Procedure file

Basic information

CNS - Consultation procedure Directive	2003/0005(CNS)	Procedure completed
Public health: high activity sealed radioactive sources, management and control Repealed by 2011/0254(NLE) Subject 3.60.04 Nuclear energy, industry and safety 3.70.08 Radioactive pollution 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport)		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy		22/04/2003
		PPE-DE GROSSETÊTE Françoise	
	Committee for opinion	Rapporteur for opinion	Appointed
	ITRE Industry, External Trade, Research, Energy	The committee decided not to give an opinion.	
	EMPL Employment and Social Affairs	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Environment	2556	22/12/2003
European Commission	Commission DG	Commissioner	
	Environment	DIMAS Stavros	

Key events

24/01/2003	Legislative proposal published	COM(2003)0018	Summary
10/02/2003	Committee referral announced in Parliament		
03/11/2003	Vote in committee		Summary
03/11/2003	Committee report tabled for plenary, 1st reading/single reading	A5-0363/2003	
18/11/2003	Decision by Parliament	T5-0489/2003	Summary
22/12/2003	Act adopted by Council after consultation of Parliament		
22/12/2003	End of procedure in Parliament		
31/12/2003	Final act published in Official Journal		

Technical information

Procedure reference	2003/0005(CNS)

Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Directive
	Repealed by 2011/0254(NLE)
Legal basis	Euratom Treaty A 031-p2; Euratom Treaty A 032
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/19172

Documentation gateway

Legislative proposal		COM(2003)0018	24/01/2003	EC	Summary
Committee draft report		PE331.645	22/05/2003	EP	
Committee report tabled for plenary, 1st reading/single reading		A5-0363/2003	03/11/2003	EP	
Text adopted by Parliament, 1st reading/single reading		T5-0489/2003 OJ C 087 07.04.2004, p. 0021-0041 E	18/11/2003	EP	Summary
Follow-up document		COM(2015)0158	16/04/2015	EC	Summary
Follow-up document		SWD(2015)0084	16/04/2015	EC	

Additional information

European Commission	EUR-Lex

Final act

Directive 2003/122
OJ L 346 31.12.2003, p. 0057

Public health: high activity sealed radioactive sources, management and control

PURPOSE : to prevent exposure to ionising radiation arising from inadequate control of high activity sealed radioactive sources and to harmonise controls in place in the Member States by setting out specific requirements ensuring that each such source is kept under control. CONTENT : the background to this proposal is that the radiation protection authorities worldwide are confronted by the issue of correct management of radiation sources, especially high activity sealed radioactive sources. The sources at greatest risk of being lost from regulatory control are disused sources held in local storage at the users' premises. The Commission estimates that there are about 30 000 such sources throughout the EU. The health and economic consequences of possible accidents involving inadequately controlled radiation sources may be particularly severe. The Commission proposes the adoption of specific legislation, based on the Euratom Treaty, supplementing the Basic Safety Standards Directive with a view to strengthening the control by the competent national authorities on those sealed radioactive sources posing the greatest risk and to emphasise the responsibilities of holders of such sources. Council Directive 96/29/Euratom sets out a number of provisions that, would prevent the risks connected with the manufacture, use and disposal of high activity sealed sources. However, with respect to potentially highly dangerous sources, additional Community provisions is needed to further reduce the likelihood of accidents involving such sources. The proposal extends to the whole European Union the most effective practices applied by some Member States. The main points of the proposal are as follows: - basically, it applies to sealed sources giving a dose rate in the order of more than 1 mSv/h at one meter distance. The resulting activity of the source depends on the radionuclides and on the quality of the radiation emitted. Such activity for the radionuclides most utilised in sealed sources is given in Annex 1. - prior authorisation is required for any practice involving a high activity source. Before issuing an authorisation, the competent authorities must ensure that arrangements have been made not only for the safe use of the source, but also for its proper management when it becomes disused. It is in fact proven that the sources most at risk of creating accidents are those that are no longer in active use and whose safe management tends to be neglected. It is therefore necessary to ensure that the control continues until the source has been transferred for its recycling, reuse or disposal under controlled conditions. - financial provisions must be made for the management of the disused sources. One element that sometimes prevents sources from being transferred for disposal is the cost of the disposal that would be normally requested to the last holder of the source. It is therefore necessary that, before the source is used in the practice from which the holder expects to obtain a benefit, financial provisions are made for the end of life of the source. - a standard record sheet must kept by holders of sources with information on the holder of the source, checks and testsperformed on the source, and its transfers. - the holder must make an annual return to the competent authorities. Failure to report indicates that the sources may be at risk. - there are common requirements for holders such as leak tests, and an obligation to notify in the event of theft or loss. - the manufacturer

must identify each high activity source by a unique number. - there are provisions on training for relevant workers handling high sources or being in the proximity of these sources. - competent authorities must be prepared to recover orphan high activity sources and to deal with radiological emergencies. - Member States must establish a system of guarantee for damage to human health caused by high activity sources as well as for the costs of interventions relating to them.?

Public health: high activity sealed radioactive sources, management and control

The committee adopted the report by Françoise GROSSETÊTE (EPP-ED, F) broadly approving the proposal under the consultation procedure, subject to a few amendments: - for the sake of clarity, the threshold of 1 mSv/h should be inserted in the articles since it appears in the explanatory memorandum and the annex; - there is a need to highlight the supplier's responsibility, as the technical expert, in the life cycle of the various sources which he makes available; - it should be made compulsory to monitor potential cross-border movements of these sources both within the EU and to non-EU countries; - as far as possible, there should be a system of harmonised penalties for infringements. ?

Public health: high activity sealed radioactive sources, management and control

The European Parliament adopted the resolution drafted by Françoise GROSSETETE (EPP-ED, France) and made some amendments to the proposal. (Please see the document dated 03/11/03.) ?

Public health: high activity sealed radioactive sources, management and control

The Commission presents a report on the experience gained in the implementation of Directive 2003/122/EURATOM on the control of high-activity sealed radioactive sources and orphan sources.

The Directive, which was adopted following the 2001 terrorist attacks in the United Stes, puts in place a legal framework for ensuring control and security of high-activity sealed radioactive sources (HASS) in Europe and obliges the Member States to establish systems for detecting orphan radioactive sources and to recover radioactive sources left from past activities.

High-activity sealed radioactive sources are containers of encapsulated radioactive material whose activity is above the limit specified in the Directive 2003/122/Euratom. They are used mostly in medicine, in non-destructive material testing and for sterilisation purposes. A typical HASS holder is a hospital, an industrial testing company or a research institute. There are a few companies manufacturing HASS in Europe, although most of the commercial sources originate from the USA or Canada. Nine Member States have an inventory of less than 100 HASS.

Satisfactory implementation: in general, the report notes that the HASS Directive has been implemented well in the EU. The objectives of the Directive have been met and there is no reason to believe that the high-activity sealed sources would not be subject to sufficient control in any of the EU Member States. The number of HASS-related inquiries to the Commission over the years has been low, indicating that the Directive requirements are well understood and accepted.

However, there still are significant differences in implementation practices among the EU Member States.

The area of most difficult implementation is the organisation of search campaigns for possible orphan sources left from past practices. In addition there are some inconsistencies in the implementation of HASS-definition, financial security of sources, training of potentially exposed personnel and source control practices.

Based on the analysis of the HASS Directive, the report makes several recommendations to Member States in order to improve implementation:

- the need to organise systematic or dedicated orphan sources recovery campaigns should be assessed in those Member States which have not yet organised such campaigns;
- the national regulatory framework could define a maximum tolerated delay of a few days within which the relevant authority must be notified of any modification of the HASS status;
- Member States using the definition of HASS as given in the current Directive should apply their national HASS provisions until the source has decayed below the exemption/clearance levels and not until the source activity has fallen below the high-activity levels.
- the type and frequency of tests to be performed by the HASS holders should be defined in the Regulation or follow guidance elaborated by the regulatory body;
- the documentation accompanying the HASS should also be checked during inspections to verify its completeness as regards the requirements of the HASS Directive;
- the maximum allowable time for storage before mandatory transfer could be laid down in national regulations;
- national regulations should insist on the organisation of training sessions of persons in installations where orphan sources are more likely to be found.

The report sets out several examples of best practices in the implementation of the Directive: (i) licensing process in the management of HASS; (ii) prompt notification to the authority of any change in the status of HASS; (iii) announced and unexpected inspections; (iv) HASS holders staff training programme; (v) defining in a regulation a reasonable maximal period for removal of disused sources from users premises, e.g. max. 2 years; (vi) enactment of specific provisions regulating the security and physical protection of HASS; (vii) identification of strategic locations at which orphan sources are likely to be found.

New directive: HASS Directive has been repealed by the Directive 2013/59/Euratom (the new Basic Safety Standards Directive), which incorporates the main provisions of the Directive and harmonises them with the IAEA guidance on radioactive sources. Member States have until 6 February 2018 to transpose the new BSS Directive into their national legislation. The new Directive represents a major revision of the whole EU radiation protection legal framework. Chapters concerning HASS fit well in this framework.

The HASS Directive has been well accepted by the EU Member States and there was no need for major modifications in the HASS control. However, the new Directive corrects several deficiencies of the HASS Directive. In particular, the harmonisation achieved with the IAEA regulations places the EU Member States in a good position to fulfil both EU and IAEA requirements on the control of high activity sealed sources and orphan sources.

The Commission encourages each Member State to take into account the content of this report, especially the best practices identified, when redrafting the national regulations and guidance on safety and security of radioactive sources in fulfilling its obligation to transpose the new Directive 2013/59/Euratom.