

Manual of European Environmental Policy

The following pages are a section from the Manual of European Environmental Policy written by the Institute for European Environmental Policy.

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This section is the text of the Manual as published in 2012. It is therefore important to note the following:

- The contents have not been updated since 2012 and no guarantee is given of the accuracy of the contents given potential subsequent developments.
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Safety standards for radiation

Note: Directive [80/836/EURATOM](#) (OJ L246 17.09.80), with amendment [84/467/EURATOM](#) (OJ L265 5.10.84), Directive [59/211/EURATOM](#) (OJ L11 20.02.59), with amendments [62/1633/EURATOM](#) (OJ L57 09.07.62), [66/3693/EURATOM](#) (OJ L216 26.11.66), [76/579/EURATOM](#) (OJ L187 12.07.76) and [79/343/EURATOM](#) (OJ L83 03.04.79), were repealed by Directive [96/29/EURATOM](#) on 13 May 2000. Directive [84/466/EURATOM](#) (OJ L265 05.10.84) was repealed by Directive [97/43/EURATOM](#) on the same date.

Formal references	
90/641/EURATOM (OJ L349 13.12.1990)	Directive on the operational protection of outside workers exposed to the risk of ionizing radiation during their activities in controlled areas
Proposed 21.12.90 – COM(89)376	
96/29/EURATOM (OJ L159 29.6.1996)	Directive laying down basic safety standards for the protection of the health of the workers and the general public against the dangers arising from ionizing radiation
Proposed 20.7.93 – COM(93)349 and 11.07.94 – COM(94)298	
97/43/EURATOM (OJ L180 9.7.1997) Proposed 26.9.1996 – COM(96)465	Directive on protection against dangers of ionizing radiation in relation to medical exposure
2003/122/EURATOM (OJ L346 31.12.2003) Proposed 24.1.2003 – COM(2003)18	Directive on the control of high-activity sealed radioactive and orphan sources
2009/71/EURATOM (OJ L172/18 2.7.2009) Proposed 26.11.2008 - COM(2008)790	Directive establishing a Community framework for the nuclear safety of nuclear installations
2011/70/EURATOM (OJ L 199/48 19.7.2011) Proposed- 3.11.2010 - COM(2010)618	Directive establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste
Binding dates	
Entry into force (96/29) and (97/43)	13 May 2000
Entry into force (03/122)	31 Dec 2003
Entry into force (2009/71)	22 July 2009
Transposition (2009/71)	22 July 2011
Entry into force(2011/70)	23 August 2011
Transposition (2011/70)	23 August 2013
National Programme content notified to the Commission by	23 August 2015
Legal base	Article 30 EURATOM

Purpose of the Directives

The EURATOM Treaty provides a framework of rules to promote the speedy development of nuclear industries. Article 2(b) calls for uniform basic safety standards to be created and applied, in order that risks to the health of workers and the general public are kept to acceptable levels. Article 30 provides the powers to lay down basic standards.

Summary of the Directives

The original Directive [80/836/EURATOM](#) applied to the production, processing, handling, use, holding, storage, transport and disposal of radioactive substances, and to any other activity involving a danger of ionizing radiation. It did not apply to natural sources of radiation, unless they resulted from industrial operations.

The Directive placed a duty on Member States to ensure that exposure to ionizing radiation was based on three basic principles of radiation protection:

- various types of activity resulting in exposure must be justified in advance by the advantage produced – the ‘justification principle’;
- all exposure must be kept as low as reasonably achievable – the ‘optimization principle’;
- the sum of doses received should not exceed the limits set out in the Directive.

The dose limits given in the Directive were to be interpreted in relation to these principles. They were not targets, but maximum limits beyond which exposure should not go. The annual effective dose limit was 50 mSv (5 rems) for exposed workers and 5 mSv (0.5 rems) for members of the general public. The justification and optimization principles involved taking account of wider considerations before emission sources were established.

The Directive prescribed an operational framework, involving the establishment, by Member States, of a system of surveillance, inspection and intervention. This included the requirement for Member States to introduce a system of compulsory reporting and prior authorization for activities involving ionizing radiation, unless specifically exempted. The methods of dose evaluation set out in the Directive did not have to be followed, as long as limits set down were complied with.

Exposed workers

Workers were divided into categories depending on acceptable exposure levels. Pregnant and nursing women, and women of reproductive capacity, had lower dose limits. Workers under the age of 18 years could not be exposed at all. Other limits for students and apprentices, and for partial body exposure, were also set out. For purposes of surveillance, distinctions were made between workers in category A, who could not be subjected to special exposures, and category B workers.

Working areas with a risk of exposure of more than one-tenth of the specified annual dose limit had to be monitored to a degree depending on the extent of hazard present. Controlled areas, where exposure could be greater than three-tenths of the annual dose limit, had to be delineated and required some control of access, as well as indication of the hazards present.

Supervised areas did not require delineation, but alongside controlled areas, they had to be covered by radiological environmental surveillance, have appropriate working instructions laid down and have signs on display indicating the presence of sources. Qualified experts were to be responsible for surveillance and protection devices and had to examine acceptability of installations, and the effectiveness of protection and measuring instruments.

Medical surveillance was to be based on pre-employment examination and periodic reviews of health and levels of actual exposure, as deemed necessary by an approved medical officer. Where findings were unfavourable, work involving exposure was not to be permitted to continue. More thorough medical surveillance was stipulated for category A workers. Records of exposure and collective monitoring were to be kept in archives for a period of 30 years following the termination of employment involving exposure.

Accidental or emergency exposures were also to be recorded, where possible on a separate exposure record.

Workers employed by outside undertakings were not adequately protected by the provisions of Directive 80/836/EURATOM. Instead Directive 90/641/EURATOM lays down standards specifically for the protection of outside workers exposed to the risk of ionizing radiation.

Exposed population

Provisions were to be adopted for adequate detection and elimination of factors which cause unjustifiable risks to the population. Member States were to establish a system of inspection to ensure that the health of the population, and reference groups of that population, could be supervised. Health surveillance was to be based on doses received, taking into account the quality and state of the radioactive contaminants as well as compliance with the limits set out. Protective equipment and safety arrangements were to be tested periodically and intervention plans established in case of emergencies.

More stringent requirements for sources of ionizing radiation were set out in Directive 84/466/EURATOM laying down basic measures for the protection of persons from medical exposure. This Directive was repealed on 13 May 2000 by Directive 97/43/EURATOM which introduced a more comprehensive system of health protection in relation to medical exposure.

Directive 96/29/EURATOM

This Directive came into effect on 13 May 2000, at which time previous Directives laying down basic safety standards for the health of the general public and workers against the dangers of ionizing radiation were repealed. The Directive contains effective dose limits, for exposed workers, of 100 mSv in a consecutive five-year period, subject to a maximum effective dose of 50 mSv in any single year. Safeguards apply to all practices involving ionizing radiation emanating from artificial sources and natural sources where these are or have been processed in view of their radioactive, fissile or fertile properties. Furthermore, the Directive provides for material to be released from regulatory control if it is of no radioactive concern from a human health point of view. Member States determine the 'clearance levels', according to criteria in the Directive.

Guidance on implementing the new Directive is set out in a Commission Communication ([COM\(98\)155](#)).

Directive 03/122/EURATOM

This Directive aims to prevent exposure of workers and the public to ionizing radiation arising from inadequate control of high-activity sealed radioactive sources and orphan sources and to harmonize controls in place in the Member States by defining specific requirements ensuring that each such source is kept under control. Member States may exclude sources from the scope of this Directive once their activity has fallen below the exemption levels specified in Directive 96/29/EURATOM. The Directive is to supplement Directive 96/29/EURATOM with a view to strengthen the control by the competent national authorities on those sealed radioactive sources posing the greatest risk and to emphasize the responsibilities of holders of such sources.

Directive 2009/71/EURATOM

This Directive establishes a Community framework for the nuclear safety of nuclear installations, setting binding principles to enhance nuclear safety to protect workers, the general public and the environment. The Directive increases the role and independence of national regulatory authorities. It also makes it clear that the prime responsibility for nuclear safety of a nuclear installation lies with the license holder and that this responsibility cannot be delegated. The Directive has to be transposed by the Member States by 22 July 2011.

Directive 2011/70/EURATOM

This Directive establishes a Community framework for ensuring responsible and safe management of spent fuel and radioactive waste. It requires Member States to provide appropriate national arrangements for a high level of safety in spent fuel and radioactive waste management and at the same time ensure necessary public information and participation. In relation to this each Member State is required to set up a national programme. Article 12 of the Directive sets out what ought to be included in these national programmes. Through this Directive internationally agreed safety standards will become legally binding and enforceable. The Directive sets also requirements on nuclear waste exports, aspects of which are discussed in more detail in the section on Shipment of Radioactive Waste

Development of the Directives

It is by virtue of chapter III of the EURATOM Treaty, titled ‘Health and Safety’ that the Council adopted Directive 59/221/EURATOM, and thus stipulated the administrative provisions necessary to comply with the Treaty. Compliance with the basic standards is facilitated by Article 35 of the Treaty, which stipulates that Member States establish facilities for the continuous monitoring of radioactivity levels. There is an accompanying right of access for the Commission to verify the operation and efficiency of these procedures.

In developing its proposals, the Commission has adopted standards based on recommendations of experts referred to in Article 31 of the EURATOM Treaty. The Article 31 Group of Experts based the system of principles and values primarily on the scientific

recommendations of the International Commission for Radiological Protection (ICRP) to encourage conformity between Community and non-Community countries. The basic principles underlying the first Directive 59/221/EURATOM have not been challenged, but have developed to permit improved organization of radiological protection. Since 1959, there have been several amendments in accordance with Article 32 of the Treaty, which allows for revisions at the request of the Commission or Member States. The Commission's role in harmonizing Community standards has become increasingly difficult due to the frequency of change in scientific knowledge and the corresponding need for amendments. For example, the compliance date for the ICRP Publication 9 (1966) was pushed back to June 1980 by the 79/343/EURATOM amendment, despite the reservations of the European Parliament. The slow development and adoption of amended standards was blamed by the Group of Experts in 1980 (COM(80)808) on the inclusion of too many complex administrative requirements. The Group recommended that it would be more beneficial to focus on more general principles, objectives and standards to be reached.

Directive 80/836/EURATOM was a complete re-write of the earlier Directives and it brought EC legislation into line with the 1977 ICRP recommendations, introducing the concepts of justification and optimization of exposure, although national legislation was not adapted in many Member States until 1986. The changes made in 1984 primarily related to the technical annexes I and III, and to the dose limits of the lens of the eye, and were in response to further ICRP recommendations.

Member States can set limits stricter than those set at Community level according to a Decision by the European Court of Justice (ECJ) (Case number [C-376/90](#)). However, there is a duty under Article 33 of the Treaty that Member States refrain from adopting any standards of their own before the Commission commented on them and the Commission has issued Recommendation [91/444/EEC](#) reminding Member States of that obligation.

In 1993, following prolonged consultation with various groups of scientific experts, the Commission presented a proposal ([COM\(93\)349](#)) to revise the standards set out in Directive 80/836/EURATOM. The proposal took account of revisions to estimates of the risk from exposure to ionizing radiations and international recommendations on how to achieve the related necessary improvement in protection. The resulting Directive 96/29/EURATOM on basic safety standards reflects these revisions, in particular those expressed in Recommendation No 60 of the ICRP in 1991. Contrary to initial intentions, the Directive did not subsume Regulation (EURATOM) No [1493/93](#) on shipments of radioactive substances.

In 2009, after consultation with experts appointed by the Scientific and Technical Committee, the Commission presented a proposal for a Community framework for the nuclear safety of nuclear installations. This would update and replace the 2002 Commission proposal for a Directive setting out basic obligations and general principles on the safety of nuclear installations, included in the initial Nuclear Safety Package. The new Directive was needed, according to the Commission, because the renewed interest in nuclear power in many Member States, and the fact that dangers arising from this do not stop at borders, required that the public get the additional guarantee of having international nuclear safety principles bound in Commission legislation. It resulted in Directive 2009/71/EURATOM.

On 3 November 2010, the European Commission presented the Proposal for a Directive on the management of spent fuel and radioactive waste ([COM\(2010\)618](#)), six years after the first Proposal ([COM\(2004\)526](#)), which Member States decided not to take further. However in

2009 the European Council and the European Parliament called on the European Commission to submit a new proposal for a Directive on Radioactive Waste Management and, after long negotiations and a public consultation, the Proposal was published in November 2010. The Proposal advocated a complete export ban but this requirement did not survive to the final Directive (see section on Shipment of Radioactive Waste)

Implementation of the Directives

In 1998 the Commission issued a communication ([COM/98/0087](#)) on the implementation of Directive 96/29/EURATOM. However no information on the implementation of this Directive in the Member States is available at present, other than that available in the court cases below.

Member States are required to report on their experiences with Directive 2003/122/EURATOM by 31.12.2010.

Enforcement and court cases

The following cases in the ECJ are relevant to this legislation:

Directive 90/641/EURATOM

- [C-146/01](#) 6/6/2002. This was a judgement against Belgium for failure to transpose Directive 90/641/EURATOM. The Commission claimed that the Kingdom of Belgium had not completely transposed, first, Article 4(2) of Directive 90/641/EURATOM, and Annexes I and II thereto, owing to the lack of national provisions for putting in place a system of radiological monitoring, and, secondly, Articles 5 and 6 of that Directive, inasmuch as the national provisions adopted did not take account of outside workers employed by undertakings established in another Member State, when such workers are already holders of an individual radiological monitoring document. The Belgian authorities maintained essentially that the Royal Decree of 2 October 1997 enabled the transposition of Directive 90/641/EURATOM to be completed. The court found however that the Belgian national legislation did not comply with Articles under the Directive.

Directive 96/29/EURATOM

- [C-376/90](#) 25/11/1992. This was a case between the Commission and Belgium over its transposition of Directive 80/836/EURATOM. The Belgian government had fixed dose limits at a higher level than had been laid down in the Directive, and the Commission argued that this entailed the incorrect transposition of the Directive by Belgium. The court eventually ruled that the Directive allows Member States to set limits stricter than those it set down.
- [C-155/06](#) 8/7/2007. This was a judgment against the United Kingdom for failing to transpose Directive 96/29/EURATOM within the prescribed time.

Directive 2009/71/EURATOM

- [C-29/99](#). This was a dispute between the Commission and the Council over the compatibility of The Convention on Nuclear Safety with the Euratom treaty. As a result of the proceedings the court decided 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’. This ruling paved the way for Directive 2009/71/EURATOM.

Related legislation

The following legislation is relevant to the Directives:

- Regulation (EURATOM) No [1493/93](#) on shipments of radioactive substances between Member States.
- Regulation (EURATOM) No [86/156/EEC](#) on emergency food protection.