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from: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

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to: Mr Uwe CORSEPIUS, Secretary-General of the Council of the European  
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Subject: Commission Staff Working Document  
Executive Summary of the Impact Assessment  
*Accompanying the document*  
Council Directive laying down basic safety standards for protection against the  
dangers arising from exposure to ionising radiation

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Delegations will find attached Commission document COM(2012) 138 final.

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**COMMISSION STAFF WORKING DOCUMENT**  
**EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT**

*Accompanying the document*

**COUNCIL DIRECTIVE**

**laying down basic safety standards for protection against the dangers arising from  
exposure to ionising radiation**

{COM(2012) 242 final}  
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**COMMISSION STAFF WORKING DOCUMENT**  
**EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT**

*Accompanying the document*

**COUNCIL DIRECTIVE**

**laying down basic safety standards for protection against the dangers arising from  
exposure to ionising radiation**

1. Problem definition

1.1. Introduction

Exposure to ionising radiation results in a health detriment. In normal situations doses are very low so that there is no clinically observable tissue effect, but there still is a possible late effect, cancer in particular. It is assumed that any exposure, however small, can be the cause of cancer later in life. This calls for a specific approach in radiation protection, which has been established for many decades by the International Commission on Radiological Protection (ICRP).

The need to protect health as well as the environment has been recognised in the Euratom Treaty (1957) and there are specific provisions laid down in Chapter III, Health and Safety, addressing these concerns. Article 31 of the Treaty calls for uniform Basic Safety Standards to be established.

Article 31 of the Euratom Treaty also lays down the procedure for the establishment of these Standards, in particular that the Commission shall seek the opinion of a Group of Experts ("Article 31 Experts"). In general, new legislation is drafted jointly by the Commission services and the Experts.

The Community legislation has always followed the recommendations of ICRP. This highly respected scientific organisation has recently issued new guidance on the system of protection (Publication 103, 2007) reflecting latest scientific findings on radiation risks and defining the system of radiological protection.

1.2. Problem definition

The current system to protect workers and the public from the effects of ionising radiation does not respond to the latest scientific findings and new societal and technological developments.

In detail:

- Health protection of workers and the public does not respond to latest scientific progress

- Protection of workers in NORM industries and in specific professional groups such as Outside Workers and interventional radiologists is insufficient
- Health protection of patients and the public does not respond to latest advances in technologies
- Health protection of the public from natural radiation sources is insufficient
- The risk of ionising radiation for non-humans species, or the environment as a whole, is not explicitly addressed, contrary to international recommendations
- The current legal framework for radiation protection is too complex.

In the light of these developments the Commission undertook a comprehensive review of the Community radiation protection legislation and asked the "Article 31 Experts" to provide guidance on this matter. In February 2010, the Experts issued an opinion on the possible revision of Community legislation, on the basis of a draft Directive.

## 2. Subsidiarity

According to Article 2(b) of the Euratom Treaty "...the Community shall, as provided in this Treaty ...establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied". Accordingly, in the Treaty's preamble, the Member States declare that they are "resolved to create the conditions necessary for the development of a strong nuclear industry" and also "anxious to create conditions of safety necessary to eliminate hazards to the life and health of the public". The Community is mandated to "establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied." Therefore, the competence of the European Atomic Energy Community (EAEC) to regulate in the field of health protection against ionizing radiation is explicitly recognised by the Euratom Treaty.

The exclusive nature of the Euratom Community's legislative powers under Articles 30 and 31 of the Euratom Treaty does not in principle require the application of the principle of subsidiarity. On the other hand these Articles require the Commission to seek for its legislative proposals the opinion of a Group of Experts nominated by the Euratom Scientific and Technical Committee and working as independent experts for the benefit of the Community.

## 3. Main policy objectives

The general objective of the initiative is to ensure a high level of protection of workers, members of the public and patients against the health detriment caused by exposure to ionising radiation, as well as to protect the environment.

This general objective is translated into four specific objectives:

1. to introduce the necessary subject matter amendments in order to respond to the latest scientific data and operational experience,
2. to clarify the requirements and to ensure coherence within the body of Community legislation,

3. to ensure coherence with the international standards and recommendations,
4. to cover the whole range of exposure situations and categories of exposure.

#### 4. Policy options

After thorough analysis of different solutions to the identified problem areas, and consideration of different solutions in terms of the extent of simplification, update and scope of the legislation, the following options were chosen for further assessment:

Option 1: Maintaining the status quo of existing legislation,

Option 2: Revision of Basic Safety Standards and Medical Directive,

Option 3: Revision and consolidation of Basic Safety Standards and Medical Directive, and integration of the Outside Workers Directive, the Public Information Directive and the High Activity Sealed Sources Directive,

Option 4: Revision of the Basic Safety Standards Directive and broadening the scope to cover public exposure to natural radiation,

Option 5: Revision of the Basic Safety Standards Directive and broadening the scope to cover protection of non-human species,

Option 6: Revision and consolidation of the Basic Safety Standards Directive and Medical Directive, integration of the Outside Workers Directive, the Public Information Directive and the High Activity Sealed Sources Directive and broadening the scope to cover public exposure to natural radiation and protection of non-human species.

#### 5. Assessment of impacts

##### 5.1. Option 1: Maintaining the status-quo of existing legislation

This option obviously does not fully meet the specific objectives of this initiative. The Basic Safety Standards Directive adopted in 1996 was a guarantee for adequate protection of workers and members of the public, in the same way as the Medical Directive in 1997 was a milestone in the protection of patients. However, science and society have evolved since, operational experience has shown a need for updating certain requirements, technological developments challenge the adequateness of the existing legislation and there are new societal expectations with regard to the coherent management of natural and man-made radiation sources as well as with regard to the protection of the environment.

Within this option an analysis was made to what extent the international Basic Safety Standards (IBSS) could fill the gap. The IBSS have a different purpose, however: they are non-binding and have a lower level of ambition in view of their application by developing countries. In the light of the Community's obligations in the Treaty, corresponding new national law should be based on Community legislation.

##### 5.2. Option 2: Amendment of the main affected Directives

This option considers how the two main pieces of legislation could be amended separately in the light of operational experience and new developments. The amendments could address most of the identified problems:

A) In the Basic Safety Standards Directive:

- introduction of the new ICRP methodology for the assessment of doses, and reduction of the organ dose limit for the lens-of-the-eye;
- a coherent approach to the management of NORM (i.e. naturally occurring radioactive material) industries;
- a graded approach to regulatory control, commensurate with the effectiveness of such oversight, including uniform clearance levels (e.g. for materials arising from the dismantling of decommissioned nuclear installations);

B) In the Medical Directive:

- strengthened requirements for the protection of patients as well as on risk assessment, reporting and response to accidental exposures especially in radiotherapy;
- a new approach to "*medico-legal exposures*" to allow for the growing use of devices for security screening, now regarded as public exposures under the Basic Safety Standards Directive.

The above amendments would have an important impact within the following areas:

- Economic impact: While it is not possible at this stage to make a quantified economic assessment, NORM industries will benefit from the harmonisation of the requirements between Member States. The introduction of uniform clearance levels may in addition have a considerable impact on reducing the cost of dismantling of nuclear installations;
- Social and health impact: The social impact relates to providing adequate protection to workers in NORM industries. The health impact will be most notable with regard to medical exposures, in particular to prevent that frequent CT-scans of young patients would show up through an increased cancer incidence many years later. Specific professional groups (for instance cardiologists) will benefit from the reduction of the dose limit to the lens-of-the-eye and avoid the occurrence of cataract.
- Regulatory burden: While the principle of Optimisation of protection, calling for doses to be "As Low As Reasonably Achievable" (ALARA), taking social and economic factors into account, is very instrumental in ensuring a proper cost-benefit balance of operational radiation protection, the new concept of a "graded approach" extends this principle to enhance the effectiveness of regulatory oversight and reduce the administrative burden to industries.

5.3. Option 3: Revision and consolidation of Basic Safety Standards and Medical Directive, and integration of the Outside Workers Directive, the Public Information Directive and the High Activity Sealed Sources Directive.

This option offers a revision of the BSS Directive, extending the requirements to medical exposure, public information, outside workers exposure and high-activity sealed sources. Within this policy the BSS Directive 96/29 and the related legislative acts would merge. This option relies on non-legislative measures for solving the problems related to the protection from natural radiation sources and the risks of ionising radiation to non-human species. In addition to the changes considered in option 2, this option would include the following amendments:

- harmonisation of the definition of High Activity Sealed Sources (HASS) with the international standards;
- specific requirements for the protection of Outside Workers with a clear definition of the responsibilities of their employer and of the undertakings conducting the practices in which they are exposed;
- requirements for informing the public before and in case of an emergency, within the overall revised scope for the management of emergency exposure situations.

Merging the five Directives would be a major achievement in terms of the coherence of Community legislation. The restructuring required to accommodate this broader scope of the BSS Directive would further benefit to the clarity of the text and to better operational implementation of the requirements. While option 3 conserves the economic, social and health benefits of option 2, and increases the impact in some of these aspects for instance through better protection and enhanced mobility of outside workers, the main benefit of option 3 lies with the simplification of Community legislation and corresponding reduction of the regulatory burden, both in terms of transposition in national law and in operational terms. Guidance on establishment of national action plans for reducing the risks from indoor radon exposure will again draw the attention of the Member States to this problem and possible actions for solving it. However this action will have added value only if Member States follow the proposed advice, which in the absence of binding requirements is probably not the case.

#### 5.4. Option 4: Revision of the Basic Safety Standards Directive and broadening the scope to cover public exposure to natural radiation

The new recommendations of ICRP allow a more coherent management of exposures to natural radiation sources, defining *reference levels* for indoor radon concentrations and for external exposure from building materials.

As underlined by WHO, the health impact of binding requirements for radon in dwellings should be very important. Member States will be required to establish a comprehensive and transparent Action Plan, adjusted to national needs and to the geological features of different regions. The implementation and enforcement of the national Action Plan are the responsibility of member States.

Harmonised requirements on building materials will permit further standardisation under the EC Construction Products legislation (Council Directive 89/106/EEC). This will however also represent a cost to the industry. While consumers and the building professions will benefit from the monitoring and labelling of the materials, the administrative burden to the industry

will be kept to a minimum by the proper choice of the *reference level* and through the list of types of materials deemed to be of concern.

5.5. Option 5: Revision of the Basic Safety Standards Directive and broadening the scope to cover protection of non-human species

ICRP now offers a methodology for the assessment of exposure to biota. The incorporation of relevant requirements in the Euratom BSS (as well as in the new international BSS) allows Member States to incorporate this in national environmental policies, in a way which is coherent with current approaches to health protection against ionizing radiation. The environmental impact of this expanded scope of Community legislation should be essentially in terms of a better understanding of the absence of any impact in normal situations, and the prevention of environmental damage in case of a nuclear accident.

The requirements for the protection of the environment are not very demanding at this stage. In addition to the methodology for the assessment of exposures to biota (Publication 108), ICRP will provide guidance on the application of a radiation protection system in 2011-2012. So there would still be time, before adoption of the Directive by the Council, to include harmonised criteria on this basis. The Article 31 Experts therefore recommended to include the requirements already now in the Commission proposal, rather than adding another piece of legislation a few years later, which would be contrary to the simplification policy of the Commission.

5.6. Option 6: Revision and consolidation of the Basic Safety Standards Directive, the Medical Directive and integration of the Outside Workers Directive, the Public Information Directive and the High Activity Sealed Sources Directive, and broadening the scope to cover public exposure to natural radiation and protection of non-human species

This option includes all the elements of Option 3. The revision of the Basic Safety Standards includes all identified issues, and broadens the scope to include the whole range of exposure situations, including indoor public exposure to radon and to building materials, and all categories of human and non-human exposures.

6. Comparison of the options

The different options have been compared on the basis of their effectiveness, efficiency and their coherence with other legislation. Option 1 partially satisfies the general objective of the action. It is included as a baseline scenario for the comparison of the other options. Option 2 fully responds to the first objective and improves to some extent the coherence of Euratom radiation protection legislation and is also coherent with international standards, thus meeting three of the specific objectives. Option 3 fully meets the objective of coherence and clarity. It also meets the Commission's policy of simplification.

Options 4 and 5 fully meet the objective of coherence with international recommendations. These options broaden the scope of current legislation and this may imply a certain administrative and economic cost. Option 6 combines Options 4 and 5, thus covering, together, the whole range of issues in radiation protection. Option 6 consolidates also all legislation in the same way as Option 3. In conclusion, with Option 6 all the objectives are reached effectively through a set of efficient measures. It is also the option which offers the



best possible coherence with other legislation. Summary comparison table is given in Annex 1.

## 7. Monitoring and evaluation

- Under Article 33 of the Euratom Treaty, Member States will submit draft legislation and administrative provisions to the Commission so that it can ensure the harmonisation of the approaches. The correct transposition of the Directive in national law will be a key indicator for its success in terms of clarity and simplification.

## Annex 1 Summary of the comparison of options 2 to 6

<b>Impact</b>	<b>Option 2</b>	<b>Option 3</b>	<b>Option 4</b>	<b>Option 5</b>	<b>Option 6</b>
<b>Economic</b>	(+)	(+)	(+)	(+)	(+)
Functioning of the internal market	(+)	(+)	(+)	(+)	(+)
Administrative burden on businesses	(+)	(+)	(+)(-)	(+) (-)	(+)(-)
Regulatory authorities	(-)	(+)	(-)	(-)	(+)(--)
<b>Environment</b>	(+)	(+)	(+)	(++)	(++)
Protection of the environment	(+)	(+)	(+)	(++)	(++)
<b>Social and Health</b>	(+)	(++)	(++)	(+)	(++)
Health and safety at work	(+)	(++)	(+)	(+)	(++)
Mobility of workers and experts	(+)	(+)	(+)	(+)	(+)
Protection of patients	(+)	(+)			(+)
Protection of the public	(+)	(+)	(++)	(+)	(++)
<b>Coherence and clarity of legislation</b>	(+)	(++)	(+)	(+)	(++)
<b>International coherence</b>	(+)	(+)	(+)	(+)	(++)
<b>Overall impact</b>	+	++	++	+	+++