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

2003/0005(CNS) - 16/04/2015 - Follow-up document

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 holder's 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.