorities

Competent authorities of Member States shall cooperate with a view to harmonising their requirements for issuing a registration and to ensuring the harmonised application and enforcement of this Regulation.

Where there are several competent authorities within a Member State, they shall liaise and cooperate closely on the basis of legal or formal agreements between them covering the responsibilities of each authority. They shall communicate with and provide information to each other, to the national contact point, and to other governmental and non-governmental organisations that have related responsibilities.

Article 10
Implementation

The Commission shall adopt implementing acts establishing the Electronic System for Carrier Registration (ESCREg) described in Article 4.

These implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 11.

Article 11
Advisory Committee

The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European parliament and of the Council of 16 February 2011 laying down the rules and the general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers¹⁰.

Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

The committee shall advise and assist the Commission in the performance of its tasks provided for in this Regulation.

The committee shall be composed of experts nominated by the Member States and of experts nominated by the Commission and shall be chaired by a representative of the Commission.

Article 12
Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Council
The President

¹⁰ OJ L 55, 28.2.2011, p. 13.

ANNEX

ANNEX

I

APPLICATION FORM FOR COMMUNITY CARRIER REGISTRATION

PLEASE SEND THIS APPLICATION ONLY USING THE EUROPEAN COMMISSION'S SECURE ELECTRONIC SYSTEM FOR CARRIER REGISTRATION (ESCReg)

IF THERE IS ANY CHANGE IN THE INFORMATION IN PART A, A NEW REGISTRATION MUST BE REQUESTED. The carrier is responsible for ensuring that the data provided in the application form for Community carrier registration submitted through this system remain accurate.

The information provided in the present application form will be processed by the European Commission in compliance with Directive 95/46/EC of the European Parliament and of the Council.

NEW CERTIFICATE OF REGISTRATION

MODIFICATION OF AN EXISTING REGISTRATION

RENEWAL OF AN EXISTING REGISTRATION

Registration Certificate number/s:

Please give details of why a change to an existing registration is being sought

1. IDENTIFICATION OF THE APPLICANT:

PART A	PART B
COMPANY NAME: FULL ADDRESS: NATIONAL REGISTRATION NUMBER:	1. Name, position, full address, telephone number and e-mail-address of the responsible representative of the carrier's organisation (person empowered to commit the carrier's organisation): 2. Name, position, full address, telephone number and e-mail-address of the contact person for the authorities on technical/administrative issues (who has the responsibility for compliance with the regulations for the activities deployed by the carrier company): 3. Name, position and full address of the safety adviser (only for inland transport modes and if different from 1 or 2): 4. Name, position and full address of the person responsible for the implementation of the Radiation Protection Programme if different from 1 or 2 or 3:

2. NATURE OF TRANSPORT:

PART A	PART B
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ROAD RAIL INLAND	WATERWAYS	<p>1 Staff involved and trained for transport (information)</p> <p>1 to 5 5 to 10 10 to 20 >20</p> <p>2 Transport activity sector: general description of the nature of the transport activities to be undertaken (information)</p> <p>medical use industrial use, non-destructive testing use, research nuclear fuel cycle use waste high consequence dangerous goods - radioactive material</p>
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3. GEOGRAPHICAL COVERAGE

Please tick in the list below those Member States in which radioactive material is planned to be transported and select the nature of the activity

If activities are also deployed in Member States other than the Member State where the application for registration is made, please provide more specific details for every country, i.e. transit only, or major loading/unloading places within the particular country, frequency:

PART A	PART B
Austria Belgium Bulgaria Cyprus Czech Republic Denmark Estonia Finland France Germany Greece Hungary Ireland Italy	transit unloading loading major loading places: major unloading places: frequency: daily weekly monthly less frequent

Latvia	
Lithuania	
Luxembourg	
Malta	
Netherlands	
Poland	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	
United Kingdom	

4. TYPE OF CONSIGNMENTS

Registration is requested for:

PART A PACKAGE TYPE - Classification following TS-R-1	PART B: Estimated number of packages /year
<p>UN 2908 RADIOACTIVE MATERIAL, EXCEPTED PACKAGE — EMPTY PACKAGING</p> <p>UN 2909 RADIOACTIVE MATERIAL, EXCEPTED PACKAGE — ARTICLES MANUFACTURED FROM NATURAL URANIUM or DEPLETED URANIUM or NATURAL THORIUM</p> <p>UN 2910 RADIOACTIVE MATERIAL, EXCEPTED PACKAGE — LIMITED QUANTITY OF MATERIAL</p> <p>UN 2911 RADIOACTIVE MATERIAL, EXCEPTED PACKAGE — INSTRUMENTS or ARTICLES</p> <p>UN 2912 RADIOACTIVE MATERIAL, LOW SPECIFIC ACTIVITY (LSA-I), non-fissile or fissile excepted</p> <p>UN 2913 RADIOACTIVE MATERIAL, SURFACE CONTAMINATED OBJECTS (SCO-I or SCO-II), non-fissile or fissile excepted</p>	

UN 2915 RADIOACTIVE MATERIAL,
TYPE A PACKAGE, non-special form, non-
fissile or fissile excepted

UN 2916 RADIOACTIVE MATERIAL,
TYPE B(U) PACKAGE, non-fissile or fissile
excepted

UN 2917 RADIOACTIVE MATERIAL,
TYPE B(M) PACKAGE, non-fissile or fissile
excepted

UN 2919 RADIOACTIVE MATERIAL,
TRANSPORTED UNDER SPECIAL
ARRANGEMENT, non-fissile or fissile
excepted

UN 2977 RADIOACTIVE MATERIAL,
URANIUM HEXAFLUORIDE, FISSILE

UN 2978 RADIOACTIVE MATERIAL,
URANIUM HEXAFLUORIDE, non-fissile
or fissile excepted

UN 3321 RADIOACTIVE MATERIAL,
LOW SPECIFIC ACTIVITY (LSA-II), non-
fissile or fissile excepted

UN 3322 RADIOACTIVE MATERIAL,
LOW SPECIFIC ACTIVITY (LSA-III), non-
fissile or fissile excepted

UN 3323 RADIOACTIVE MATERIAL,
TYPE C PACKAGE, non-fissile or fissile
excepted

UN 3324 RADIOACTIVE MATERIAL,
LOW SPECIFIC ACTIVITY (LSA-II),
FISSILE

UN 3325 RADIOACTIVE MATERIAL,
LOW SPECIFIC ACTIVITY (LSA-III),
FISSILE

UN 3326 RADIOACTIVE MATERIAL,
SURFACE CONTAMINATED OBJECTS
(SCO-I or SCO-II), FISSILE

UN 3327 RADIOACTIVE MATERIAL,
TYPE A PACKAGE, FISSILE, non-special
form

UN 3328 RADIOACTIVE MATERIAL,
TYPE B(U) PACKAGE, FISSILE

UN 3329 RADIOACTIVE MATERIAL,
TYPE B(M) PACKAGE, FISSILE

UN 3330 RADIOACTIVE MATERIAL,

<p>TYPE C PACKAGE, FISSILE</p> <p>UN 3331 RADIOACTIVE MATERIAL, TRANSPORTED UNDER SPECIAL ARRANGEMENT, FISSILE</p> <p>UN 3332 RADIOACTIVE MATERIAL, TYPE A PACKAGE, SPECIAL FORM, non-fissile or fissile excepted</p> <p>UN 3333 RADIOACTIVE MATERIAL, TYPE A PACKAGE, SPECIAL FORM, FISSILE</p>	
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5. RADIATION PROTECTION PROGRAMME (RPP)

<p>PART A:</p> <p>By ticking this box:</p> <p>I declare that we have an RPP that is fully implemented and strictly applied</p>	<p>PART B:</p> <p>reference and date of the document describing the RPP</p> <p>Upload of the RPP</p>
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6. QUALITY ASSURANCE PROGRAMME (QAP)

This QAP must be available for inspection by the competent authority (in accordance Article 1(7)(3) of the ADR)

<p>PART A:</p> <p>By ticking this box:</p> <p>I declare that we have a QAP that is fully implemented and strictly applied</p>	<p>PART B:</p> <p>Reference and date of the document</p>
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7. Declaration

I, the carrier, hereby certify that I comply with all the relevant international, Community and national regulations relating to the transport of radioactive materials.

I, the carrier, hereby certify that the information contained in this form is correct.

Date Name Signature

**ELECTRONIC CERTIFICATE OF CARRIER REGISTRATION FOR THE
TRANSPORT OF RADIOACTIVE MATERIAL**

NOTE:

A COPY OF THIS CERTIFICATE OF REGISTRATION SHALL ACCOMPANY EACH TRANSPORT FALLING UNDER THE SCOPE OF THIS REGULATION.

This certificate of registration is issued in compliance with Council Regulation (Euratom) xxxxx

This certificate does not relieve the carrier from compliance with the other applicable transport regulations.

1) REGISTRATION REFERENCE NUMBER: BE/ xxxx / dd-mm-yyyy

2) NAME OF THE AUTHORITY / COUNTRY:

3) COMPANY NAME & ADDRESS

4) MODE OF TRANSPORT:

ROAD

RAIL

INLAND WATERWAYS

7) MEMBER STATES where the certificate is applicable

8) PACKAGE TYPE – UN NUMBER (*see annex 1- same format*)

9) DATE

ELECTRONIC SIGNATURE

VALIDITY PERIOD : DATE + 5 years

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

- 1.1. Title of the proposal/initiative
- 1.2. Policy area(s) concerned in the ABM/ABB structure
- 1.3. Nature of the proposal/initiative
- 1.4. Objective(s)
- 1.5. Grounds for the proposal/initiative
- 1.6. Duration and financial impact
- 1.7. Management method(s) envisaged

2. MANAGEMENT MEASURES

- 2.1. Monitoring and reporting rules
- 2.2. Management and control system
- 2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

- 3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected
- 3.2. Estimated impact on expenditure
 - 3.2.1. *Summary of estimated impact on expenditure*
 - 3.2.2. *Estimated impact on operational appropriations*
 - 3.2.3. *Estimated impact on appropriations of an administrative nature*
 - 3.2.4. *Compatibility with the current multiannual financial framework*
 - 3.2.5. *Third-party participation in financing*
- 3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

COUNCIL REGULATION establishing a Community system for registration of carriers of radioactive materials

1.2. Policy area(s) concerned in the ABM/ABB structure¹¹

Energy
Nuclear safety

1.3. Nature of the proposal/initiative

The proposal/initiative relates to a **new action**

The proposal/initiative relates to a **new action following a pilot project/preparatory action**¹²

The proposal/initiative relates to **the extension of an existing action**

The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objectives

1.4.1. *The Commission's multiannual strategic objective(s) targeted by the proposal/initiative*

1. Sustainable Growth

1a. Competitiveness for growth and employment

The general objectives of the proposal are directly linked to the fundamental objectives of EU policy, as applied in this specific field, that is,

- to ensure and maintain adequate safety standards to protect the public and the environment during transports of radioactive materials and
- to aim at an European single market for transport services of radioactive materials

1.4.2. *Specific objective(s) and ABM/ABB activity(ies) concerned*

The specific objectives of the proposed Community action should be

- to guarantee safety and health protection of citizens during the transport of radioactive materials in the territory of the EU,
- to contribute to remove obstacles to the internal market in this sector,
- to increase transparency in TRAM legislation allowing carriers and users to easily find the information needed and authorities involved,
- to create the appropriate legislative and organisational conditions to ensure delivery in time and in good conditions of lifesaving radioisotopes essential for trials and therapy treatments concerning a large number of diseases.

¹¹ ABM: Activity-Based Management – ABB: Activity-Based Budgeting.

¹² As referred to in Article 49(6)(a) or (b) of the Financial Regulation.

Finally, operational objectives are related to the specific outputs of Community action:

- to apply internationally accepted regulations so as to make repetitive Member States rules obsolete,
- to allow carriers to transport materials in the Community without the need for additional administrative procedures for registration or licenses in other Member States,
- to establish national Contact Points guiding carriers to the information and authorities needed,
- to drop notification requirements for individual transports for radioactive materials – apart from fissile and high-consequence radioactive materials.

With regards to expenditure the objective is to develop and maintain a the European System of Carrier Registration.

ABM/ABB activity(ies) concerned

32 05 Nuclear Energy

1.4.3. *Expected result(s) and impact*

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

Results

- to ensure and maintain adequate safety standards to protect the public and the environment during transports of radioactive materials and
- to aim at a European single market for transport services of radioactive materials

Impact:

By providing for, among others, the mutual recognition of licences for carriers, the Regulation is expected to lead to annual savings of € 13.6 million per year across the economy. The proposed approach would reduce the bureaucratic burden on carriers, users and producers while freeing resources in authorities, which then could be partially, at least, used for compliance checks.

The savings coming from an improved regulatory frame total (Fewer derogations from the regulative framework; better and harmonised rules at European level; Reduced complexity of regulations; Decrease of costs due to less administrative burden; Costs of additional requirements in national law; Less time needed for approvals) would total €9.8 million while costs for transport operations would be reduced by €5.2 million (Decrease in delays of trans-boundary shipments; Decrease of denials and non-compliance of shipments; Tear down entry barriers for small and medium-sized enterprises).

These savings of €15 million would be countered by public sector costs of €1.4 million per year including the set-up and running costs of the registration system.

The Regulation will effectively simplify the current approval systems, introduce transparency and eliminate barriers to a functioning internal market while maintaining a high level of safety.

1.4.4. *Indicators of results and impact*

Specify the indicators for monitoring implementation of the proposal/initiative.

The European Commission will closely follow the impacts of the Regulation through intensive consultation of the stakeholders involved: Member States, carriers and those demanding such transport services.

The lack of reliable statistics in the area makes it difficult to quantify exact targets. The close contacts Commission services have with all stakeholders should allow, however, whether the specific objectives of this initiative are met:

- to guarantee safety and health protection of citizens during the transport of radioactive materials in the territory of the EU,
- to contribute to remove obstacles to the internal market in this sector,
- to increase transparency in legislation allowing carriers and users to easily find the information needed and authorities involved,
- to create the appropriate legislative and organisational conditions to ensure delivery in time and in good conditions of lifesaving radioisotopes essential for trials and therapy treatments concerning a large number of diseases

With regards to the registration system, the following indicators will be used:

- To have the system operational in time and on budget;
- The features provided fully comply with the Regulation;
- The system is user friendly

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

The registration system must be fully and reliably available.

1.5.2. Added value of EU involvement

Taking into account

- the need to provide for high safety standards for the transport of radioactive materials in all 27 Member States ,
 - the need to tackle the problems encountered in trans-boundary transports, in particular, the variety in the implementation of Articles 3 and 4 of the Basic Standards Directive,
- it is more than evident that EU action can help to harmonise and simplify rules in the Community and increase transparency while continuing to guarantee a high level of safety.

1.5.3. Lessons learned from similar experiences in the past

Opening the full potential of the internal market has provided benefits to both consumers and producers or service providers.

1.5.4. Coherence and possible synergy with other relevant instruments

The Regulation is fully in line with the general objectives of the EU/Euratom (single market, protection of workers and the public).

1.6. Duration and financial impact

Proposal/initiative of **limited duration**

– Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

– Financial impact from YYYY to YYYY

Proposal/initiative of **unlimited duration**

– Implementation with a start-up period from Year N¹³ to Year N+3,

– followed by full-scale operation.

1.7. Management mode(s) envisaged¹⁴

Centralised direct management by the Commission

Centralised indirect management with the delegation of implementation tasks to:

– executive agencies

– bodies set up by the Communities¹⁵

– national public-sector bodies/bodies with public-service mission

– persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

Shared management with the Member States

Decentralised management with third countries

Joint management with international organisations (*to be specified*)

If more than one management mode is indicated, please provide details in the "Comments" section.

Comments

¹³ Year N is the first year after the Adoption of a Council Regulation establishing a Community system for registration of carriers of radioactive materials.

¹⁴ Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

¹⁵ As referred to in Article 185 of the Financial Regulation.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

DG Energy proposes to follow the expert advice received and to evaluate the effects of this Regulation two years after it enters into force. This interim evaluation could reveal any difficulties and bottlenecks to be solved. After this initial evaluation it might be useful to revisit the issue at a five-year interval to monitor what barriers may still exist for the smooth operation of the transport of radioactive materials in the European Union.

2.2. Management and control system

2.2.1. Risk(s) identified

MS unwilling to make the necessary investments (in terms of effort) in the project
Legal base delay. The proposal is being adopted by the EC but with an unknown time horizons on the Council outcomes
Legal base blockage for whatever reason (eg. The proposal will not reach the requested majority in the Council)
The final text of the Regulation will differ significantly with respect to the actual version
National authorization procedures are difficult to be integrated in a unified EU27 framework
The subcontractor may not deliver the project at the required quality level and, as a result, the reliability of the total system may not meet performance specifications.
Requirements mismatch
Architecture faults; difficulty in integrating commercial off-the-shelf software

2.2.2. Control method(s) envisaged

The development of the registration systems follows the guidelines set by DIGIT and will make use of the DIGIT Framework Contracts in place and therefore follow the standard procedure in agreement with the Financial Regulation including all the controls foreseen there. In addition, hosting will be done through administrative agreement with DIGIT.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

DG ENER will apply all regulatory control mechanisms.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Description.....]	Diff./non-diff. (16)	from EFTA ¹⁷ countries	from candidate countries ¹⁸	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
N° 1	32.0502 "Sureté Nucléaire et Radioprotection"	Diff	NO	NO	NO	NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Heading.....]	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
	[XX.YY.YY.YY]		YES/N O	YES/N O	YES/N O	YES/NO

¹⁶ Diff. = Differentiated appropriations / Non-diff. = Non-Differentiated Appropriations

¹⁷ EFTA: European Free Trade Association.

¹⁸ Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

EUR million (to 3 decimal places)

Heading of multiannual financial framework:	1a	Competitiveness for growth and employment
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DG: ENER			N	N+1	N+2	N+3	N+4 and next			TOTAL
• Operational appropriations ¹⁹										
32.0502	Commitments	(1)	0.142	0.471	0.412	0.193	0.177	0.177	0.177	
	Payments	(2)	0.100	0.450	0.400	0.200	0.200	0.200	0.199	
Appropriations of an administrative nature financed from the envelope for specific programmes ²⁰										
Number of budget line		(3)								
TOTAL appropriations	Commitments	=1+1a +3	0.142	0.471	0.412	0.193	0.177	0.177	0.177	

¹⁹ The commitments are split as follows; the payments are slightly deferred taking into account how the contractors are expected to be reimbursed. The running costs covering maintenance, support and infrastructure will be phased in and be stable at €177000 from 2016 .

	N	N+1	N+2	N+3	N+4
Development	114	352	116		
Test	9	44	122		
Maintenance			29	58	52
Support			50	50	50
Training			20	10	
Infrastructure	19	75	75	75	75
	142	471	412	193	177

²⁰ Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

for DG ENER	Payments	=2+2a +3	0.100	0.450	0.400	0.200	0.200	0.200	0.197	
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• TOTAL operational appropriations	Commitments	(4)	0.142	0.471	0.412	0.193	0.177	0.177	0.177	
	Payments	(5)	0.100	0.450	0.400	0.200	0.200	0.200	0.197	
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
TOTAL appropriations under HEADING N°1 of the multiannual financial framework	Commitments	=4+ 6	0.142	0.471	0.412	0.193	0.177	0.177	0.177	
	Payments	=5+ 6	0.100	0.450	0.400	0.200	0.200	0.200	0.197	

If more than one heading is affected by the proposal / initiative:

• TOTAL operational appropriations	Commitments	(4)								
	Payments	(5)								
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
TOTAL appropriations under HEADINGS 1 to 4 of the multiannual financial framework (Reference amount)	Commitments	=4+ 6								
	Payments	=5+ 6								

Heading of multiannual financial framework:	5	" Administrative expenditure "
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EUR million (to 3 decimal places)

		Year N	Year N+1	Year N+2	Year N+3	N+4 and next		TOTAL
DG: ENER								
• Human resources		0,191	0,318	0,191	0,095	0,095	0,095	0,095
• Other administrative expenditure		0,05	0,05	0,05	0,05	0,03	0,03	0,03
TOTAL DG ENER	Appropriations	0,241	0,368	0,241	0,145	0,125	0,125	0,125

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)	0,241	0,368	0,241	0,145	0,125	0,125	0,125
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EUR million (to 3 decimal places)

		Year N	Year N+1	Year N+2	Year N+3	N+4 and next		TOTAL
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	0,383	0,838	0,653	0,338	0,302	0,302	0,302
	Payments	0,341	0,818	0,641	0,345	0,325	0,325	0,320

3.2.2. Estimated impact on operational appropriations

- The proposal/initiative does not require the use of operational appropriations
- The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to 3 decimal places)

Indicate objectives and outputs ↓			N		N+1		N+2		N+3		N+4 and next						TOTAL			
	OUTPUTS																			
	Type of output ²¹	Average cost of the output	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Total number of outputs	Total cost
SPECIFIC OBJECTIVE No 1 ²² ...																				
European System for Carrier Registration				0.142		0.471		0.412		0.193		0,177		0.177		0.177				

²¹ Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

²² As described in Section 1.4.2. "Specific objective(s)..."

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

- The proposal/initiative does not require the use of administrative appropriations
- The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million (to 3 decimal places)

	N	N+1	N+2	N+3	N+4 and next		TOTAL
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HEADING 5 of the multiannual financial framework								
Human resources	0,191	0,318	0,191	0,095	0,095	0,095	0,095	
Other administrative expenditure	0,05	0,05	0,05	0,05	0,03	0,03	0,03	
Subtotal HEADING 5 of the multiannual financial framework	0,241	0,368	0,241	0,145	0,125	0,125	0,125	

Outside HEADING 5²³ of the multiannual financial framework								
Human resources								
Other expenditure of an administrative nature								
Subtotal outside HEADING 5 of the multiannual financial framework								

TOTAL	0,241	0,368	0,241	0,145	0,125	0,125	0,125	1,37
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²³ Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

3.2.3.2. Estimated requirements of human resources

- The proposal/initiative does not require the use of human resources
- The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full amounts (or at most to one decimal place)

	N	N+1	N+2	N+3	N+4 and next		
• Establishment plan posts (officials and temporary agents)							
XX 01 01 01 (Headquarters and Commission's Representation Offices)	1,5	2,5	1,5	0,75	0,75	0,75	0,75
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
10 01 05 01 (Direct research)							
• External personnel (in Full Time Equivalent unit: FTE)²⁴							
XX 01 02 01 (CA, INT, SNE from the "global envelope")							
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)							
XX 01 04 yy ²⁵	- at Headquarters ²⁶						
	- in delegations						
XX 01 05 02 (CA, INT, SNE - Indirect research)							
10 01 05 02 (CA, INT, SNE - Direct research)							
Other budget lines (specify)							
TOTAL	1,5	2,5	1,5	0,75	0,75	0,75	0,75

Nuclear safety is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary agents	Development of the European System of carrier Registration
External personnel	

²⁴ CA= Contract Agent; INT= agency staff ("*Intérimaire*"); JED= "*Jeune Expert en Délégation*" (Young Experts in Delegations); LA= Local Agent; SNE= Seconded National Expert;

²⁵ Under the ceiling for external personnel from operational appropriations (former "BA" lines).

²⁶ Essentially for Structural Funds, European Agricultural Fund for Rural Development (EAFRD) and European Fisheries Fund (EFF).

3.2.4. *Compatibility with the current multiannual financial framework*

- Proposal/initiative is compatible with both 2007-2013 and 2014-2020 multiannual financial frameworks.
- Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

- Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework²⁷.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. *Third-party contributions*

- The proposal/initiative does not provide for co-financing by third parties

²⁷ See points 19 and 24 of the Interinstitutional Agreement.

3.3. Estimated impact on revenue

- Proposal/initiative has no financial impact on revenue.
- Proposal/initiative has the following financial impact:
 - on own resources
 - on miscellaneous revenue

EUR million (to 3 decimal places)

Budget revenue line:	Appropriations available for the ongoing budget year	Impact of the proposal/initiative ²⁸						
		Year N	Year N+1	Year N+2	Year N+3	... insert as many columns as necessary in order to reflect the duration of the impact (see point 1.6)		
Article								

For miscellaneous assigned revenue, specify the budget expenditure line(s) affected.

Specify the method for calculating the impact on revenue.

²⁸

As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25% for collection costs.