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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

Experience gained in the implementation of Directive 2003/122/EURATOM on the control of high-activity sealed radioactive sources and orphan sources

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Contents

1. INTRODUCTION

In the aftermath of the 2001 terrorist attacks in the USA many national security organisations expressed concern that terrorist groups could use radioactive sources as a weapon to create fear and public disorder. Both the International Atomic Energy Agency and the European Union took action to put in place international legal framework for ensuring safety and security of these sources, especially the ones with the highest activity.

Directive 2003/122/Euratom ('HASS Directive') [1] entered into force on 31 December 2003 and its legal enactment period ended two years later. The Directive 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. Each EU Member State has designated a competent authority to carry out tasks in accordance with the Directive [2,3].

Article 14 of the HASS Directive requires the Commission to report on the experience gained in the implementation of the Directive. An implementation review has been carried out in order to provide an overview of the situation in the EU on (1) the control of high activity sources in use, (2) the management of disused sources and (3) strategies for handling orphan sources[1]. It is based on Member States' national HASS Directive implementation reports, questionnaires, interviews and fact-finding missions among the European stakeholders[2]. The review results indicate variable practices in the practical implementation of the Directive requirements. Some States have very advanced HASS control arrangements and administration, whereas some States fulfil the EU requirements with quite modest administration. This is not surprising, since the number of high-activity sealed sources in the EU Member States range from only a few in some Member States to several thousands in others.

Generally the HASS Directive has been well implemented in all Member States; 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 area of most difficult implementation is the organisation of search campaigns for possible orphan sources left from past practices[3]. 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.

HASS Directive has been repealed by the Directive 2013/59/Euratom (new Basic Safety Standards Directive, BSS)[4], which incorporates the main provisions of the Directive and harmonises them with the IAEA guidance on radioactive sources. The EU Member States have until 6 February 2018 to transpose the new BSS Directive into their national legislation. During the transposition process the Commission will attract specific attention of the Member States to the areas where there has been implementation difficulties in order to better overcome them in the new transposing legislation.

The new Basic Safety Standards Directive does not require reporting on implementation so there will not be a follow-up to this report.

Croatia was not an EU Member State at the time of the HASS Directive implementation review and, consequently, is not included in this report. However, the HASS Directive has later been transposed

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1 Orphan source is a radioactive source, which is not under regulatory control.

2 More detailed information on the situation of HASS in EU States, USA and Canada is available at the Commission publication Radiation protection N° 179, *Study on the current status of radioactive sources in the EU, on the origin and consequences of loss of control over radioactive sources and on successful strategies concerning the detection and recovery of orphan sources*, 2014.

3 The Directive requires the Member States to organise orphan source search campaigns "as appropriate", so there is room for national decision making on the need to organise these campaigns.

4 Art. 107 of the new BSS Directive, with effect from 6 February 2018

into the national legislation of Croatia. For this reason, it would be appropriate, after a certain length of time has elapsed, to review also Croatia's experience in the implementation of the Directive. Therefore, the Commission is prepared to carry out a review in Croatia after the Directive's provisions have been in force for three to four years in this Member State.

2. HIGH-ACTIVITY SEALED SOURCES IN EUROPE

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 sterilization purposes. Typical HASS nuclides are long-lived Co-60, Ir-192, Sr-90 and Cs-137. 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.

The European inventory of HASS comprises about 30 700 sources, of which 50% is represented by Germany and France. Nine Member States have an inventory of less than 100 HASS. Most of the sources used for non-destructive testing are mobile, therefore presenting a particular security challenge.

About 3 200 HASS holders are recorded in the Member States, of which 63% is represented by Germany, France, Poland and the United Kingdom. Typically there are 1-40 individual HASS per holder (in some cases multiple source devices are counted as one source).

Due to their high activity and often mobile physical set-up, HASS security is a particular challenge to national authorities, especially since a malicious act involving radioactive material could have very significant consequences to the functioning of the society. In addition an accidental loss of HASS-control may lead to radiation overexposure incidents or very significant economic costs if such a source is melted in a scrap metal recycling process.

There have been a few incidents in the European Union where control of a registered HASS was lost or an unregistered HASS was found. Very few of these (below ten) have involved harmful exposure and even fewer cases have involved malicious intent. It is estimated that criminal incidents made up only a minor percentage - less than 8 per cent - of all reported source incidents in 2007-2009. Discovery of radioactive sources or contaminated items in scrap metal is by far the most frequent incident encountered, occurring at scrap metal facilities and national borders during export of scrap. The second most frequent event reported by the EU States is the discovery of orphan sources in public places, municipal dumps or on the premises of bankrupt companies.

3. IMPLEMENTATION OF DIRECTIVE 2003/122/EURATOM IN EU-27

3.1. Introduction

Article 14 of the HASS Directive requires the Member States to report on the experience gained on the implementation of the Directive by 31 December 2010. After having received this report from each Member State, the Commission carried out a study to assess the implementation of the Directive. The study completed the information reported by the Member States, provided an overview of the implementation and identified both deficiencies and best practices.

3.2. Implementation overview

Figure 1 presents on overview of the HASS Directive implementation status in the 27 EU Member States. Results are presented as *implemented* (OK), *require attention* (PoA) and *difficulties in implementation* (NOK). The graph analysis shows that there is, in general, good compliance with the HASS Directive requirements. The objectives of the Directive have been met and there is no reason to believe that the high-activity sources would not be subject to sufficient control in any of the EU Member States.

Figure 1. Overview of HASS Directive implementation in the 27 EU Member States (OK – Point of Attention PoA – Difficulties in implementation NOK)

3.3. Areas of inconsistent implementation of the Directive

Although in general compliant with the requirements of the HASS Directive, five subjects frequently show inconsistencies in implementation:

(1) In 12 Member States there are inconsistencies in the implementation of the legislative framework. Typically different activity levels than those set in the HASS Directive are considered to define HASS (for instance IAEA levels[5]). This implies that the implementation of the definition of HASS in the national regulation is not fully in line with the Directive. In addition, several Member States which use the same HASS definition as the one given in the HASS Directive consider in practice the actual activity of the source when implementing the national provisions. As such, a source whose activity has fallen below the high-activity levels of the Directive Annex I will not be covered by the requirements of the Directive.

(2) In several Member States the requirements linked to the control of HASS by the holder are not fully consistent with Directive requirements. For example there are no systematic leak tests of the HASS performed by the HASS holders or the test programme carried out by the source holders is limited (only visual verification, no dose rate measurements).

(3) In ten Member States the documentation accompanying the HASS is not fully compliant with the requirements of the Article 7 of the Directive, which requests that the manufacturer provides a photograph of each manufactured source design type and of the typical source container. The holder shall ensure that each source is accompanied by written information, including photographs of the source, source container, transport packaging, device and equipment, as appropriate. Moreover, historical sources without an ID number are also present in some Member States.

[5] IAEA Safety Standards, Categorization of radioactive sources for protecting people and the environment, No RS-G-1.9, International Atomic Energy Agency, 2005.

(4) The main point of attention regarding the long-term management of HASS concerns the allowed period for storing disused HASS at the holder's premises. The HASS Directive pleads for a transfer of each disused source without undue delay after it goes out of service. However, several Member States do not define in their regulatory regime the maximal period for storing disused sources at the holder's premises, after which transfer becomes mandatory. In a few Member States the financial guarantee for the safe long-term management of disused sources can in some situations be uncertain, or the HASS holders are not obliged to make adequate arrangements for the long-term management of disused HASS during the licensing process.

(5) The last subject requiring attention is the training and the information of workers potentially confronted with orphan sources. In four Member States such training is not organised, while in eight other Member States this training is not required by regulation, not given to all types of workers, or not carried out in all facilities at risk, or neither documented nor repeated.

3.4. Areas of difficult implementation of the Directive

Only one requirement is poorly implemented in about half of the Member States: the organisation of orphan sources recovery campaigns. Indeed, Article 9.4 of the HASS Directive requests that the Member States ensure that campaigns are organised, as appropriate, to recover orphan sources left behind from past activities. Organisation of these campaigns has turned out to be difficult in 14 Member States for various reasons.

In three Member States the requirements concerning record keeping (Article 5) have been difficult to implement because direct notification of modifications of the status of HASS to the authority is not always ensured.

3.5. Implementation of the Directive by the Commission

The HASS Directive limits the responsibilities of the Commission to the following: the Commission makes available the standard record sheet, it may update the required information on Annex II (Article 5) and it publishes the list of Member States' competent authorities and contact points (Article 13). The standard record sheet outlining the required information for each HASS is available at the Commission website[6] and the information on Member State authorities has been published [2,3]. To date, the Commission has not deemed necessary to update the Annex II and has therefore not established the advisory committee under Article 17.

3.6. Recommendations for improved implementation of the Directive

Based on the analysis of the HASS Directive enactment, several recommendations can be addressed to the Member States in order to improve its implementation:

- The need for organising systematic or dedicated orphan sources recovery campaigns should be assessed in those Member States which have not yet organised such campaigns. A first step towards assessing the need of a recovery campaign would be the analysis of historical records available at the authority and at the manufacturers/suppliers. During inspections at facilities where disused sources are more likely to be found (hospitals, universities, research centres, military sites, etc.), more thorough investigations could be carried out at the premises to search for legacy sources possibly present on the site.
- To ensure the immediate notification of any modification of the HASS status, the national regulatory framework could define a maximum tolerated delay of a few days within which the relevant authority must be notified.
- Pending the transposition of the new EU Basic Safety Standards Directive, in which the HASS definition is revised, 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

[6] http://ec.europa.eu/energy/en/topics/nuclear-energy/radiation-protection/control-other-radioactive-sources

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 according to the guidance elaborated by the regulatory body. These tests should be performed by a skilled person with adequate radiation protection competences. If a recognised radiation protection officer is not available among the HASS holder's staff, the tests should be carried out by a recognised technical support organisation. In any case, the documentation recording the results of the tests on the HASS has to be checked by the authority during inspections to ensure that they were effectively performed and that the outcomes of the tests have been taken into account by the holder.
- The documentation accompanying the HASS should also be checked during inspections to verify its completeness as regards the requirements of the HASS Directive.
- To avoid the risk of loss of control of disused HASS stored at the holder's premises, the maximum allowable time for storage before mandatory transfer could be laid down in national regulations. Compliance with this requirement should be checked during inspections and the necessary enforcement actions should be taken once non-compliance is observed. To avoid undesirable situations, adequate arrangements for the long-term management of disused HASS should be a prerequisite for authorisation for any practice.
- To ensure the proper training and information of persons in installations where orphan sources are more likely to be found or processed as well as in significant nodal transit points, national regulations should insist on the organisation of training sessions. The requirement should impose training courses for all types of installations at risk and for both categories of people (management and workers). Both the content and the frequency of the training sessions should be either defined or approved by the relevant authority. The training and information programme should include practical exercises, such as visual detection of sources and their containers, and actions to be taken on-site in the event of the detection or suspected detection of a source.

3.7. Best practices in implementation of the Directive

Based on the analysis of the level of implementation of the HASS requirements in the 27 Member States, several best practices can be identified. Examples of these are provided below.

- Licensing process is a key step in the management of HASS. Prior authorisation for any practice with a HASS specifies for example, that adequate arrangements, including financial guarantees, have been made for the long-term management of the HASS, including cases in which the holder or supplier becomes insolvent or goes out of business. The long-term arrangement excludes long-term storage of the disused HASS at the holder's premises. The authorisation also describes the tests that are to be performed by the holders on the HASS and their frequency, as well as the training sessions that will be organised for the exposed workers and the frequency at which they will be repeated.
- To ensure prompt notification to the authority of any change in the status of HASS, a maximum tolerated delay of a few days is defined in national regulations enacting the HASS Directive.
- Announced and unannounced inspections are regularly carried out by the national competent authorities to check both the safety and security issues. The inspections aim at verifying all HASS records kept by the holder in order to check the correctness of the information notified to the authority. The documentation accompanying the source is also verified. During inspections, records relating to HASS testing and the training of the staff of HASS holders are verified. In addition to these documentary checks, visual inspections of the sources and measurements are performed by the inspectors, allowing them to assess the integrity of the source and its proper use.

- The HASS holder's staff training programme is defined or approved by the authority and the frequency of repetition is set at a reasonable time interval (for instance, annually). Training courses are recorded and comprehension tests are organised. Training records are checked during inspections.
- HASS Directive requires holders of sources to return each disused source to the supplier, place it in a recognised installation, or transfer it to another authorised holder without undue delay after it goes out of service, unless otherwise agreed by the competent authority. As "undue delay" is not precisely defined in the Directive, the period before mandatory transfer greatly varies among the Member States, ranging from less than one year to several years or no defined time frame. The best practice consists of defining in a regulation a reasonable maximal period for removal of disused sources from users' premises, e.g. max. 2 years. Take-back provisions alone do not guarantee the effective removal of disused sources from holders' premises - financial arrangements, such as monetary deposits by the holders or suppliers are necessary. Such arrangements, financed by the source user community, are also available for the long-term management of disused HASS transferred to a recognised storage facility. Where the transfer of disused HASS to a recognised storage facility is one of the long-term management options, the Member State provides for access to a facility of sufficient capacity.
- Establishment and enactment of specific provisions regulating the security and physical protection of HASS is another good practice observed in several Member States. The security requirements are based on a graded approach, taking into account the risk posed by the sources.
- To avoid incidents with orphan sources, the Member State identifies strategic locations at which they are likely to be found, or where they could enter the country. Moreover, the regulatory authority imposes the installation of detection and monitoring equipment at these locations. Orphan source recovery campaigns are organised, especially in old or former installations where radioactive substances were or are still used. The financial burden for recovering and managing orphan sources is not supported by the community through the State budget but borne by the concerned source user communities. The response and alerting procedures for installations where orphan sources are more likely to be found are approved by the authority and exercises are organised to test them.
- Managers and workers potentially confronted with an orphan source in all types of installations at risk are regularly trained in compliance with the requirements of the national regulations. The content of the training course is either defined or approved by the authority, which ensures that the sessions are documented and effectively given. The understanding of the trainees is evaluated. To increase the awareness of the persons potentially confronted with orphan sources the authority organises information sessions and develops guides, documentation, educational films, posters, etc.

4. DIRECTIVE 2003/122/EURATOM REQUIREMENTS AS A PART OF THE NEW EU BASIC SAFETY STANDARDS

4.1. Introduction

The new EU Basic Safety Standards (BSS) Directive 2013/59/Euratom [4] was adopted on 5 December 2013. In addition to updating the current BSS Directive [5] the new Directive incorporates and updates requirements of five other existing Directives, including the HASS Directive. The new BSS Directive takes into account the latest ICRP[7] guidance and the new International Basic Safety Standards drafted by the IAEA. The EU Member States have four years (until 6 February 2018), to enact the new Directive in their national legislations.

[7] International Commission on Radiological Protection

There are separate chapters on the control of sealed sources and on orphan sources in the new BSS Directive. These chapters include the current HASS Directive provisions, with only a few significant modifications, outlined below.

4.2. Regulatory harmonisation with the IAEA

In order to create a regulatory control system for high-activity sealed sources it is necessary to define a nuclide specific activity level, above which a source should be controlled as HASS. When the HASS Directive was drafted the activity values defined for the IAEA transport regulations[8] (A_1-values divided by 100) were selected as the basis for the HASS definition. Later on the IAEA developed the D-values[9] to define a 'dangerous' source and used them as a basis for its source categorization system, which led to differing source definitions in the HASS Directive and the IAEA Code of Conduct on the Safety and Security of Radioactive Sources (CoC)[10]. The new EU BSS removes this discrepancy by adopting the IAEA D-values as a basis for the HASS definition. This means that IAEA Category 1, 2 and 3 sources are required to be controlled as HASS in the EU.

The revision was undertaken because several EU Member State authorities indicated that having two different HASS definitions at international level is a problematic situation. The HASS Directive and the IAEA CoC have similar aims, so they should be applied on the same group of sources. Also in principle the IAEA and the EU should seek harmonisation of international standards.

It was also felt that, for many nuclides, the HASS Directive activity levels were quite low, so not all HASS sources truly "*imply considerable potential risks for human health or environment*", as is stated in the Directive recitals, whereas the scientific basis for the IAEA D-values is sound and to a certain degree supported by actual doses in real source accidents.

This harmonisation means that the Member State authorities will have to adapt their national limits accordingly. Moreover, since the D-values are mostly higher than the HASS Directive (A_1/100) values, the change means relaxing the requirements for most nuclides (voluntary removal of some sources from the HASS registers). In practice the number of the sources falling between the old and new definition is very small, since most of the registered HASS sources have activities much larger than the new BSS Directive activity limit. For four nuclides[11] the new activity limit is lower than the old limit; for these nuclides the new BSS Directive implies more stringent regulatory control.

Another important change in the HASS definition is that the definition now refers to current activity, not to the activity at the time of manufacture or placing on the market. This means that when the source activity has decayed below the D-value it can be removed from the HASS register and no longer has to be controlled as HASS.

It should be noted that the Directive sets the minimum standard. Member States are free to use also more restrictive requirements in their national regulations.

4.3. Other changes

Other source related changes introduced by the new EU BSS reflect the experience gained from the application of the HASS Directive and the feedback from recent radioactive source and contamination events. The most significant changes are outlined below:

- Definitions for sealed sources and source containers have been slightly modified.

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[8] Regulations for the Safe Transport of Radioactive Material, Safety Standards Series, Safety Requirements No.TS-R-1, International Atomic Energy Agency, Vienna, 2009.

[9] Dangerous quantities of radioactive material (D values) (EPR-D-VALUES 2006), International Atomic Energy Agency, 2006.

[10] Code of Conduct on the Safety and Security of Radioactive Sources, International Atomic Energy Agency, Vienna, 2004.

[11] Po-210, Pu-238, Cm-244 and Am-241

- There are new requirements for metal contamination situations. A metal scrap recycling installation is required to notify the competent authority if it suspects or has knowledge of any melting or metallurgical processing of an orphan source. It shall require that the contaminated materials are not used, placed on the market or disposed of without the involvement of the competent authority. The Member States shall encourage the establishment of systems to detect the presence of radioactive contamination in metal products imported from third countries, in places such as major metal importing installations and significant nodal transit points.
- Member States are required to ensure that the management of installations where orphan sources are most likely to be found or processed, including large metal scrap yards and major metal scrap recycling installations, and in significant nodal transit points, are informed of the possibility that they may be confronted with a source. If workers may be confronted with a source, they must be advised and trained in the visual detection of sources and their containers, informed of basic facts about ionising radiation and informed of and trained in the actions to be taken on-site in the event of the detection or suspected detection of a source.
- The HASS record sheet (BSS Directive Annex XIV) has been improved by updating the terminology and removing the inconsistencies appearing in the HASS Directive record sheet.
- There are new general requirements for unsealed sources. Member States shall ensure that arrangements are made for keeping control of unsealed sources with regard to their location, use and recycling or disposal. In addition the Member States shall require the undertaking, as appropriate and to a possible extent, to keep records of unsealed sources under its responsibility. Member States shall require each undertaking holding an unsealed radioactive source to notify the competent authority promptly of any loss, theft, significant spill or unauthorised use or release.

5. CONCLUSIONS

HASS Directive has been implemented well in the EU, although there still are significant differences in implementation practices among 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.

Directive 2003/122/Euratom is repealed, with effect from 6 February 2018, by the Directive 2013/59/Euratom, which incorporates the main provisions of the Directive and harmonises them with the IAEA guidance on radioactive sources. The EU Member States have until 6 February 2018 to transpose the new BSS Directive into their national legislation. The new Basic Safety Standards Directive represents a major revision of the whole EU radiation protection legal framework. Chapters concerning HASS fit well in this framework, since the HASS Directive has been well accepted by the EU Member States and there was no need for major modifications in the HASS control, although the new BSS Directive corrects several deficiencies of the HASS Directive. In particular, the achieved harmonisation 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 identified best practises, 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. Commission radiation protection series publication RP 179 presents a more detailed overview of the HASS situation in Europe and outlines also the corresponding arrangements in Canada and the USA.

References

[1] Council Directive 2003/122/EURATOM of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources, EU Official Journal L 346 of 31.12.2003.

[2] Commission communication, Competent authorities referred to in Council Directive 2003/122/EURATOM on the control of high-activity sealed radioactive sources and orphan sources, EU Official Journal C 122/2 of 27.4.2013.

[3] Commission communication, Competent authorities referred to in Council Directive 2003/122/EURATOM on the control of high-activity sealed radioactive sources and orphan sources, EU Official Journal C 347/02 of 28.11.2013.

[4] Council Directive 2013/59/EURATOM of 5 December 2013 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, EU Official Journal L 13/1 of 17.1.2014.

[5] Council Directive 96/29/EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation, EU Official Journal L 159 of 29.6.1996.