Basic information

2011/0254(NLE) NLE - Non-legislative enactments Directive	Procedure completed
Basic safety standards for protection against the dangers arising from exposure to ionising radiation Repealing Directive 96/29/Euratom 1993/1026(CNS) Repealing Directive 97/43/Euratom 1996/0230(CNS) Repealing Directive 2003/122/Euratom 2003/0005(CNS) **Subject** 3.40.07 Building industry 3.60.04 Nuclear energy, industry and safety 3.70.01 Protection of natural resources: fauna, flora, nature, wildlife, countryside; biodiversity 3.70.08 Radioactive pollution 4.15.15 Health and safety at work, occupational medicine 4.20 Public health 4.20.05 Health legislation and policy	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	ULMER Thomas (PPE)	08/11/2011
	Shadow rapporteur TĂNĂSESCU Claudiu Ciprian (S&D) PANAYOTOV Vladko Todorov (ALDE) RIVASI Michèle (Verts/ALE) OUZKÝ Miroslav (ECR) WILS Sabine (GUE/NGL)	

Committee for opinion	Rapporteur for opinion	Appointed
EMPL Employment and Social Affairs (Associated committee)	MCINTYRE Anthea (ECR)	27/10/2011
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	

Committee for opinion on the legal basis	Rapporteur for opinion	Appointed

	JURI Legal Affairs	VOSS Axel (PPE)	04/09/2013

Council of the European Union	Council configuration	Meetings	Date
	Transport, Telecommunications and Energy	3278	2013-12-05

European Commission	Commission DG	Commissioner
	Energy	OETTINGER Günther

Key events

Date	Event	Reference	Summary
29/09/2011	Initial legislative proposal published	COM(2011)0593	Summary
30/05/2012	Legislative proposal published	COM(2012)0242	Summary
03/07/2012	Committee referral announced in Parliament		
22/11/2012	Referral to associated committees announced in Parliament		
04/07/2013	Vote in committee		
25/09/2013	Committee report tabled for plenary, 1st reading/single reading	A7-0303/2013	Summary
23/10/2013	Debate in Parliament		
24/10/2013	Decision by Parliament	T7-0452/2013	Summary
24/10/2013	Results of vote in Parliament		
05/12/2013	Act adopted by Council after consultation of Parliament		
05/12/2013	End of procedure in Parliament		
17/01/2014	Final act published in Official Journal		

Technical information

Procedure reference	2011/0254(NLE)
Procedure type	NLE - Non-legislative enactments
Procedure subtype	Consultation of Parliament
Legislative instrument	Directive
Amendments and repeals	Repealing Directive 96/29/Euratom 1993/1026(CNS) Repealing Directive 97/43/Euratom 1996/0230(CNS) Repealing Directive 2003/122/Euratom 2003/0005(CNS)
Legal basis	Euratom Treaty A 032 Euratom Treaty A 031

Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/07306

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE501.908	20/12/2012	
Amendments tabled in committee		PE506.023	27/02/2013	
Amendments tabled in committee		PE506.142	12/03/2013	
Committee opinion	EMPL	PE500.513	10/04/2013	
Specific opinion	JURI	PE519.530	23/09/2013	
Committee report tabled for plenary, 1st reading/single reading		A7-0303/2013	25/09/2013	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0452/2013	24/10/2013	Summary

European Commission

Document type	Reference	Date	Summary
Initial legislative proposal	COM(2011)0593	29/09/2011	Summary
Document attached to the procedure	SEC(2011)1098	29/09/2011	
Document attached to the procedure	SEC(2011)1099	29/09/2011	
Legislative proposal	COM(2012)0242	30/05/2012	Summary
Document attached to the procedure	SWD(2012)0137	30/05/2012	
Document attached to the procedure	SWD(2012)0138	30/05/2012	
Commission response to text adopted in plenary	SP(2013)872	27/11/2013	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	PT_PARLIAMENT	COM(2012)0242	22/02/2013	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary

EESC	Economic and Social Committee: opinion, report	CES0488/2012	22/02/2012	

Additional information		
Source	**Document**	**Date**
National parliaments	IPEX	
European Commission	EUR-Lex	
European Commission	EUR-Lex	

Final act

Corrigendum to final act 32013L0059R(02)
OJ L 072 17.03.2016, p. 0069

Directive 2013/0059
OJ L 013 17.01.2014, p. 0001 Summary

Basic safety standards for protection against the dangers arising from exposure to ionising radiation

2011/0254(NLE) - 30/05/2012 - Legislative proposal

PURPOSE: to lay down laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

PROPOSED ACT: Council Directive.

BACKGROUND: 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.

Euratom legislation has always followed the recommendations of the International Commission on Radiological Protection (ICRP). This highly respected scientific organisation has recently issued new guidance on the system of radiation protection (Publication 103, 2007).

The problem at EU level can be summarised as follows: (i) scientific progress is not fully reflected in present legislation; (ii) there are inconsistencies between the existing pieces of legislation; (iii) the scope of the present legislation does not fully cover natural radiation sources or the protection of the environment.

This translates 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 European legislation;
3. to ensure coherence with the international recommendations;
4. to cover the whole range of exposure situations and categories of exposure.

IMPACT ASSESSMENT: several options were analysed:

- ***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 (non-legislative measures to address natural radiation issues and the protection of non-human species, see Annex XI),
- ***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.

Option 6, which combines Options 4 and 5, covers all aspects of the objective of broadening the scope of radiation protection legislation. Their combination, in Option 6, together with undertaking an effort for consolidation similar to Option 3, is most effective in achieving all objectives. The analysis of the options in terms of efficiency **supports the conclusion that Option 6 should be pursued**, as the most effective, efficient and coherent policy option.

LEGAL BASIS: Articles 31 and 32 of the Treaty establishing the European Atomic Energy Community.

It should be noted that prior to proposing the current text, the Article 31 Group of Experts gave its opinion on the revised Basic safety standards Directive, there was still discussion whether a Directive on radioactive substances in water intended for human consumption should be based on Euratom Treaty or EC Treaty. In these circumstances it was decided to proceed with the proposal for a revised Basic Safety Standards Directive as agreed upon in February 2010 by Article 31 Group of Experts (as presented by the Commission in its summary dated 29 September 2011 - initial legislative proposal published). The current proposal constitutes the definitive text published by the Commission.

CONTENT: the recast of five Directives yields a voluminous single Directive, with over 100 articles and numerous annexes. In view of the extent and complexity of the changes, a formal recast procedure is not pursued.

A description of the main features of each chapter may be summarised as follows:

Subject matter and scope: this chapter defines the scope of the new Directive: the general purpose of the Directive across different categories of exposure and different exposure situations and specific purposes resulting from integration of the requirements for high-activity sealed radioactive sources and for public information, and the exclusion of non-controllable exposures).

The scope is broadened to include:

- the exposure of space crew to cosmic radiation;
- domestic exposure to radon gas in indoor air;
- external exposure to gamma radiation from building materials, and
- the protection of the environment beyond environmental pathways leading to human exposure.

System of radiation protection: this title includes the general principles of radiation protection: justification, optimisation and dose limitation. It explains the more prominent role of dose constraints and reference levels in the process of optimisation, with Annex I giving the bands of reference levels proposed by the ICRP for existing and emergency exposure situations. The dose limits are not modified, except for **a uniform definition of the annual occupational dose limit** (no averaging over 5 years) and a lower organ dose limit for the lens of the eye, as recommended by the ICRP. The new Directive no longer includes the technical measurements entering into the definition of the effective dose and other factors entering into the assessment of doses, but refers to ICRP Publication 103 for this purpose. In addition, the Directive no longer includes the long lists of radionuclide-specific dose coefficients (doses per unit intake by ingestion or inhalation), but will refer to a forthcoming consolidated publication of the ICRP which can be downloaded free of charge.

Requirements for radiation protection education, training and information: this chapter brings together the miscellaneous requirements governing education and training in the different Directives and includes provisions for recognition of the 'Radiation Protection Expert' and 'Medical Physics Expert'.

Justification and regulatory control of practices: the application of the principle of justification remains a national responsibility. Specific attention is given to the justification of practices involving the deliberate exposure of humans for non-medical imaging (e.g. security screening in airports).

The regime for regulatory control is now presented as a three-tier system (notification, registration, licensing), replacing the earlier two-tier system of reporting and 'prior authorisation'. A more detailed list of which types of practice are subject to either registration or licensing is given.

Protection of workers, apprentices and students: this title includes, with little amendment, the provisions on occupational exposure in Directive 96/29 /Euratom. It also includes the specific requirements in the Outside Workers Directive, and introduces a clear allocation of responsibilities between the employer and the undertaking where the practice is conducted. The data system for individual radiological monitoring of exposed workers and the minimum set of data to be communicated for outside workers has been updated**.**

This chapter now also covers occupational exposure in all exposure situations, which provides more explicit protection for emergency workers as well as for workers exposed to high levels of **indoor radon** in their workplace.

Protection of patients and other individuals subjected to medical exposure: this chapter includes the relevant requirements from the Medical Directive, but strengthens them, in particular with regard to:

- the application of the justification principle;
- information to patients on the health risks and benefits;
- information on doses;
- diagnostic reference levels;
- involvement of the Medical Physics Expert;
- prevention of accidental and unintended medical exposures.

Protection of members of the public: this chapter includes the public exposure requirements in Directive 96/29/Euratom, with more explicit consideration of the issuing of discharge authorisations for radioactive effluent

The section on emergency exposure situations includes the requirements of the Public Information Directive.

The section on existing exposure situations addresses indoor exposure to radon, with a somewhat lower maximum reference level for existing dwellings than in Commission Recommendation 90/143/Euratom, in line with ICRP and WHO recommendations. It also includes requirements for the classification of building materials on the basis of a radioactivity index and a uniform reference level for the annual dose resulting from residence in a building constructed with such materials.

Protection of the environment: this chapter, in line with the broader scope of the Directive as in the International Basic Safety Standards, aims to provide a means to demonstrate compliance with environmental criteria. It is up to national authorities to assess the doses to representative animals and plants in terms of protection of the ecosystem.

Appropriate technical measures also need to be taken to avoid the environmental consequences of an accidental release and to monitor existing levels of radioactivity in the environment, from the perspectives of both environmental protection and human health.

Requirements for regulatory control: this chapter includes all the responsibilities of the regulatory authorities in all exposure situations. The first section on 'institutional infrastructure' calls for a clear definition of the responsibilities of different authorities. The Commission is to receive periodically updated information and publish this in the Official Journal. This section also defines the responsibilities of the 'Radiation Protection Expert', the 'Radiation Protection Officer' (in the current BSS these concepts were merged within the function of 'Qualified Expert') and the 'Medical Physics Expert'.

Final provisions: a 2-year transposition deadline is deemed sufficient. Specific new features, such as the protection of the environment, can be transposed later. In line with the Euratom Treaty, the Basic Standards are to be uniformly applied in the Member States, though without prejudice to those requirements for which flexibility is clear from the wording of the text. However, dose limits, default exemption values, the reference level for building materials, etc. are explicitly intended for uniform transposition and application.

BUDGETARY IMPLICATIONS: there are no implications for the EU budget.

Basic safety standards for protection against the dangers arising from exposure to ionising radiation

2011/0254(NLE) - 29/09/2011 - Initial legislative proposal

PURPOSE : to lay down laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

PROPOSED ACT : Council Directive.

BACKGROUND : 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.

Euratom legislation has always followed the recommendations of the International Commission on Radiological Protection (ICRP). This highly respected scientific organisation has recently issued new guidance on the system of radiation protection (Publication 103, 2007).

The problem at EU level can be summarised as follows: (i) scientific progress is not fully reflected in present legislation; (ii) there are inconsistencies between the existing pieces of legislation; (iii) the scope of the present legislation does not fully cover natural radiation sources or the protection of the environment.

This translates into four specific objectives:

- to introduce the necessary subject-matter amendments in order to respond to the latest scientific data and operational experience;
- to clarify the requirements and to ensure coherence within the body of European legislation;
- to ensure coherence with the international recommendations;
- to cover the whole range of exposure situations and categories of exposure.

IMPACT ASSESSMENT : several options were analysed :

- ***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 (non-legislative measures to address natural radiation issues and the protection of non-human species, see Annex XI),
- ***Option 4***: Revision of the Basic Safety Standards Directive and broadening the scope to cover public exposure to natural radiation
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- ***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.

Option 6, which combines Options 4 and 5, covers all aspects of the objective of broadening the scope of radiation protection legislation. Their combination, in Option 6, together with undertaking an effort for consolidation similar to Option 3, is most effective in achieving all objectives. The analysis of the options in terms of efficiency **supports the conclusion that Option 6 should be pursued**, as the most effective, efficient and coherent policy option.

LEGAL BASIS : Articles 31 and 32 of the Treaty establishing the European Atomic Energy Community.

CONTENT : the recast of five Directives yields a voluminous single Directive, with over 100 articles and numerous annexes. In view of the extent and complexity of the changes, a formal recast procedure is not pursued.

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The scope is broadened to include:

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System of radiation protection: this title includes the general principles of radiation protection: justification, optimisation and dose limitation. It explains the more prominent role of dose constraints and reference levels in the process of optimisation, with Annex I giving the bands of reference levels proposed by the ICRP for existing and emergency exposure situations. The dose limits are not modified, except for **a uniform definition of the annual occupational dose limit** (no averaging over 5 years) and a lower organ dose limit for the lens of the eye, as recommended by the ICRP. The new Directive no longer includes the technical measurements entering into the definition of the effective dose and other factors entering into the assessment of doses, but refers to ICRP Publication 103 for this purpose. In addition, the Directive no longer includes the long lists of radionuclide-specific dose coefficients (doses per unit intake by ingestion or inhalation), but will refer to a forthcoming consolidated publication of the ICRP which can be downloaded free of charge.

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BUDGETARY IMPLICATIONS : there are no implications for the EU budget.

Basic safety standards for protection against the dangers arising from exposure to ionising radiation

2011/0254(NLE) - 29/09/2011

PURPOSE : to lay down laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

PROPOSED ACT : Council Directive.

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- diagnostic reference levels;
- involvement of the Medical Physics Expert;
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Protection of members of the public: this chapter includes the public exposure requirements in Directive 96/29/Euratom, with more explicit consideration of the issuing of discharge authorisations for radioactive effluent

The section on emergency exposure situations includes the requirements of the Public Information Directive.

The section on existing exposure situations addresses indoor exposure to radon, with a somewhat lower maximum reference level for existing dwellings than in Commission Recommendation 90/143/Euratom, in line with ICRP and WHO recommendations. It also includes requirements for the classification of building materials on the basis of a radioactivity index and a uniform reference level for the annual dose resulting from residence in a building constructed with such materials.

Protection of the environment: this chapter, in line with the broader scope of the Directive as in the International Basic Safety Standards, aims to provide a means to demonstrate compliance with environmental criteria. It is up to national authorities to assess the doses to representative animals and plants in terms of protection of the ecosystem.

Appropriate technical measures also need to be taken to avoid the environmental consequences of an accidental release and to monitor existing levels of radioactivity in the environment, from the perspectives of both environmental protection and human health.

Requirements for regulatory control: this chapter includes all the responsibilities of the regulatory authorities in all exposure situations. The first section on 'institutional infrastructure' calls for a clear definition of the responsibilities of different authorities. The Commission is to receive periodically updated information and publish this in the Official Journal. This section also defines the responsibilities of the 'Radiation Protection Expert', the 'Radiation Protection Officer' (in the current BSS these concepts were merged within the function of 'Qualified Expert') and the 'Medical Physics Expert'.

Final provisions: a 2-year transposition deadline is deemed sufficient. Specific new features, such as the protection of the environment, can be transposed later. In line with the Euratom Treaty, the Basic Standards are to be uniformly applied in the Member States, though without prejudice to those requirements for which flexibility is clear from the wording of the text. However, dose limits, default exemption values, the reference level for building materials, etc. are explicitly intended for uniform transposition and application.

BUDGETARY IMPLICATIONS : there are no implications for the EU budget.

Basic safety standards for protection against the dangers arising from exposure to ionising radiation

2011/0254(NLE) - 25/09/2013 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted the report by Thomas ULMER (EPP, DE) on the proposal for a Council directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

The Committee on Employment and Social Affairs, exercising its powers as an associated committee under Rule 50 of the Rules of Procedure, was also consulted on this report.

Legal basis: Members propose a different legal basis to the one proposed by the Commission. They would like the proposal to be based on Article 192 (1) the Treaty on the Functioning of the European Union, rather than Articles 31 and 32 of the Treaty establishing the European Atomic Energy Community

They also note:

- Article 191 of the Treaty on the Functioning of the European Union (TFEU) provides the legal basis for preserving, protecting and improving the quality of the environment and protecting human health, including against dangers arising from exposure to ionising radiation.
- Article 153 TFEU allows for the establishment of safety standards to protect the health of workers and of the general public.
- Article 168 TFEU allows for the establishment of basic standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.

Purpose of the directive: the Directive establishes the basic safety standards for the protection of the health of workers, general public, patients and other individuals subject to medical exposure against the dangers arising from ionising radiation **for the purpose of guaranteeing a uniform threshold level of protection in Member States**. It sets out requirements for the control of the safety and security of radioactive sources and the provisions of **mandatory** information in an emergency exposure situation.

Scope: the Directive applies to any planned, existing, **accidental** or emergency exposure situation which involves a risk from exposure to ionising radiation with regard to the health protection of workers, members of the public, or patients and other individuals subject to medical exposure or with regard to the protection of the environment.

New provisions are introduced on : i) disposal of radioactive material and temporary or final radioactive waste storage; ii) practices exposing workers to cosmic radiation, including the operation of aircraft and spacecraft as well as frequent flying.

Members specify that **occupational exposure** means exposure of workers, including employees and self-employed as well as trainees and volunteers, incurred in the course of their work as well as **apprentices** aged 16 years or over

Interventional radiology: the proposal aims to cover interventional radiology within its scope, meaning the use of **X-ray imaging techniques**, in addition to those involving ultrasound or magnetic resonance imaging or other non-ionising radiation techniques, to introduce and guide devices in the body for diagnostic or treatment purposes. However, the Directive covers only high-dose radiological devices. This includes devices which employ a radiation dose higher than 100 Gy*cm².

Medical devices: in the area of medical exposure, Members propose to prevent duplication of work in connection with medical devices which give off ionising radiation, and considered that these medical devices should be dealt with under the Medical Devices Directive **(93/42/EEC),** which already lays down comprehensive monitoring and supervisory arrangements.

With regard to **testing of medical equipment**, in performing such testing, Member States shall comply with the Commission guidelines (in particular RP162)1 and European and international standards currently applicable to medical radiological equipment (IECTC62 on Electrical equipment in medical practice, IAEA Standards, ICRP Guidelines).

Protection of the environment against ionising radiation: the presence of radioactive substances in the environment has consequences for the health of the general public. In addition to direct environmental exposure pathways, the aim is to protect the environment as a whole, including the exposure of biota, within a comprehensive and coherent overall framework. However, **more resources should go to examining in detail the impact that ionising radiation has on both mankind and the environment**. Accordingly, Members deleted the corresponding provisions.

Minimum requirement: Members want Member States to establish legal requirements and an appropriate regime of regulatory control which, for all exposure situations reflect a system of radiation protection based on up-to-date, robust scientific evidence, following principles of **justification, optimisation, dose limitation and reparation for damages**. For each of these principles, new provisions are added in order to limit as much as possible the risk of exposure.

On **reparation for damages**, Members require the establishment of a mechanism which guarantees reparation for all physical damage and personal injury likely to be caused by an emergency at the installation before authorising the construction of a nuclear installation or renewing its operating licence.

Consultation with workers: for occupational exposure, the dose constraint shall be established in consultation with workers' representatives.

Organisational measures to minimise the risk of exposure: similarly, Members propose to strengthen the provision enabling better regulation of the procedures regarding exposure for workers so as to minimize risk as much as possible. The text provides for other measures regarding training and organisation.

Information for the public: Members feel that the public should be better informed of the risks and doses to which it is exposed. The values chosen for the dose constraints must be published, so that any member of the public can check that he or she has not received, as a result of aggregate planned and existing anthropic exposure situations, a dose in excess of the legal limit.

There are also provisions regarding informing the public in **emergency situations**. In such cases, Member States must publish all information necessary for an assessment of the situation and its development – in particular weather data and forecasts, air movements and ground deposits, ambient dose rates and contamination levels of critical foodstuffs

Member States must ensure that members of the public likely to be affected in the event of an emergency are given information about the health protection measures applicable to them and about the action they should take in the event of such an emergency. This shall concern, at the very least, people living **within 50km of an installation at risk**.

Stakeholders: the committee requires that Member States ensure that all stakeholders, in particular the persons likely to be affected by the health impact of the practice, whether in normal operating circumstances or in an emergency, are involved in the decision-making process. That involvement must be arranged sufficiently far ahead of the deadline for a decision so that alternative solutions can be properly studied. This type of provisions also applies to revision of the relevant legislation.

Penalties: the report states that Member States shall prohibit and sanction the addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics, and, more generally, in consumer goods, and shall prohibit the import or export of such products.

Monitoring by Member States: there are new provisions strengthening the level of monitoring for non-medical imaging exposure. In addition, Member States must specify the information which the undertaking is required to provide in order to enable the competent authority to assess the levels of exposure of members of the public and workers and the radiological risks, in normal and emergency situations.

Stricter provisions: should a Member State plan to adopt standards stricter than those laid down by this Directive, it must inform the Commission and the other Member States accordingly.

Annexes: lastly, the committee amended the annexes to the proposal to correspond to the amendments in the body of the text.

Basic safety standards for protection against the dangers arising from exposure to ionising radiation

2011/0254(NLE) - 24/10/2013 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 455 votes 102 with 20 abstentions, a legislative resolution on the proposal for a Council directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

The main amendments adopted in plenary were as follows:

Change of legal basis: in an amendment adopted by 305 votes to 263 with 5 abstentions, Parliament proposed a new legal basis in place of the one envisaged by the Commission in its proposal. Parliament wanted the proposal to be based on Article 192 (1) TFEU and not Articles 31 and 32 of the Treaty establishing the European Atomic Energy Community.

Members also note:

- Article 191 of the Treaty on the Functioning of the European Union (TFEU) provides the legal basis for preserving, protecting and improving the quality of the environment and protecting human health, including against dangers arising from exposure to ionising radiation.
- Article 153 TFEU allows for the establishment of safety standards to protect the health of workers and of the general public.
- Article 168 TFEU allows for the establishment of basic standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.

Purpose of the directive: Parliament specified that the draft directive must aim to establish the basic safety standards for the protection of the health of workers, general public, patients and other individuals subject to medical exposure against the dangers arising from ionising radiation for the purpose of **guaranteeing a uniform threshold level of protection in Member States**, **without barring Member States from maintaining or establishing higher basic safety standards than set out in the Directive**.

The latter also set out requirements for the control of the safety and security of radioactive sources and the provisions of **mandatory** information in an emergency exposure situation.

Scope: Parliament made a series of amendments to the scope of the proposal so that the Directive might apply to any planned, existing, **accidental or emergency exposure** situation which involves a risk from exposure to ionising radiation with regard to the health protection of workers, members of the public, or patients and other individuals subject to medical exposure or with regard to the protection of the environment.

New provisions were introduced on: i) disposal of radioactive material and temporary or final radioactive waste storage; ii) practices exposing workers to cosmic radiation, including the operation of aircraft and spacecraft as well as frequent flying. On the other hand, the plenary rejected the amendment proposed by its competent committee providing for awareness-raising regarding the potential risks of cosmic radiation on **citizens** who flew frequently.

Members specified that **occupational exposure** means exposure of workers, including employees and self-employed as well as trainees and volunteers, incurred in the course of their work as well as **apprentices** aged 16 years or over.

Medical devices: in the area of medical exposure, Parliament proposed to prevent duplication of work in connection with medical devices which gave off ionising radiation, and considered that these medical devices should be dealt with under the Medical Devices Directive (93/42/EEC), which already lays down comprehensive monitoring and supervisory arrangements.

With regard to testing of medical equipment, Parliament specified that in performing such testing, Member States must comply with the Commission guidelines (in particular RP162)1 and European and international standards currently applicable to medical radiological equipment (IECTC62 on Electrical equipment in medical practice, IAEA Standards, ICRP Guidelines).

Contrary to the amendments made by its competent committee, Parliament retained the Commission's proposals on interventional radiology.

Protection of the environment against ionising radiation: the draft directive stated that the presence of radioactive substances in the environment has consequences for the health of the general public. In addition to direct environmental exposure pathways, the aim was to protect the environment as a whole, including the exposure of biota, within a comprehensive and coherent overall framework. However, Parliament felt that more resources should go to examining in detail the impact that ionising radiation has on both mankind and the environment. Accordingly, Members deleted the corresponding provisions.

Minimum requirement: Parliament asked Member States to establish legal requirements and an appropriate regime of regulatory control which, for all exposure situations reflect a system of radiation protection based on up-to-date, robust scientific evidence, following principles of justification, optimisation, dose limitation and reparation for damages. For each of these principles, new provisions were added in order to limit as much as possible the risk of exposure.

With regard specifically to:

- **dose limitation**, Parliament required that the sum of doses received by a member of the public from all regulated radiation sources and all existing anthropic exposure situations must not exceed the dose limits laid down for public exposure. The sum of doses to an exposed worker from all regulated radiation sources must not exceed the dose limits laid down for occupational exposure. **These dose limits will not apply to medical exposures**;
- **reparation for damages**, Parliament required the establishment of a mechanism which guarantees reparation for all physical damage and personal injury likely to be caused by an emergency at the installation before authorising the construction of a nuclear installation or renewing its operating licence.

Organisational measures to minimise the risk of exposure: Parliament proposed to strengthen the provision enabling better regulation of the procedures regarding exposure for workers so as to minimize risk as much as possible. The text provides for other measures regarding training and organisation.

Information for the public and the limit of a dose: Members feel that the public should be better informed of the risks and doses to which it is exposed. The values chosen for the dose constraints must be published, so that **any member of the public** can check that he or she has not received, as a result of aggregate planned and existing anthropic exposure situations, a dose in excess of the legal limit (this being **1mSv per year**.)

There are also provisions regarding **informing the public in emergency situations**. In such cases, Member States must publish all information necessary for an assessment of the situation and its development – in particular weather data and forecasts, air movements and ground deposits, ambient dose rates and contamination levels of critical foodstuffs

Member States must ensure that members of the public likely to be affected in the event of an emergency are given information about the health protection measures applicable to them and about the action they should take in the event of such an emergency. This shall concern, at the very least, people living within **50km of an installation at risk**.

Stakeholders: Parliament required that Member States ensure that all stakeholders, in particular the persons likely to be affected by the health impact of the practice, whether in normal operating circumstances or in an emergency, were involved in the decision-making process. That involvement must be arranged sufficiently far ahead of the deadline for a decision so that alternative solutions could be properly studied. This type of provisions also applied to revision of the relevant legislation.

Penalties: Parliament stated that Member States must prohibit and sanction the addition of radioactive substances in the production of foodstuffs, toys, personal ornaments and cosmetics, and, more generally, in consumer goods, and must prohibit the import or export of such products.

Monitoring by Member States: there are new provisions strengthening the level of monitoring for **non-medical imaging exposure**. In addition, Member States must specify the information that the undertaking is required to provide in order to enable the competent authority to assess the levels of exposure of members of the public and workers and the radiological risks, in normal and emergency situations.

Stricter provisions: should a Member State plan to adopt standards stricter than those laid down by this Directive, it must inform the Commission and the other Member States accordingly.

Annexes: lastly, Parliament amended the annexes to the proposal to correspond to the amendments in the body of the text.

Basic safety standards for protection against the dangers arising from exposure to ionising radiation

2011/0254(NLE) - 05/12/2013 - Final act

PURPOSE: to lay down laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

NON LEGISLATIVE ACT: Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

CONTENT: this Directive brings **together five Council Directives in a single Directive.**

The five Directives are:

- Council Directive 96/29/Euratom laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation. This establishes uniform basic safety standards against the dangers of radiation and applies to all practices which involve a risk from ionising radiation.
- Directive on protection in relation to medical exposure (97/43/Euratom),
- Directive on the control of high-activity sealed radioactive sources and orphan sources (2003/122/Euratom)
- Directive on the operational protection of outside workers (90/641/Euratom),
- Directive on informing the general public (89/618/Euratom).

Objective: the Directive establishes uniform basic safety standards for the protection of the health of individuals subject to **occupational, medical and public exposures** against the dangers arising from ionising radiation.

Scope: the Directive applies to **any planned, existing or emergency exposure situation** which involves a risk from exposure to ionising radiation which cannot be disregarded from a radiation protection point of view or with regard to the environment in view of long-term human health protection.

It applies in particular to:

- the manufacture, production, processing, handling, disposal, use, storage, holding, transport, import to, and export from the Community of **radioactive material**;
- the manufacture and the operation of **electrical equipment emitting ionising radiation** and containing components operating at a potential difference of more than 5 kilovolt (kV);
- human activities which involve the presence of **natural radiation sources** that lead to a significant increase in the exposure of workers or members of the public, in particular: (i) the operation of aircraft and spacecraft, in relation to the exposure of crews; (ii) the processing of materials with naturally-occurring radionuclides;
- the exposure of workers or members of the public to **indoor radon**, the external exposure from building materials and cases of lasting exposure resulting from the after-effects of an emergency or a past human activity;
- the preparedness for, the planning of response to and the management of emergency exposure situations that are deemed to warrant measures to protect the health of members of the public or workers.

Exclusion from the scope: the Directive does not apply to exposure to the natural level of radiation, such as radionuclides contained in the human body and cosmic radiation prevailing at ground level, or exposure of members of the public or workers other than air or spacecrew to **cosmic radiation in flight or in space**.

System of radiation protection: Member States shall establish legal requirements and an appropriate **regime of regulatory contro**l which, for all exposure situations, reflect a system of radiation protection based on the principles of:

1. **justification:** decisions introducing a practice shall be justified in the sense that such decisions shall be taken with the intent to ensure that the individual or societal benefit resulting from the practice outweighs the health detriment that it may cause;
2. **optimisation:** exposure and the number of individuals exposed must be as low as reasonably achievable taking into account the current state of technical knowledge;
3. **dose limitation**: in planned exposure situations, the sum of doses to an individual shall not exceed the dose limits laid down for occupational exposure or public exposure. Dose limits shall not apply to medical exposures.

Optimisation of exposure: the directive lays down **dose constraints** for occupational, public, and medical exposure for the purpose of **prospective optimisation of protection**. Reference levels are established for exposure situations, which must not be exceeded.

Dose limitation: a series of provisions are laid down to **prevent or limit exposure** to certain categories of workers: (i) workers under age 18; (ii) pregnant or breastfeeding women; (iii) apprentices and students.

Specific provisions have been laid down:

- **for occupational exposure**: Member States shall ensure that dose limits for occupational exposure apply to the sum of **annual occupational exposures** of a worker from all authorised practices. The limit on the effective dose for occupational exposure shall be **20 mSv in any single year** (with some exceptions to this rule);
- **for public exposure**: Member States shall set the limit on the effective dose for public exposure at 1 mSv in a year;
- **for medical exposure**: Member States shall ensure that all doses due to medical exposure for radiodiagnostic, interventional radiology, planning, guiding and verification purposes are **kept as low as reasonably achievable** consistent with obtaining the required medical information, taking into account economic and societal factors.

Other protection measures:

- **Information and training**: the Directive lays down requirements for radiation protection education, training and information. Member States shall establish an **adequate legislative and administrative framework** ensuring the provision of appropriate radiation protection education, training and information to all individuals whose tasks require specific competences in radiation protection.
- **Justification and regulatory control of practices**: Member States should be required to submit certain practices involving a hazard from ionising radiation to a system of regulatory control or to prohibit certain practices. The application of radiation protection principles in relation to **consumer products** requires the regulatory control of practices to start at the stage of design and manufacture of products or at the time of import of such products. Therefore, the manufacture or import of consumer products should be regulated and specific procedures should be introduced. It should be noted that Member States shall **prohibit the deliberate addition of radioactive substances in certain consumer products** (such as foodstuffs, animal feeding stuffs, cosmetics, toys and personal ornaments) and shall prohibit the import or export of such products.
- **Graded approach to regulatory control**: Member States shall require practices to be subject to regulatory control for the purpose of radiation protection, by way of notification, authorisation and **appropriate inspections**, commensurate with the magnitude and likelihood of exposures resulting from the practice, and commensurate with the impact that regulatory control may have in reducing such exposures or improving radiological safety.

Exemptions: Member States should be able to grant specific exemption from authorisation for certain practices involving activities above the exemption values.

ENTRY INTO FORCE: 06.02.2014.

TRANSPOSITION: 06.02.2018.