

Regulatory Control of Sealed Sources in Germany including Regulations Regarding Spent and Disused Sources – 13176

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ABSTRACT

Effective regulatory control is essential to ensure the safe and secure use of radioactive material and the appropriate management of radioactive waste.

To ensure a sustainable control of high radioactive sources, the European Commission published the Council Directive 2003/122/EURATOM on the control of high-activity sealed radioactive sources and orphan sources, which had to be transferred into national legislation by all member states of the European Union. Major requirement of the Directive is a system to ensure traceability of high-activity sealed sources from “cradle to grave” as well as the provision to take back disused sources by the supplier or manufacturer.

With the Act on high-activity sealed radioactive sources Germany implemented the requirements of the Directive 2003/122/EURATOM and established a national registry of high-activity sealed sources in 2006. Currently, about 27.000 high-activity sealed sources are recorded in this national registry.

INTRODUCTION

More than 100.000 radioactive sources, of which nearly 10.000 are high-activity sealed sources (HASS)¹ according to the definition, are currently used in Germany in the fields of industry, medicine, research and agriculture. In industry, sealed sources are most commonly utilized for calibration, material testing, product irradiation and sterilization as well as for fill level and density measurement. In medicine the sources are primarily used for radiation therapy and blood irradiation.

Effective regulatory control is essential to ensure the safe and secure use of radioactive material and the appropriate handling of radioactive waste. Because of several accidents with radiation sources in the 1990ies, the safety and security of sealed sources, especially of high activity sealed sources, has been discussed under the leadership of the International Atomic Energy Agency (IAEA) over the past years. Consequently, international standards and conventions have been improved and the regulatory infrastructure of many countries has been enhanced.

¹ HASS – High Activity Sealed Source: radioactive source, whose activity corresponds or exceeds an activity value listed for every nuclide in the Radiation Protection Ordinance [7]. This value is equivalent to 1 % of the A_1 -value according to the IAEA Regulations for the Safe Transport of Radioactive Material [4].

Based on the IAEA recommendations of the Code of Conduct on the Safety and Security of Radioactive Sources (CoC) [1], the European Council Directive 2003/122/EURATOM on the control of high-activity sealed radioactive sources and orphan sources [2], the so-called HASS-Directive, was issued, which is mandatory for all member states of the European Union. The European HASS-Directive was implemented into German legislation by the Act on high-activity sealed radioactive sources (Act on HASS) [3] in August 2005.

EUROPEAN HASS-DEFINITION COMPARED TO THE IAEA CATEGORIES

Because of historical reasons there are two different categorization schemes with international significance for the classification of sealed radioactive sources.

On the one hand, the European Union has set up a two-category system by its HASS-Directive [2]. The HASS-Directive defines certain security and protection requirements for high-activity sealed sources. A source is considered to be a HASS - and thus, to be dangerous -, if its activity is more than one hundredth of the A1-value, in which A1 is the activity limit of “special form radioactive material”, adopted from the transport regulations [4]. All member states of the European Union were obliged to adopt this categorization scheme in order to comply with the European Directive.

On the other hand, the IAEA has developed a scientific background to assess the hazard potentially posed by a radioactive source resulting in a specific limit of activity for each nuclide, when it is considered dangerous - the so-called D-value. Based on different multiples of that quantity, a set of 5 categories is defined in the IAEA Safety Guide on Categorization of Radioactive Sources [5], where category 1 represents the most dangerous sources (activity $> 1000xD$) and category 5 those posing the lowest danger (activity $< 0.01xD$). Several safety standards and safety guides published by the IAEA are based on that categorization. In particular, certain requirements for the management of sealed sources that may pose a significant risk to individuals, society and the environment, are laid down with the CoC [1]. The regulations of the CoC [1] shall be applied to sources of at least category 3 (activity $> D$), whereas a central registration of sources is required only for sources of at least category 2 (activity $> 10xD$).

A comparison of the different activity limits for nuclides mainly used in sealed sources is shown in Figure 1.

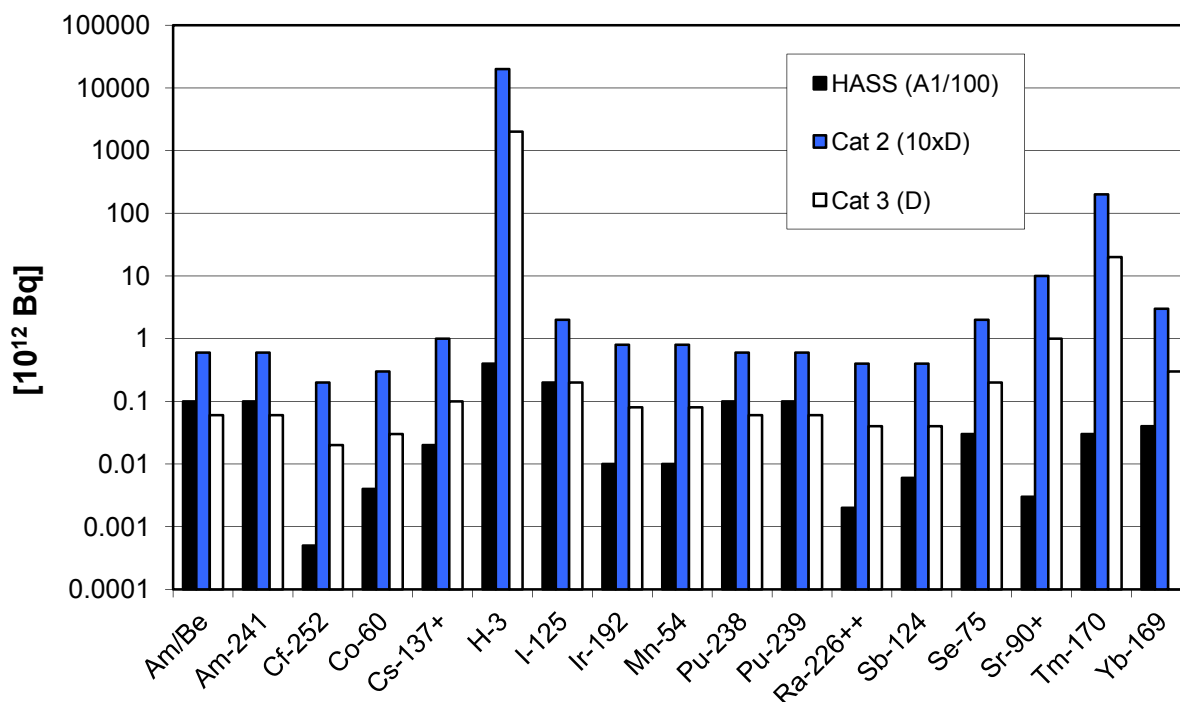


Fig. 1 Activity values A1/100 compared to the IAEA Category 2 and 3.

It has to be recognized that the activity of category 2 according to the CoC [1] is in any case higher than the HASS-threshold A1/100 (see Fig. 1). Thus, any registry based on the HASS-Directive [2] exceeds the criteria proposed by the IAEA, respectively the CoC [1]. But, not all category 3 sources are covered by European regulations. In particular, HASS requirements do not apply for some of the sources containing Am-241 or Pu-238/-239, where the category 3 activity limit is below the HASS-threshold. However, most of all sources, which contain an activity of less than the activity threshold of category 3 and therefore are not considered as dangerous sources by the IAEA, are categorized as HASS within the European Union.

Findings of international conferences identified the necessity of a harmonization of the different categorization systems. The draft version of the upcoming new European Basic Safety Standards for protection against the dangers arising from exposure to ionizing radiation (European Basic Safety Standards) adopted the activity threshold of category 3 (D-value) of the IAEA as a new HASS-threshold.

REGULATORY CONTROL IN GERMANY

In Germany, the 16 German Federal States, so-called *Bundeslaender*², are responsible for the regulatory control regarding radiation safety, especially granting licenses for the safe and secure handling of radioactive material. Various organizational structures of the competent authorities in the different *Laender* result in approximately more than 50 local authorities responsible for radiation safety in all of Germany.

The legal framework

The legal framework on nuclear safety and radiation protection consists of the Act on the Peaceful Utilization of Atomic Energy and the Protection against its Hazards (Atomic Energy Act) [6] and a number of associated legislative provisions, whereof the Ordinance on the Protection against Damage and Injuries caused by Ionizing Radiation (Radiation Protection Ordinance) [7] regulates the handling of radioactive sources.

With the Act on HASS of 2005, additional regulations for high activity sealed sources were implemented and resulted in an amendment of the Atomic Energy Act [6] and the Radiation Protection Ordinance [7].

Regulations for sealed radioactive sources

Use and handling of radioactive sources in Germany is under regulatory control and requires a license. Only sources, which contain radioactive material with a total activity below the exemption value³, or which are inserted into devices with a type approved design⁴, can be possessed and utilized without further regulatory control.

Usually, a license is granted for the possession and handling of radioactive material up to a certain limited activity. Licensees are obliged to install a radiation safety regime, which includes

- the appointment of a radiation protection officer,
- the organization of work by following rules laid down in Radiation Protection Instructions and
- training and regular instructions of persons, who work with radioactive material.

Records have to be kept on any extraction, production, acquisition, transfer and other dispositions of radioactive substances and have to be communicated to the competent authority. The records

² hereinafter referred to as *Laender*

³ The exemption values for every radionuclide are legally fixed by the Radiation Protection Ordinance [7].

⁴ Type approvals are granted by the BfS. Main requirements for a type approval: the radioactive source is immovably inserted into the device and not touchable and the local dose rate in 10cm distance from the surface of the device is $\leq 1\mu\text{Sv/h}$.

have to be kept for 30 years. Furthermore, the competent authority has to be notified by the licensee about the inventory of radioactive material regularly. Periodical maintenance and inspections as well as leakage tests are prescribed by the licensing authority.

Storage and Transport

However, the authorization of storage and transport of nuclear fuel is a federal responsibility, carried out by the Federal Office for Radiation Protection (*Bundesamt fuer Strahlenschutz - BfS*) as competent authority. The *BfS* grants licenses for the transport of nuclear fuel and of some specific sources within the German territory. Additionally, the licensing for interim storage facilities for nuclear waste is done by the *BfS*. Inspection of the compliance of such transports with the German Atomic Energy Act and the regulations for the transport of dangerous goods is in the responsibility of the *Laender* authorities, except for transport by rail, which is in the responsibility of the Federal Railway Authority (*Eisenbahn-Bundesamt - EBA*), and by air, which is in the responsibility of the Federal Office for Civil Aviation (*Luftfahrt-Bundesamt - LBA*).

Specific regulations for high-activity sealed sources

The key regulations of the European HASS-Directive [2] regarding high-activity sources are:

- requirements for the identification and documentation of HASS
- specific regulations for the leakage tests of HASS,
- the obligation to take back a disused HASS by the supplier or manufacturer,
- financial precautions for orphaned sources,
- a system to ensure the traceability of high-activity sealed sources from “cradle to grave”.

The most important requirements implemented in the German legislation are:

- Every high-activity sealed source has to be registered by the licensee and is recorded in a central database, the national HASS-registry, which is operated by the *BfS*. The registry allows both, federal as well as *Laender* authorities to trace back the registered sources within Germany and to verify, if the use of HASS by licensees is in compliance with their license. Any notification has to be done using the standard record sheet of the European HASS-Directive, which has been adopted in detail by the German Radiation Protection Ordinance (see Fig. 2).
- HASS are delivered to the manufacturer, supplier, importer or another holder of a license after their end of use or stored as radioactive waste in an interim storage facility.
- Anyone, who has manufactured or shipped high-activity sealed sources has to take them back or has to ensure, that they are taken back by third parties in a safe manner.
- Leakage tests on a regular basis are mandatory.
- If HASS are going to be im- or exported, the Federal Office for Economics and Export

Control (*Bundesamt fuer Wirtschaft und Ausfuhrkontrolle - BAFA*) will be involved. The import of HASS with an activity above the A_1 -value requires an import license (see also HASS definition on page 1).

(1) HASS- ID No.: ^{a)}	(2) License holder (owner) Name: Address: ^{b)} Country: ^{c)} Manufacturer: ^{d)} <input type="checkbox"/> Supplier: ^{e)} <input type="checkbox"/> User: ^{d)} <input type="checkbox"/>	(3) Location of the HASS (use or storage) if differing from (2) Name: Address: Stationary use: <input type="checkbox"/> Storage (mobile): ^{f)} <input type="checkbox"/>
(4) ^{g)} Registration Registered the first time on: Archiving of the registration documents on:	(5) License Number: Displayed on: Expired on:	(6) Operational control of the HASS: ^{h)} Date: Date: Date:
(7) HASS characteristics	(8) Receipt of the HASS Receipt on: ⁱ⁾	Date: Date: Date: Date: Date: Date: Date: Date:
Radioisotope: Radioactivity at the date of manufacture: Date of manufacture or of the first introduction into trade: Manufacturer/Supplier: ^{j)} Name: Address: Country:	Achieved from: Name: Address: Country: Manufacturer: <input type="checkbox"/> Supplier: <input type="checkbox"/> Other user: <input type="checkbox"/>	(9) Transfer of the HASS Transferred on: ^{k)}
Physical and chemical characteristics: Type of source: Capsule: ISO classification: ANSI classification: Certificate about special form ^{l)} :	(9) Transfer of the HASS Transfer to: Name: Address: Country: Manufacturer: ^{d)} <input type="checkbox"/> Supplier: ^{e)} <input type="checkbox"/> Other User: ^{d)} <input type="checkbox"/> Established organization ^{m)} : <input type="checkbox"/>	(10) Other information Loss: <input type="checkbox"/> Date: <input type="checkbox"/> Theft: <input type="checkbox"/> Date: <input type="checkbox"/> Retrieval: ⁿ⁾ <input type="checkbox"/> Date: <input type="checkbox"/> Place: Further remarks: ^{o)}
		yes <input type="checkbox"/> no <input type="checkbox"/>

- ^{a)} ID number of the high-activity radiation source according to § 68, para. (1a)
- ^{b)} Postal address including telephone number and e-mail account
- ^{c)} Germany and federal state
- ^{d)} License holder for the handling of high-activity radiation source according to § 9 of the Atomic Energy Act or § 7 of the Radiation Protection Ordinance
- ^{e)} License holder according to § 3 of the Atomic Energy Act or § 19, para. (1), first sentence of the Radiation Protection Ordinance
- ^{f)} Declaration in case of a mobile high-activity radiation source and if the HASS does not stay more than four weeks at the same place to be completed by the registering organization
- ^{g)} Date of integrity and leakage testing according to § 70, para. (1), third sentence of the Radiation Protection Ordinance
- ^{h)} Date of acquiring the physical authority
- ⁱ⁾ If the manufacturer of the radiation source is located outside the Community, the name and address of the carrier or the supplier shall be indicated additionally
- ^{j)} Date of abandoning the physical authority
- ^{k)} Also finding of a HASS
- ^{l)} Information about the use of a high-activity radiation source, e.g. as part of an irradiation device or for material test
- ^{m)} Information of the date when a special form approval was granted or changed if applicable
- ⁿ⁾ State collecting facility or installation established by the federation for the safekeeping and disposal of radioactive waste according to § 9a para (3), first sentence of the Atomic Energy Act

Fig. 2 Standard record sheet for high-activity radiation sources (HASS)

Spent or disused sources

Spent or disused sources or spent devices containing radioactive material in Germany are either returned to the manufacturer or supplier or delivered to interim storage facilities operated by the *Laender*, so-called *Landessammelstellen*. Currently, there are twelve of such facilities in Germany. The radioactive waste from industry and research and small amounts of radioactive waste from medicine (less than 0.5 per cent) accruing on the territory of the respective federal state is temporarily stored in these facilities until its disposal in a federal final repository. The German final repository for low-level and intermediate-level waste will be the *Konrad* mine in lower Saxony.

Special requirements apply for HASS and for type approved devices: HASS have to be taken back by the manufacturer or supplier without exemption. Type approved devices shall be delivered to the holder of the type approval immediately after their end of use.

In many cases sources returned to the manufacturer still contain radioactive material with sufficient activity to be re-used or recycled. These sources can be re-encapsulated or over-encapsulated and brought back to use.

THE GERMAN HASS-REGISTRY

The German HASS-registry is an electronic database, which is online since 2006. It manages information between license holders, the local authorities of the *Laender* and the central administration at BfS. It allows both, federal as well as local authorities, to trace back the registered sources within Germany and to verify, if the use of HASS by licensees is in compliance with their license.

Every licensee is obliged to send notifications about receipt, transfer, location change, control, loss, theft or finding of a HASS to the registry. The notifications must contain the following data according to the standard record sheet (Fig. 2):

- license holder (name, address)
- license (date of issue, limitation)
- HASS characteristics (identification number, nuclide, activity, physical and chemical properties, manufacturer)
- use and operational controls of the HASS
- location of the HASS
- leakage tests (once per year)
- if transferred, recipient or sender of the HASS

The data are communicated only electronically via secure internet connections. Separate web applications for licensees and authorities provide different connections to the database.

Tasks and access rights

Access to the registry is granted on different levels, depending on the different duties and responsibilities according to the Radiation Protection Ordinance [7] (see also Fig. 3):

- Federal Office for Radiation Protection
 - system and user administration
 - statistical analyses
 - evaluation
 - reporting

- full access
- Licensees:
 - notifications to the registry
 - no access to the data in database
- Competent Authorities of the *Laender*:
 - verification of the notifications of the licensees
 - access to search and report functionality (database searches)
- Federal Office of Economics and Export Control
 - transmission of data on licenses granted for the transboundary shipment of a high activity sealed source from a state which is not a Member State of the European Communities [7]
 - access to search and report functionality (database searches)
- Federal Administrative Office, Federal Civil Aviation Authority, Federal Railroads Office, Supreme *Laender* authorities, Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (*BMU*), Federal Office for the Protection of the Population and Emergency Aid (*BBK*), Federal Office of Criminal Investigation (*BKA*), Law enforcement authorities of the *Laender*
 - investigations (law enforcement)
 - access to search and report functionality (database searches)

Information about data in the registry can be given on request to other Federal State Police Authorities, Customs Authorities, Military Counter-Intelligence Service (*MAD*), Federal Intelligence Service (*BND*) and comparable international authorities.

The data in the registry have to be kept for 30 years. Currently, more than 95.000 notifications representing 27.000 sources are stored in the database. The yearly increase amounts to more than 10.000 notifications. Since its start in 2006, the software of the German HASS-registry is being continuously improved. The system runs very reliable.

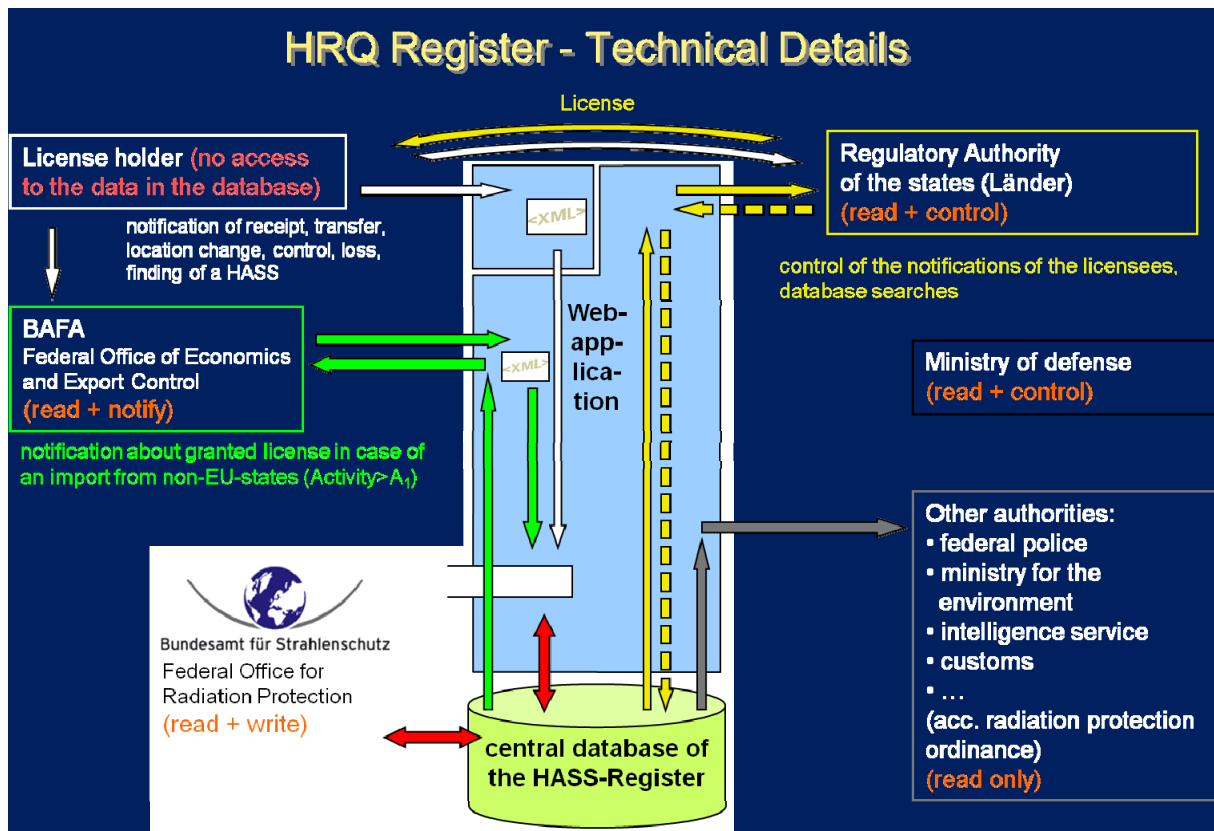


Fig. 3 Scheme of the German HASS-registry

CONCLUSIONS

With the implementation of the requirements of the European HASS-Directive, Germany laid down a set of regulations for high activity sealed sources. A modern and reliable system for the tracking of high activity sealed sources within the territory of the Federal Republic of Germany has been established, which is a major contribution to enhance the safety and security of radioactive sources.

In a more and more globalized world, where radioactive material is transported across borders, the cross-border cooperation and the harmonization of standards and regulations are indispensable to maintain and to increase the safety and security. In the near future, with the revised European Basic Safety Standards and the adoption of the IAEA-source categorization, the European Union will make another step forward in order to harmonize with the international standards and regulations on radiation safety.

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