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Control of high-activity sealed radioactive sources in Europe: Implementation of Directive 2003/122/EURATOM in EU-27 and the current EU regulatory development activities

Accompanying the document

Report from the Commission to the Council, the European Parliament and the European Economic and Social Committee on Experience gained in the implementation of Council Directive 2003/122/EURATOM on the control of high-activity sealed radioactive sources and orphan sources

{COM(2015) 158 final}

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Executive summary

European Union Council Directive 2003/122/EURATOM (so called 'HASS Directive') requires the EU Member States to put in place several measures in order to guarantee the safety and security of high-activity sealed radioactive sources (HASS) and to search for orphan sources. These legally binding measures are in line with the requirements of the IAEA Code of Conduct on the Safety and Security of Radioactive Sources. This document discusses the results of the recent HASS Directive implementation review and the results of a supporting study project under the EU CBRN Action Plan. The document also outlines the current development of the HASS-legislation in the EU, especially in terms of the new EU Basic Safety Standards (BSS) Directive.

To assess the implementation status, compliance of the current situation prevailing in each Member State[1] with 17 major requirements of the HASS Directive was checked through the analysis of information collected by questionnaires, interviews and fact-finding missions among the European stakeholders. There is in general a good compliance of the implementation of the HASS Directive requirements. The only difficult area in implementation is the organization of orphan source recovery campaigns, which have been implemented in only about 50% of the Member States.

The analysis of the level of implementation of the HASS requirements in the 27 Member States was deepened to identify the best practices, weak points and points of attention from the safety and security perspective. Indeed, there are significant differences in implementing practices among the EU Member States. The best implemented requirements deal with the availability of a complete central inventory of all sources above exemption levels, the regular performance of inspections covering both safety and security issues, the checking of all HASS records during inspections, mechanisms of financial security for the long-term management of HASS, the identification of strategic locations where orphan sources are likely to be found, the availability of emergency team 24/7, and the establishment of on-site emergency plan for HASS holder approved by the authority. Based on the analysis of weak points and points of attention, several recommendations are suggested to improve the implementation. They concern the current definition of HASS, the concept of undue delay for removal of disused sources from users' premises, the immediate notification of any modification of HASS status, the type and frequency of tests to be performed on HASS, the arrangements to be made for the financial guarantees for management of disused HASS and orphan sources, the organization of recovery campaigns for orphan sources, and the training of personnel potentially confronted to orphan sources.

Analysis of HASS incidents in Europe reveals that very few incidents involving harmful radiation exposure and even fewer cases involving malicious intent have been reported. Criminal incidents made up only a minor percentage - less than 8 per cent - of all incidents reported to Interpol 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 also at national borders.

Directive 2003/122/Euratom has on 6 December 2013 been repealed by the Directive 2013/59/Euratom (the new Basic Safety Standards Directive) [1], which incorporates the main provisions of the HASS 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.

[1] Croatia was not a member of the EU during the review process and it is not included in this report.

1. INTRODUCTION

The HASS Directive [2] entered into force on 31 December 2003 and its legal enactment period ended two years later. Each EU Member State has designated a competent authority to carry out tasks in accordance with the Directive [3]. Article 14 of the Directive requires the Member States to report on its implementation before the end of 2010. The Commission is then required to provide an implementation report of the Directive to the European Parliament, Council and the European Economic and Social Committee.

All EU Member States have enacted the HASS Directive in their national legislation, but the review results indicate variable practices in the practical implementation of the Directive requirements. This is not surprising, since the number of HASS sources in the EU Member States range from only a few to several thousands. The quality of the reporting was also highly variable, illustrating the fact that some States have very advanced HASS control arrangements and administration, whereas some States fulfil the EU requirements with quite modest administration.

The implementation review was initiated by the European Commission 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. It is based on Member States' (EU-27) national HASS Directive implementation reports, questionnaires, interviews and fact-finding missions among the European HASS Competent Authorities.

2. HIGH ACTIVITY SEALED SOURCES INVENTORY IN EUROPE

According to the data reported by EU Member States, the European inventory of HASS comprises about 30 700 HASS, of which 50% is represented by only Germany and France. Nine Member States have an inventory of less than 100 HASS. About 3 200 HASS holders are recorded in 24 Member States, of which 63% is represented by Germany, France, Poland and the UK. Typically there are 1-40 individual HASS per holder (in some cases multiple source devices are counted as one source).

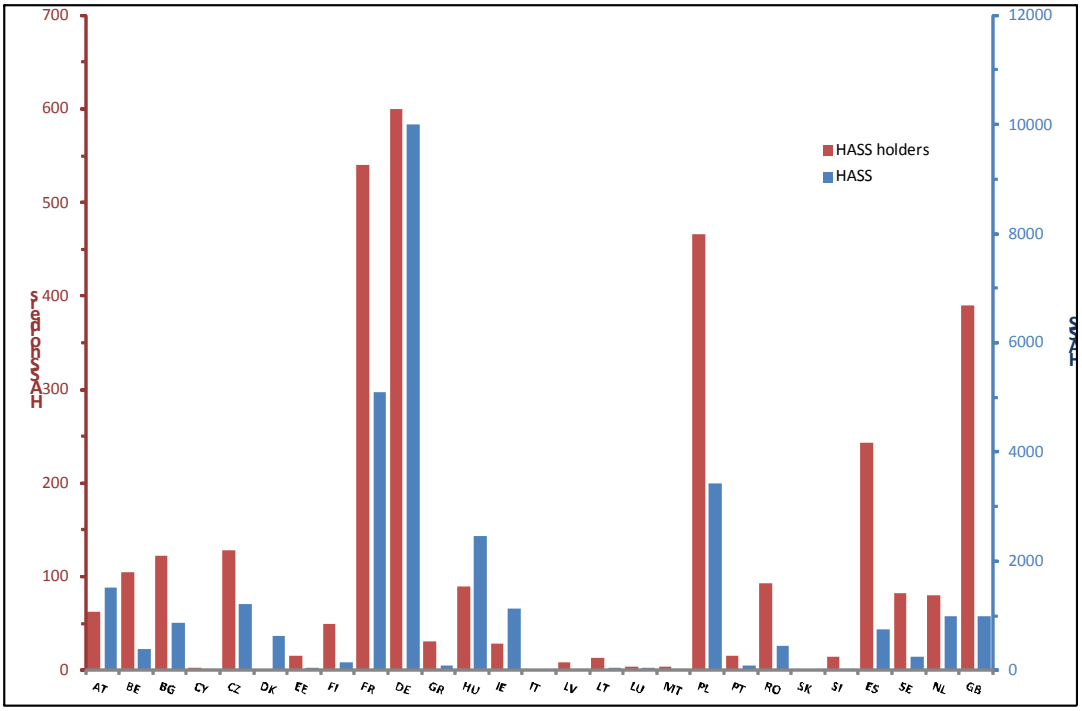

Figure 1. Number of HASS and HASS holders in the EU member States

3. IMPLEMENTATION OF DIRECTIVE 2003/122/EURATOM

3.1. Overview

Figure 2 presents an 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). As can be deduced from the graph analysis, there is, in general, a good compliance with the HASS Directive requirements.

Figure 2. Overview of HASS Directive implementation in the 27 EU Member States (OK – Point of Attention PoA – Difficulties in implementation NOK)

3.2. Areas of inconsistent implementation of the Directive

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

(1) The points for attention related to the legislative framework that are observed in 12 Member States are the following:

- Different activity levels than those set in the HASS Directive are considered to define HASS (for instance IAEA Category 3 levels).
- The report sent to the EC on the experience gained in the implementation of the HASS Directive is limited.
- The implementation of the definition of HASS in the national regulation is not compliant with the Directive. Indeed, several Member States which use the same HASS definition as that given in the HASS Directive consider in practice the actual activity levels of the source when implementing the national provisions. As such, a source whose activity has fallen below the high-activity levels of the Directive will be covered by the requirements for non-HASS.

(2) The main points for attention linked to the control of HASS by the holder are the following:

- No systematic leak tests of the HASS are performed by the HASS holders.

- 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 provide 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.

(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 several Member States the financial guarantee for the safe long-term management of disused sources is uncertain. Finally it seems that HASS holders are not obliged to make adequate arrangements for the long-term management of disused HASS during the licensing process in one Member State, although it is required by article 3.2 (b) of the HASS Directive.

(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 either not required by regulation, or not given to all types of workers, or not carried out in all facilities at risk, or neither documented nor repeated.

3.1. 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. However, several arguments were forwarded by the Member States to justify why such recovery campaigns are not organised. These main arguments are:

- HASS are under control and cannot become orphan sources.
- The inventory of HASS is complete and up-to-date.
- Detection means are installed at borders of the country.
- No orphan sources have been discovered yet.
- No recognised storage facility is available for the storage of recovered orphan sources.
- Recovery campaigns were organised before the HASS Directive was enacted.

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.

3.2. Recommendations for improved implementation of the Directive

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

(1) 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, such as hospitals, universities, research centres, military sites, etc., more thorough investigations could be carried out at the premises, using measuring devices, to search for legacy sources possibly present on the site.

(2) 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.

(3) 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 is decayed below the exemption/clearance levels and not until the source activity has fallen below the high-activity levels.

(4) The type and frequency of tests to be performed by the HASS holders should be defined in the regulation or in a 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 organisation, such as a 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.

(5) The documentation accompanying the HASS should also be checked during inspections to verify its completeness as regards the requirements of the HASS Directive.

(6) 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.

(7) To ensure the proper training and information of persons in installations where orphan sources are more likely to be found or processed and 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.

3.3. Best practices in implementation

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

(1) The 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 the long-term storage of the disused HASS at the holder's premises. The authorisation also describes the tests that will 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.

(2) To ensure the prompt notification to the authority of any change with regard to the status of HASS, a maximum tolerated delay of few days is defined in national regulations enacting the HASS Directive.

(3) Announced and unannounced inspections are regularly carried out 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.

(4) 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). The training courses are recorded and comprehension tests are organised. The training records are checked during inspections.

(5) The 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 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. Besides, 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.

(6) The 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 defined are based on a graded approach, taking into account the risk posed by the sources.

(7) To avoid incidents with orphan sources, the Member State identifies strategic locations at which they are likely to be found or from which they can 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 the orphan sources is not be 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 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 regulation. 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, movies, posters, etc.

4. IMPLEMENTATION STATUS IN THE MEMBER STATES (EU-27)

4.1. Austria

4.1.1. Regulatory framework with respect to HASS

4.1.1.1. Regulatory authority

As Austria is a federal state the functions are divided between federal and local authorities. The regulatory authority with respect to HASS is the Federal Ministry of Agriculture, Forestry, Environment and Water Management, responsible for legislation and general administrative activities, operating of radiation protection registers, especially the radioactive source register, implementation of EU legislation, international contacts and information exchange on bilateral level, EU-level and international level.

4.1.1.2. Legislative framework

Austria has fully implemented the HASS Directive into the national legal framework.

The requirements of the HASS Directive are included into the *Radiation Protection Act* and the General Radiation Protection Regulation in force (Radiation Protection Act, BGBL Nr. 227/1967, last amendment BGBL I Nr.35/2012 and General Radiation Protection Regulation BGBL, II Nr. 191/2006, last amendment BGBL, II Nr. 76/2012). Beside the obligation to transpose the HASS Directive into national legislation, the federal authority is responsible for financial participation in the costs of recovering, managing and disposing of orphan sources (article 9), financial security of orphan sources (article 10), international cooperation (article 11) and report on experience (article 14). The local district authorities are responsible for authorization (article 3), transfers (article 4), records (article 5), and activities for safe and secure management of orphan sources (article 9), inspections (article 12) and penalties article 15.

The activity levels in the Austrian legislation for HASS follow Annex 1 of the HASS Directive. All sources with activity levels below the high-activity levels but above the exemption levels need authorization. This requirement of the General Radiation Protection Regulation was still in force before the transposition of the HASS Directive. A HASS stays covered by the HASS regulation until the activity level falls below the clearance levels. This is valid also for existing sources which would have been declared as HASS before the transposition of the HASS Directive.

4.1.2. Prevention and Deterrence

4.1.2.1. Authorization for practice with HASS

Before issuing an authorization for the use of HASS, all relevant issues are considered by the Regulatory Authority, including external accidents (fire, flooding…), emergency procedures and the long term management of the disused source. Authorization is only granted after all relevant information is received and has been judged by the Regulatory authority as being adequate. An authorization for a HASS has never been refused in Austria.

Regarding the topics before issuing an authorization a possible problem has been identified. In Austria disused radioactive sources should be returned to the manufacturer/supplier of the source. Usually this is subject to a contract between supplier/manufacturer and holder. In case of bankruptcy of manufacturer/supplier the source will stay under surveillance of the authority and the authority will take care for the long term management.

4.1.2.2. Records keeping and updating

The Federal Ministry of Agriculture, Forestry, Environment and Water Management is operating a national radioactive source database for sealed and unsealed sources within the Central Radiation Protection Register. Holders have the obligation to notify only sealed sources. The information on unsealed sources is only from transmitted quarterly reports.

The holder of a HASS has the obligation to record each source into this database electronically and immediately at the acquisition time. Therefore a holder gets protected access to the database. After saving an input into this database, each change is recorded in a log file to prevent misuse. All the stored information is available to the respective holder, the respective competent authorities as well as the operating Ministry. The stored information is available for inspection. During inspections the competent authority checks the match between the actual situation of the HASS and the information stored in the database and this for each HASS. All information following the Standard Record Sheet for Hass has to be recorded. The HASS register is a part of this source register, reflecting all recording requirements of the HASS Directive. Customs organizations and police organizations have access to the database on justified request. Any change in handling a source (transfer, disuse) is to be recorded into the database immediately.

4.1.2.3. National inventory

There is a central national HASS register in Austria. Typically the radio-nuclides are Co-60, Ir-192 and Cs-137 in medical facilities, Se-75, Sr-90, Cs-137 and Ir-192 in industry and Co-60 in the irradiation facility.

There is no HASS manufacturer in Austria. Correct identification and marking of HASS is verified by a TSO report (accredited testing centre) for all incoming sources: this is a requirement laid down in the General Radiation Protection Regulation.

4.1.2.4. Inspections and penalties

Periodic inspections (maximum every year) are organized by the competent local authorities. In case of an incident or any other suspicious situation, follow-up inspections are conducted. Inspections are usually announced and are performed by an inspection team. The inspection team is usually headed by a lawyer of the competent local authority and supported by a radiation protection expert and, if necessary, special security experts (inspectors). Requirements on technical background of the experts and their equipment are laid down during the accreditation process and verified by regular audits.

In case of non-respect of regulations, a system of administrative penalties is in place. These depend on the type of infraction and can range up to €50000. These penalties have not been applied in case of HASS up to now.

4.1.2.5. Control of HASS by the holder

The competent authority verifies regular performance of suitable tests by the holder to control good conditions of each HASS during inspection; this includes usually visual verification, leak tests and dose rate measurement. The frequency is laid down in the license.

The competent authority requests all information on the control measures implemented to prevent inadequate use, unauthorized access, loss or theft, fire protection etc., during the authorization process and verifies it during inspections.

4.1.2.6. Sources holders' training

The content of the training program of HASS holder's staff is defined by the authority as well as by the holder. The training material is prepared by the holder and the frequency is usually laid down in

the license (minimum once a year). The performance and efficiency of training sessions is verified by checking training records during inspections. Management staff is trained in possible consequences of loss, theft or inadequate use or damage of sources.

The radiation protection officer is trained in radiation protection principles, specific requirements of safe management of sources, possible consequences of loss, theft or inadequate use or damage of sources, and notification to the competent authorities and emergency responses in case of an accident.

Usually the documentation accompanying the HASS includes source identification, information and photographs of the source design type, information and photographs of a typical source container, information and photographs of transport packing and information and photographs of device and equipment.

4.1.2.7. Identification and marking of HASS

HASS need to be systematically accompanied by the necessary documentation with all relevant information. There are four historical sources without ID on the Austrian territory.

4.1.2.8. Transfers of HASS

Each transfer of HASS needs authorization and has also to be recorded in the central source database. Before the transfer of a HASS, the holder ascertains that the recipient holds appropriate authorization by request of copy of the authorization from the recipient.

The competent authority is informed of individual transfers of HASS by issuing an authorization/permit to the holder for the transfer, as well as by issuing an authorization/permit for the transport. In case of international import (from non EU- country) an import permit is requested. There is no evidence of loss or out of control incidents due to unrecorded transfers.

4.1.2.9. Long-term management of disused HASS

The national regulatory framework does not define a limited useful life for HASS. Currently an authorization is only granted if the long-term management route is already specified and planned.

The country's policy on disused sources gives priority to returning the disused source to the supplier. Another possibility is transfer to another authorized user. If this would not be possible, the disused sources should be considered as radioactive waste and be transferred to the national authorised waste treatment and storage facility or an adequate facility. The actual situation of disused HASS corresponds to this policy. In some seldom occurring cases disused sources are stored at the holder's premises. The national waste treatment and storage facility is also encouraged to possibly send back disused sources to the manufacturer.

The long-term management of disused sources is funded through take-back provisions incorporated in the supply contracts and through a fund set up by Holders.

4.1.3. Detection

4.1.3.1. Detection of orphan sources

Metal scrap yards, scrap recycling facilities, metallurgic industry and conventional waste management facilities are locations in Austria where routine monitoring for orphan sources is performed. Necessary equipment is provided by the respective companies, as e.g. scrap yards have to certify that supplied scrap is free of radioactive content. There is no permanent monitoring for radiation sources at the state's borders. Radiation detection equipment is also available in the radiation monitoring labs and for the intervention teams e.g. specialised police units.

4.1.3.2. Campaigns for orphan sources recovery

In the late eighties and early nineties of the last century campaigns have been organized to investigate schools, universities and research institutes as well as in hospitals with radium irradiation facilities with the aim to recover disused sealed and unsealed, solid and liquid radioactive material and orphan sources. These activities have been financed by the competent authorities and the recovered radioactive material has been transferred to the waste treatment and storage facility. Currently a campaign for retrieving remaining sources from past practices, primarily concerning production and selling of radium sources and devices using radium in Austria in the first decades of the 20th century, is ongoing. These activities are financed by the competent Ministry.

4.1.3.3. International cooperation and information exchanges

Austria is actively participating in international cooperation and information exchange, mainly through the established IAEA channels. The country is contributing to the IAEA Incident and Trafficking Database (ITDB). The responsible authority is the Federal Ministry of economic Affairs.

4.1.4. Preparedness and Response

4.1.4.1. Emergency plans and procedures

Austria has a general emergency response plan in operation, also applicable in the case of radiological emergencies. However, HASS or orphan sources are not specifically addressed in the plan. HASS holders on the other hand do require an on-site emergency response plan, which needs to be established including the local municipality and local, maybe also regional, Fire Brigade and Rescue Service.

In each of the 99 Austrian districts the district police station is equipped with adequate measuring equipment and a sufficient number of policemen is educated and trained in managing recovered and/or supposed radioactive material. A similar situation exists with respect to the fire brigades and rescue services.

The number of educated and trained persons is adequate to guarantee interventions 24/7. In addition, dedicated vehicles (mobile laboratories) are available as well as helicopters with special equipment to detect radioactive material. Depending on the emergency situation the regional emergency centres or the federal emergency centre coordinate the activities. If necessary, experts from TSO’s are also involved for special duties, like radiological assessment, source transport and final contamination control. Contact points are the provincial alarming centres and the federal alarming centre.

4.1.4.2. Training and information of persons potentially confronted with an orphan source

Within the national emergency plan all required actions are attributed to responsible organisations. All activities are coordinated, depending on the situation, on provincial level and/or federal level.

A quite extensive and adequate training and information plan is mandatory for all people who could potentially be confronted to orphan sources at both worker and management levels. The training for the workers is more detailed than the training for the management. These training sessions are to be repeated every 5 years. There is a comprehension test organised. The emergency trainings include also practical exercises on recovering, identification and management of radioactive sources.

4.2. Belgium

4.2.1. Regulatory framework with respect to HASS

4.2.1.1. Regulatory authority

The primary Regulatory authority in the field of safety and security of ionising radiation sources in the country is the Federal Agency for Nuclear Control (FANC), which is an independent agency under the tutelage of the Minister of Interior. Its main functions related to HASS include licensing, inspection and international collaboration. These functions are not limited to HASS, but cover all ionising radiation sources. This regulatory authority is supplied by recognised radiation protection control organisations that perform on a regular basis controls in the installations using ionising radiation sources.

The National Institute for Radioactive Waste and Enriched Fissile Materials (NIRAS-ONDRAF) is the national manager of radioactive waste in the country. This institute is responsible for the financial aspects of radioactive wastes, including HASS and orphan sources.

4.2.1.2. Legislative framework

The legislative framework in the country is based upon the Law laying down the Protection of the Public and the Environment against the hazards of Ionising Radiation and concerning the Federal Agency for Nuclear control of 15th April 1994. One main regulation foresees in its implementation:

- *Royal Decree laying down the General Regulations on the Protection of the Public, the Workers and the Environment against the hazards of Ionising Radiation (20th July 2001);*

In addition to this, several other royal decrees regulate specific aspects. These include:

- *Royal Decree laying down the Nuclear and Radiological Emergency Plan for the Belgian Territory (17th October 2003);*
- *Royal Decree regulating the Import, Transit and Export of Radioactive Material (24th March 2009);*
- *Royal Decree concerning the Detection of Radioactive Material in certain Material and Waste Streams and concerning the Management of Installations sensitive to Orphan Sources (14th October 2011).*
- *This regulatory framework is completed with a number of decisions by the Agency. The most relevant to the field of HASS and orphan sources is:*
- *Decision containing guidelines to follow when Detecting or finding an Orphan Source in Royal Decree concerning the Detection of Radioactive Material in Installations of the Non-nuclear Sector prone to Orphan Sources (3rd November 2011).*

This framework regulates the use of all types of radiation sources, including HASS. The HASS Directive is fully implemented into the Belgian regulations. The same definition and related radiological criteria are being used for defining HASS as those used in the Directive.

The main differences between HASS and non HASS are to be found in records keeping, identification and marking and reporting. Requirements for users, authorisation regime, inspection, training and financial security are similar for HASS and non HASS.

4.2.2. Prevention and Deterrence

4.2.2.1. Authorization for practice with HASS

Before issuing an authorization for the use of HASS, all relevant issues are considered by the Regulatory Authority, including external accidents (fire, flooding …), emergency procedures and the long term management of the disused source. Authorization is only granted after all relevant information is received and has been judged as being adequate by the Regulatory Authority. FANC has never had to refuse an authorisation for HASS.

4.2.2.2. Records keeping and updating

All HASS holders are required to maintain records of the HASS under their responsibility. A written copy and/or an electronic copy of these records are to be sent to the Regulatory authority at the time of acquisition of the source and then on a yearly basis. A maximum tolerated delay of 30 calendar days is defined in the regulation to notify any modification. The authorization for a transfer of a HASS must be obtained before the actual movement of the source (prior authorization). Records sent to the authority are often incomplete or contain inaccurate information. To solve this, FANC has recently made the qualified expert of the installation explicitly responsible for transmitting on time the complete and correct information.

4.2.2.3. National inventory

The information received through these records is used to maintain an electronic national inventory of HASS. The Regulatory authority supposes that there are a few old sources in the country that are not recorded in this database. The HASS inventory does not separate the HASS by use. Hence it does not easily allow having an idea of the number of HASS in each sector of activity. Together with the HASS inventory, the FANC maintains a database of the authorizations of the holders of all sources of ionising radiation.

4.2.2.4. Inspections and penalties

During inspections, a systematic verification between the records in possession of the Regulatory authority and the actual situation at the licensee is performed for all HASS. Inspections are performed by the Regulatory authority (in relation with safety and basis security issues) and by 2 recognised TSO's (in relation with safety issues only). In Belgium, non-proliferation verifications remain limited to nuclear materials and are hence not considered for HASS that are not considered nuclear material under safeguard.

As a general rule, controls by TSO are announced to the licensee and come with a frequency of 4 per year whilst Regulatory Authority's inspections are annually planned. In addition, unannounced inspections take place as well as inspections organised as part of follow-up actions after incidents or accidents.

In case of non-respect of regulations, a system of penal and administrative penalties is in place. These penalties depend on the type of infraction, but are not specifically related to HASS. They can range from €500 to €1000000 or imprisonment between 3 months and 2 years. The system of penalties has not been used yet.

4.2.2.5. Control of HASS by the holder

Regular testing by the licensee of safety and security performances are required by the Regulatory Authority. Leak tests are performed yearly. The reports on the results are not systematically transferred to the Regulatory Authority, but systematic verification of the execution of the tests is performed during inspection.

4.2.2.6. Sources holders' training

HASS holder's staff requires training, which is defined and delivered by the holder. Training sessions are given annually to the exposed workers, but a comprehension test is not always organized. These trainings cover all relevant topics and are recorded and documented by the holder and the Regulatory authority verifies the training records during inspections. Non-exposed workers receive only training on the radiation protection principles.

4.2.2.7. Identification and marking of HASS

There is only one HASS manufacturer in Belgium. There is no control by the Belgian authorities on the correct identification and marking of the HASS produced. HASS need to be systematically accompanied by the necessary documentation. This documentation contains only the source ID and photographs of the source design type. Some old sources for research have no ID in Belgium.

4.2.2.8. Transfers of HASS

In case of transfer of HASS, the Regulatory authority is informed of the transfer through the cross-check between the prior-authorisation request and the records of the holder and through issuing an authorisation/permit for the transport. The holder transferring a HASS also needs to verify that the recipient holds a valid authorisation for the possession of the source. This is done by requesting a copy of the authorisation to the recipient. For international transfer out of EU, an acknowledgement receipt of the source is requested to the new recipient. No cases where HASS got out of control during transfer are known to the Regulatory Authority.

4.2.2.9. Long-term management of disused HASS

With respect to the long-term management of HASS, the regulations do not define specific criteria for recommended working life or for sealed source performance. The holder of HASS is forced to make adequate arrangements for the long term management of HASS. The country's policy on disused sources gives priority to reuse of the source by another holder. If this would not be possible, returning the disused source to the supplier would be the preferred alternative to treating the disused source as radioactive waste and transferring it to an authorised waste treatment or storage facility. The actual situation of disused HASS however is such that reuse is rarely the case, so that the first solution would be return to the supplier, followed by treatment as radioactive waste. There is a maximal period of 5 years without use during which the holders can store a disused source at his premises. After that period, the HASS has to be considered as radioactive waste and transferred within 6 months to the national authorised storage facility for radioactive waste, operated by Belgoprocess in Dessel. This facility accepts disused HASS and its foreseen capacity is judged to be sufficient.

Situations with sources without a long-term management have already occurred, typically in Universities and in relation with bankruptcy of the holder or with orphan sources. These cases have been dealt with through funding by a nationally installed insolvency fund based on contributions from the radioactive waste producers and managed by the national organisation for radioactive waste management NIRAS/ONDRAF.

4.2.2.10. Security measures

With respect to security measures (fences, video surveillance, access control, locks, security staff, etc.), a national regulation is in preparation, but has not yet entered into force.

4.2.3. Detection

4.2.3.1. Detection of orphan sources

In cooperation with the stakeholders and the environmental administration of the three Belgian regions, the FANC has identified material flows, treated by the waste recycling and processing industries that risk containing orphan sources. These flows have been matched against the EC waste classification codes and are considered “orphan source sensitive flows”. Non-nuclear industries processing these flows are considered as “orphan source sensitive”. All the related facilities will have to apply minimum requirements for personnel training, vigilance measures and reaction to the discovery of a source. A reaction procedure has been set up and will also be made compulsory. Amongst the orphan source sensitive facilities, some have a higher probability of being confronted with orphan sources. Consequently, those facilities will have to comply with the obligation of systematic and automatic screening of all incoming orphan source sensitive material flows. The regulations specify the minimal requirements for the detection equipment to be foreseen. Next to these orphan sensitive industries, borders, harbours and transit hubs are considered strategic locations for detecting orphan sources.

4.2.3.2. Campaign for orphan sources recovery

Recovery campaigns have been organised, e.g. in schools, hospitals and pharmacies. These are not foreseen in the regulations, but are organised in function of needs and requests, in collaboration between the FANC, NIRAS and the recognised TSO. They are funded through the ‘polluter pays’ principle, using the scaling advantage for reducing the costs. In case the polluter cannot be identified, the insolvency funds of NIRAS, supplied through radioactive waste producers, will bear the costs.

4.2.3.3. International cooperation and information exchanges

Belgium is actively participating in international cooperation and information exchange, mainly through the established IAEA channels. The country is contributing to the IAEA Incident and Trafficking Database (ITDB) for over 10 years. Over the previous 10 years, Belgium made 3 notifications to the IAEA, on theft, loss and discovery of radioactive sources and it has been informed regularly by other countries on events involving radioactive material.

4.2.4. Preparedness and Response

4.2.4.1. Emergency plans and procedures

Belgium has a general emergency response plan in operation, also applicable in the case of radiological emergencies. However, although applicable, HASS or orphan sources are not specifically addressed in the plan. HASS holders also require an on-site emergency response plan, which needs to be approved by the qualified expert of the installation. The orphan source sensitive facilities do not require an emergency response plan, but require a vigilance procedure and a reaction procedure, in line with the applicable regulations.

In case of emergencies involving HASS or orphan sources, also in the orphan source sensitive facilities, the Regulatory authority has an emergency team available to intervene 24/7. This team is composed of 2 persons and has full radiological intervention equipment available, either directly, either through partners (e.g. mobile laboratories). The team can also call specialised companies, like TSO, transport companies, etc. Up to now the national emergency plan has not been initiated in Belgium in relation to situations involving HASS or orphan sources. The reaction scheme for orphan source sensitive facilities foresees a notification within 24h through a dedicated e-mail address. This system has been activated 217 times over the past 10 years.

4.2.4.2. Training and information of persons potentially confronted with an orphan source

Within the national emergency plan all required actions are attributed to responsible organisation. An extensive and adequate training and information plan is mandatory for all people who could potentially be confronted to orphan sources both at the level of the workers as at the level of the management. These training sessions are repeated yearly. There is no comprehension test organised. The emergency trainings include also practical exercises on identification of sources of ionising radiation.

4.3. Bulgaria

4.3.1. Regulatory framework with respect to HASS

4.3.1.1. Regulatory authority

The competent organisation in relation with HASS management is the Nuclear Regulatory Agency (NRA) and its inspections services. The Head of the NRA is the central authority and is designated to implement government regulation on the safe use of nuclear power and ionising radiation, as well as safe radioactive waste and spent fuel management. Military sources are also under the supervision of the NRA.

4.3.1.2. Legislative framework

The HASS Directive is currently fully transposed in the national regulatory framework. The legislative framework in the country is based on the following regulations, amended and supplemented with HASS requirements.

- *REGULATION ON RADIATION PROTECTION DURING ACTIVITIES WITH SOURCES OF IONISING RADIATION (Promulgated in "State Gazette", No. 74, August 24th, 2004, amended and supplemented SG No. 74/08.09.2006, effective 1.01.2007, amended SG No. 46/12.06.2007, effective 12.06.2007) (This regulation was in force for all radioactive sources before the transposition of the HASS Directive.)*
- *ACT ON THE SAFE USE OF NUCLEAR ENERGY (ASUNE) - Promulgated in the State Gazette No 63/2002, last amended and supplemented SG 80/2010 Regulation on the Procedure for Issuing Licenses and Permits for Safe Use of Nuclear Energy (Promulgated in the State Gazette No. 41/18.05.2004 Amended SG No. 78/30.09.2005)*
- *REGULATION ON THE TERMS AND PROCEDURE FOR DELIVERY OF RADIOACTIVE WASTE TO THE RADIOACTIVE WASTE STATE-OWNED COMPANY (Promulgated in SG, No.64 of 23 July 2004) Regulation for the procedure for assessment, collection, spending and control of the financial resources and definition of the amount of contributions due on the "Radioactive waste" Fund*
- *REGULATION ON EMERGENCY PLANNING AND EMERGENCY PREPAREDNESS IN CASE OF NUCLEAR AND RADIOLOGICAL EMERGENCIES (Adopted: Council of Ministers Decision No. 133 of 29 November 2011, Promulgated in the State Gazette 94/2011) National Emergency Plan - special procedure concerning orphan sources*
- *REGULATION OF THE CONDITIONS AND PROCEDURE FOR NOTIFICATION OF THE NUCLEAR REGULATORY AGENCY ABOUT EVENTS IN NUCLEAR FACILITIES AND SITES WITH SOURCES OF IONISING RADIATION. Adopted with CM Decree № 188, July 30, 2004, Promulgated in State Gazette 71/2004, amended SG issue 46/2007)*

4.3.2. Prevention and Deterrence

4.3.2.1. Authorization for practice with HASS

The authorisation for practice with HASS is done according to the following regulations:

- *REGULATION ON THE PROCEDURE FOR ISSUING LICENSES AND PERMITS FOR SAFE USE OF NUCLEAR ENERGY (Promulgated in the State Gazette No 41/2004, Amended SG No. 78/2005)*
- *REGULATION ON RADIATION PROTECTION DURING ACTIVITIES WITH SOURCES OF IONISING RADIATION (Promulgated in "State Gazette", No. 74/2004, amended and supplemented SG No. 74/2006, amended SG No. 46/2007)*
- *REGULATION ON PROVIDING OF PHYSICAL PROTECTION OF NUCLEAR FACILITIES NUCLEAR MATERIAL AND RADIOACTIVE SUBSTANCES (Promulgated in State Gazette No. 77/2004, amended SG No. 96/2005, supplemented SG No. 44/2008).*

All topics are being taken under consideration: justification of use; responsibilities; staff competencies; adequacy of the source with respect to its utilisation; available documentation and procedures for work and maintenance; emergency procedures and communication links; adequate arrangement for long term management of the disused sources; adequate financial security aspects for long term management of the disused sources; control measures to prevent inadequate use, unauthorised access, loss or theft of the HASS and control measures have been implemented to prevent damage of HASS by fire, flooding, etc.

The maximum licence period for the use of HASS is 10 years. On few occasions authorization for the use of a HASS has been refused because some requirements for radiation protection, safety and security of HASS were not met.

4.3.2.2. Records keeping and updating

HASS holders are required to keep records of all HASS under their responsibility in accordance with ASUNE and using the forms given in Annex II of the Directive. The HASS holder provides NRA with the recorded information periodically (12 months). Moreover, the information is provided at the acquisition time, when the holder no longer holds/uses the source and when the holder no longer uses any other source. When the sources are stolen or lost, the information should be provided immediately to the Ministry of Interior, the NRA and the Ministry of Public health. The maximum tolerated delay to provide the information is three months after the end of the year.

4.3.2.3. National inventory

The NRA maintains National Register of the Radioactive Sources that comprises all sealed sources category 1 to 5 - including HASS and other sources. The National Register is based on the IAEA recommendations given in the Code of Conduct (2004). It comprises all sealed and unsealed sources as well as X-ray devices and accelerators that are under regulatory control.

The information requested in the standard record sheet is in agreement with Annex II of the HASS directive. The register of HASS is available to police and to customs organisations, respectively. Holders' records are available for inspection by competent authorities. During inspections, the Authority checks the match between the actual situation of the HASS and the information recorded by the Holder, according to the Guidance for inspections approved by the NRA Chairman. The verification is made randomly on a certain number of HASS and at least for all the HASS every 12 months.

4.3.2.4. Inspections and penalties

20 inspectors of the NRA are in charge of the inspections of HASS holders for the aspects related to safety, security and radiation protection. Inspections are organised periodically (announced), randomly (unannounced) or as follow-up in case of an incident or any other suspicious situation.

The inspectors are trained on confrontation with a source; visual detection of sources and containers; requirements for safe management of sources; possible consequences of loss, theft or inadequate use or damage of sources; procedures for prompt notification to the Authority and emergency responses in case of accident. The standard equipment of inspectors consists of individual dosimeters; contamination detectors; list and pictures of typical sources and containers; specific tools are available (shielding, long arm pliers, etc.). The inspection is paid by an annual tax linked to the authorisation.

The Penalties are regulated by *the ACT ON THE SAFE USE OF NUCLEAR ENERGY (Promulgated in the State Gazette No 63/2002,* last amended and supplemented SG 80/2010) which includes special Chapter Eleven *ADMINISTRATIVE PENALTY PROVISIONS (Section I:ADMINISTRATIVE LIABILITY and Section II: ADMINISTRATIVE ENFORCEMENT MEASURES).*

4.3.2.5. Control of HASS by the holder

The inspection for leaks of HASS is a specific requirement for Licensees. Every licensee shall ensure control on the conditions of used or stored HASS by carrying regular leak test with frequency determined by the NRA. A qualified personnel has to be appointed for control and recording of HASS.

4.3.2.6. Sources holders' training

A comprehensive system for training and informing people working with high activity sources has been implemented in Bulgaria. The definition of the training program of the HASS holder staff is done according to the *REGULATION ON THE TERMS AND PROCEDURE FOR OBTAINING OF VOCATIONAL QUALIFICATION AND ON THE PROCEDURE FOR ISSUING OF LICENSES FOR SPECIALISED TRAINING AND OF INDIVIDUAL LICENSES FOR USE OF NUCLEAR POWER (Promulgated in "State Gazette", No. 74/2004, amended SG No. 46/2007)*.

The training sessions are recorded but no comprehension test is organized. The performance and efficiency of the training sessions is verified by checking training records during inspection and through regular reporting by the holder. The categories subjected to training are the management staff, the radiation protection officer and the exposed workers. The NRA published on its website a number of manuals, textbooks, monographs and other radiation protection-related training materials to help people who work in an ionisation radiation environment.

4.3.2.7. Identification and marking of HASS

The correct identification and marking of the HASS by the manufacturer/supplier is not currently verified by the Regulatory Authority. The recommended working life is given in the certificate of the source. Bulgaria does not produce any radioactive sources.

4.3.2.8. Transfers of HASS

On average, about 30 to 40 high-activity sources are imported each year in Bulgaria. Most of them are for gammagraphy (iridium-192, selenium-75) and more rarely for gammatherapy (cobalt-60) and brachytherapy or for metrology and technological control devices (caesium-137, americium-241, iridium-192, etc.).

Permit holders (importers) and licensees (users) inform the NRA of the movement and location of the respective ionising radiation sources. Licensees are required to notify the NRA of all new circumstances and events relating to the change of ownership, location and of any accident or

emergency with ionising radiation sources. In the event of failure to notify the authority, the administrative penal provisions set out shall be applied.

The NRA issues an authorisation/permit for the transport and issues an authorisation to the Recipient in case of a National transfer. Additionally, the NRA is informed of individual transfer of HASS by the National Authority of the Recipient's country in case of an International transfer.

4.3.2.9. Long-term management of disused HASS

According to the design documentation of the sources, the NRA defines a limited useful life for HASS of 10 years of safe operating lifetime. Once the safe operating lifetime is ended, it should be treated as radioactive waste. If the holder still wants to use the source it is its obligation to re-test the source for a new working period. Reuse has to be authorized by the NRA.

The preferred strategy for the long-term management is the return to the supplier of the disused sources but represents more the exception rather than the rule although sources import is allowed on condition of their guaranteed return to the manufacturer upon termination of use. The solutions actually implemented are the transfer to authorised radioactive waste treatment/storage. Sources are declared as radioactive waste to the "State Enterprise Radioactive Waste" (SERAW) which has been licensed by NRA to carry out activities relating to the safe management of radioactive waste. The facility used at present is not adapted to the potential amount of disused sources; therefore the construction of a new authorized facility is planned. Disused source storage at the user's premises is allowed only on a case by case basis.

The long-term management of disused HASS is funded by provisions incorporated in the supply contract and by the fund pre-paid by the Holder to the State or competent authority.

4.3.2.10. Security measures

According to *REGULATION On Providing of Physical Protection of Nuclear Facilities Nuclear Material and Radioactive substances (Promulgated in State Gazette No. 77/2004, amended SG No. 96/2005*, supplemented SG No. 44/2008), the minimum compulsory security requirements for HASS are:

- holder's premises during use: fences, video surveillance, access control, security staff;
- holder's premises during storage: fences, video surveillance, access control, security staff, locked premises, sources with a lock;
- place of use for mobile sources: fences, security staff, sources with a lock;
- authorized radwaste storage facility: fences, video surveillance, access control, security staff, locked premises, sources with a lock, fire detection.

4.3.3. Detection

4.3.3.1. Detection of orphan sources

The strategic locations identified to detect orphan sources are metal scrap yards and recycling facilities; metallurgical industries; conventional waste management facilities, borders/customs and harbours; airports. The detection equipment is of portable type and/or portals. The controls are voluntary with exception of the conventional waste management facilities where the controls are mandatory.

4.3.3.2. Campaign for orphan sources recovery

The regulatory framework does not ensure that campaigns to recover orphan sources are organised and no budget is assigned to that. Nevertheless some recovery campaigns have been organised by NRA

and SERAW. The costs related to recovery and LT management of orphan sources is supported by State and source holders.

4.3.3.3. International cooperation and information exchanges

Bulgaria contributes to the IAEA Incident and Trafficking Database.

4.3.4. Preparedness and Response

4.3.4.1. Emergency plans and procedures

Bulgaria has a national radiological emergency response plan in place with relation to HASS and orphan sources. It has been approved by the competent Authority (NRA). Response procedures in the event of emergencies with orphan sources are annexed to the National Emergency Plan. These documents regulate the responsibilities for cooperation of interested departments and reduce the potential overlapping of role. This is particularly the case for all communications and instructions to the public.

There is an emergency team available to intervene 24/7 in case of emergency.

There are compulsory emergency preparedness and response requirements for the HASS holders which have to be approved by the authority. Similar requirements are available for facilities where orphan sources are likely to be found.

4.3.4.2. Training and information of persons potentially confronted with an orphan source

The NRA organises courses and carries out training on the application of the new legislation in the field of emergency planning and response for employees of the MIA, SANS, General Department "Border Police" and State Agency Customs as well as for companies working with scrap metal. These training course are however not obligatory according to the regulations, neither documented nor regularly repeated.

4.4. Cyprus

4.4.1. Regulatory framework with respect to HASS

4.4.1.1. Regulatory authority

The Regulatory authorityis the Radiation Inspection and Control Service (RICS) of the Department of Labour Inspection, Ministry of Labour and Social Insurance.

The use of ionising radiation in the country is mainly dedicated to applications in medicine, and some applications in industry, construction and education/research. Most of the high-activity sealed sources falling within the scope of the Directive are disused and kept in a dedicated authorised safe storage catering for all disused sources in the country.

All practices involving the use of high-activity sealed sources and all premises, where exposure to ionising radiation occurs or may occur, need prior authorisation and are regularly inspected by RICS to verify compliance with the legislation requirements.

The obligations of the licensees include risk assessment, training of the staff, preparation of emergency preparedness and response plans, maintenance of equipment, sources and containers, adequate management of waste and disused sources, keeping of suitable records of all sources in their possession, appropriate testing of both the sources and the equipment, and prompt notification of the authority after an incident or accident resulting from unintentional exposure of workers or members of the public.

There is a system for the detection of orphan sources in places where these could be possibly encountered, such as in large metal scrap yards, customs and major ports, where radiation monitoring equipment has been installed and is in use. So far, there has been a number of campaigns for the identification or recovery of orphan sources from past activities.

4.4.1.2. Legislative framework

The legal framework consists of

- *"The Protection from Ionising Radiation and Nuclear Safety Laws of 2002 to 2011" promulgated in 2002 and amended in 2009 and 2011 and relevant sets of Regulations issued under these Laws.*
- *The Council Directive 2003/122/EURATOM of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources* was fully transposed into the national legislation as a set of Regulations under the above mentioned Laws with the title *"The Protection from Ionising Radiation (Control of High-Activity Sealed Sources and Orphan Sources) Regulations of 2006" (P.I. 30/2006, OJ 4075, 31.01.2006).*

A source is excluded from the regulatory control when its activity level is below the exemption level specified in Directive 96/29/EURATOM.

A source with high activity, which classified it as a HASS according to the Directive, whose activity has been reduced below the HASS specified levels, when the HASS Directive was transposed, is covered by the provisions and amendments of the Protection from Ionising Radiation and Nuclear Safety Laws of 2002 to 2011. The Protection from Ionising Radiation (Control of High-Activity Sealed Sources and Orphan Sources) Regulations of 2006 specify which sources are classified as HASS and provide a special form to be completed for the record keeping of HASS sources. They also impose some additional requirements for the owners and users of HASS sources. The licensing procedure is the same for all sources.

4.4.2. Prevention and Deterrence

4.4.2.1. Authorization for practice with HASS

Before issuing an authorisation, all relevant factors are being taken under consideration: justification of use; responsibilities; staff competencies; adequacy of the source with respect to its utilisation; available documentation and procedures for work and maintenance; emergency procedures and communication links; adequate arrangement for long term management of the disused sources; control measures to prevent inadequate use, unauthorised access, loss or theft of the HASS and control measures to prevent damage of HASS by fire, flooding, etc. Until present, RICS has not refused an authorisation.

4.4.2.2. Records keeping and updating

HASS holders are required to keep records of all HASS under their responsibility. A HASS holder provides to RICS the recorded information at the acquisition time, every 12 months and also whenever such information is requested by the RA. No notification needs to be immediately done after modifications of the status of the HASS (in use, disused, transferred …).

4.4.2.3. National inventory

The recorded information is kept in a national inventory of authorised HASS holders and their HASS. The information is provided in writing (in paper or electronic form) and the data is processed in an electronic database (RAIS). The registry of authorised HASS holders is available to the customs authorities and the police at their request.

4.4.2.4. Inspections and penalties

Inspectors of RICS are in charge of the inspections of HASS holders in the fields of Safety, Security and Non-proliferation. The inspections are carried out periodically (announced or unannounced) and as a follow-up action in case of incidents. The frequency of inspections for each holder depends on the type of sources, the risk involved, their mobility, results of previous inspections etc. (Graded Approach). The inspections are funded directly by the Government.

The penalties in case of breaches are a maximum of €34.500 fine, two years imprisonment or both penalties simultaneously. No penalties have been imposed yet.

4.4.2.5. Control of HASS by the holder

The regulatory authority verifies the regular performance of suitable tests (visual verification, leak tests, dose rate measurement) by the holder to control the good conditions of each HASS during inspections and by receiving the tests results.

4.4.2.6. Sources holders' training

The content of the training programme is defined by the HASS holder and approved by the RA, while the training sessions are given by the holder and by any training organisation approved by the RA. The training sessions are recorded but no comprehension test is organized. The performance and efficiency of the training sessions are carried out by checking training records during inspections and by regular reporting as required to the RA. The personnel categories subjected to training are the management staff, the radiation protection officer and the potentially exposed workers.

4.4.2.7. Identification and marking of HASS

The documentation accompanying a HASS includes the source identification, on the source or on the container, information and photographs of the source, container and transport packaging. To the knowledge of the authority, there are no HASS in the territory without identification number. No working life is recommended for the use of HASS.

4.4.2.8. Transfers of HASS

The authority is informed of individual transfer of a HASS by issuing a permit to the holder for the transfer and by issuing authorisation for both the transport of the source and the recipient in case of national transfer. In case of international transfer, the authority is informed by the national RA of the recipient country. The holder ascertains that the recipient holds the appropriate authorisation by asking for a copy of it. Cyprus has not encountered up to now situations with sources out of control due to unrecorded transfers.

4.4.2.9. Long-term management of disused HASS

The national regulatory framework does not specify a limited useful life for HASS. Authorisation for holding HASS is issued only if the long-term management route is already specified and planned. The applied strategy for the long-term management is the return to the supplier of the disused sources. The import of a new source is nowadays conditioned to its re-export after use. "Take-back" provisions have to be incorporated into the supply contract.

The storage at the holder's premises seems also to be a solution, which could be implemented for a certain period of time, until export. An authorised storage facility is available at national level with limited capacity for temporary storage only.

4.4.2.10. Security measures

The security requirements for HASS foresee fences, recorded control access, locked premises and locked sources as well as fire detection. Video surveillance is not considered necessary.

4.4.3. Detection

4.4.3.1. Detection of orphan sources

A threat assessment concerning orphan sources has been performed at national level by the authority, giving as strategic locations for finding orphan sources metal scrap yards, borders/customs, harbours and airports. All of these sites are currently monitored or equipped with radiation monitoring portals, scanners and other portable monitoring equipment. The use of detection equipment is compulsory in metal scrap yards, ports and airports. The equipment used is approved by the authority, which has also various types of sensitive equipment for the detection of orphan sources.

4.4.3.2. Campaign for orphan sources recovery

Starting from systematic analysis of historical records available at the authority, in industries and other workplaces, the authority has organised a number of campaigns for the identification or recovery of orphan sources from past activities, such as from a decommissioned phosphoric acid plant, and other practices in medicine, industrial radiography, tobacco industry, brewery, copper mining, and brick/ceramics plants.

All HASS in Cyprus are accounted for. Training and information has been provided to all stakeholders involved.

4.4.3.3. International cooperation and information exchanges

Cyprus is being informed by foreign countries about sources that have been stolen, lost, discovered, etc. Cyprus participates in the IAEA Incident and Trafficking Database but until present no cases have been reported.

4.4.4. Preparedness and Response

4.4.4.1. Emergency plans and procedures

Cyprus has a national radiological emergency response plan in place to deal with orphan sources and HASS. The emergency response plan has not been initiated up to now because no orphan sources were detected or incidents involving HASS occurred. There are compulsory emergency preparedness and response requirements for the HASS holders and users as well as for operators of institutions where orphan sources are most likely to be found. These requirements as well as the procedures must be approved by the regulatory authority.

There is a unique contact point designated in case of detection of an orphan source and there are both a general and a dedicated emergency call numbers. Information campaign is restricted to people and institutions likely to be confronted with orphan sources and to emergency services.

The authority emergency team is available 24/7 in case of emergency. The equipment available is composed of measurement devices, individual protection equipment, shielding containers and decontamination material. The emergency response plan has not been initiated up to now because no orphan sources were detected or incidents with HASS occurred.

4.4.4.2. Training and information of persons potentially confronted with an orphan source

The personnel potentially confronted with orphan sources are trained and the courses are obligatory according to the regulations. The training is addressed to workers and managers in the emergency and transport sectors and in the facilities. The courses are documented and regularly repeated. The training sessions include practical exercises depending on the audience but no comprehension test is organised.

4.5. Czech Republic

4.5.1. Regulatory framework with respect to HASS

4.5.1.1. Regulatory authority

The regulatory body responsible for HASS in the Czech Republic is the State Office for Nuclear Safety (SÚJB). The SÚJB is a regulatory body responsible for governmental administration and supervision in the fields of uses of nuclear energy and radiation and of radiation protection. Duties relevant to HASS include particularly:

- Radiation protection and emergency preparedness of workplaces handling ionising radiation sources, including HASS;
- Licensing of activities e.g. for the siting and operation of workplaces handling very significant ionising radiation sources, for handling ionising radiation sources and for radioactive wastes;
- Reviewing and approving documentation related to radiation protection, ensuring security for radioactive material, emergency rules for the transport of selected radioactive sources and internal emergency plans of workplaces handling ionising radiation sources;
- Specifying conditions and requirements for radiation protection of the public and personnel handling ionising radiation sources (e.g. laying down limits and defining controlled zones), specifying emergency planning zones and licensees' emergency preparedness requirements;
- Managing the national record-keeping systems for licensees, selected import and export items, ionising radiation sources, and exposure of the public and personnel handling ionising radiation sources.

Training and information is within the responsibility of the licensees.

Financial security of orphan sources falls under the responsibility of SÚJB and the report on experience is also covered by SÚJB.

4.5.1.2. Legislative framework

The Czech Republic has fully implemented the HASS Directive into the national legal framework.

References are:

- *Act. No. 18/1997 Coll. on Peaceful Utilization of Nuclear Energy and Ionising Radiation (Atomic Act)*
- *Regulation No. 307/2002 Coll. implemented 1.1,2005.*

The activity levels in the legislation for HASS follow Annex 1 of the HASS Directive. All sources with activity levels below the high-activity levels but above the clearance levels are covered also by the above mentioned regulations, these requirements have been in force before the transposition of the HASS Directive. The main differences in the requirements regarding the HASS are records, financial security for orphan sources and report on experience.

4.5.2. Prevention and Deterrence

4.5.2.1. Authorization for practice with HASS

Before issuing an authorization for the use of HASS, all relevant issues are considered by the Regulatory Authority, including external accidents (fire, flooding …) and emergency procedures. Authorization is only granted after all relevant information is received and has been judged as being adequate by the Regulatory Authority.

An authorization for HASS has never been refused in the Czech Republic

4.5.2.2. Records keeping and updating

All HASS holders are required to maintain records of the HASS under their responsibility. An electronic or written copy of these records is to be sent to the Regulatory authority at acquisition of the source and periodically every 12 month. At important modifications, the records do not have to be sent to the Regulatory Authority. Regulations do not foresee an allowable delay for providing the records to the Regulatory Authority. The recorded information supplied by the HASS holder is in general complete.

4.5.2.3. National inventory

The information received through these records is used to maintain an electronic national inventory of authorised HASS holders and the HASS they hold, which is covering all information requested in the standard record sheet. There is a common database of radioactive sources, HASS sources are indicated. There are no HASS in the country not covered in the national data base or identified in the holder's records. The register of authorised source holders is available to customs and police organizations on request.

4.5.2.4. Inspections and penalties

The holder's records are available for inspection. During inspections, a systematic verification between the records in possession of the Regulatory Authority, the records by the holder and the actual situation at the licensee is performed for all HASS. Inspections (announced on a yearly basis and unannounced) are performed by the Regulatory Authority, taking care of safety, security and non-proliferation measures by a common inspection in all fields. Inspections can also take place as a follow-up in case of an incident or any other suspicious situation. The inspections are funded directly by the State. Inspectors receive training in nearly all relevant fields. The necessary equipment for performing an inspection is available and specific to the duties (safety, security and non-proliferation).

In case of non-respect of regulations, a system of administrative penalties is in place. These administrative penalties depend on the type of infraction and can range up to 50 million CZK. The system of penalties has been used in the cases of usage without authorization, breach of obligation for radiation protection in usage of HASS.

4.5.2.5. Control of HASS by the holder

Regular testing by the licensee of safety and security performances is part of the inspection. Safety tests of HASS carried out by the holder include visual verification, leak tests and dose rate measurements with individually decided frequency according to the monitoring plan and the QA programme. The competent authority is informed on the control measures implemented to prevent inadequate use etc. during the authorisation process, by regular reporting by the holder and through inspections.

4.5.2.6. Sources holders' training

Content of the training program of HASS holder's staff is defined by the authority and the holder. Training material is prepared by the holder. Training sessions can also be subcontracted. The frequency is once a year for radiation workers. Training sessions are recorded. A comprehensive test is organised. The performance and efficiency of training sessions is verified by checking the training records during inspection. Non-exposed workers and management staff are not trained.

Radiation protection officers are trained in radiation protection principles, specific requirements of safe management of sources, possible consequences of loss, theft or inadequate use or damage of sources, and notification to the competent authorities and emergency responses in case of accident. Exposed workers are trained in radiation protection principles, possible consequences of loss, theft or inadequate use or damage of sources, and notification to the competent authorities and emergency responses in case of accident.

4.5.2.7. Identification and marking of HASS

Usually the documentation accompanying HASS includes source identification, information and photographs of source design type, information and photographs of typical source container, information and photographs of transport packing, information and photographs of device and equipment. No HASS are reported to be present in Czech Republic without ID, but some older sources could have the same identification number.

Correct identification and marking is verified during the licensing process (QA Programme) and checked during inspection. Recommended limited working life by the manufacturer is available.

4.5.2.8. Transfers of HASS

Before the transfer of a HASS the holder ascertain that the recipient holds an appropriate authorization by asking a copy of the authorization to the recipient. There is no evidence of loss or out of control because of unrecorded transfer.

4.5.2.9. Long-term management of disused HASS

The national regulatory framework does not define a limited useful life for HASS. It is the obligation of the holder to decide whether a source is considered to be disused. When the useful life of a HASS is expired the holders have to consider either:

- source to be still suitable and therefore re-test it for a new working period;
- source to be disused and send it back to the supplier/manufacturer or to another authorised user;
- source to be disused and to store/dispose it.

The country's policy on disused sources gives priority to returning the disused source to the supplier or transfer to another authorized user. If this would not be possible, the disused source should be considered as radioactive waste and be transferred to the national authorised waste treatment and storage facility. The actual situation of disused HASS corresponds to this policy. Storage of disused sources at the premises is however possible.

The national waste treatment and storage facility accepts disused sources; its capacity is adapted to the potential of disused sources. A situation dealing with disused sources without any financial solution for long-term management occurred. Long term management of disused HASS is usually funded by the holder, but can be financed by the State, if necessary.

Before a licence is terminated the licensee shall, with the approval of the SÚJB, provide on a contractual basis a legal successor or ensure safe termination of radiation practices. In any case the

State takes care of disused sources without financial security and orphan sources, even if it is not expressed in the legal framework explicitly as an obligation.

4.5.2.10. Security measures

There are security requirements laid down in the Atomic Law and in Regulation 307/2002 Coll. on radiation protection.

4.5.3. Detection

4.5.3.1. Detection of orphan sources

A threat assessment regarding orphan sources was performed by the Regulatory Authority, yielding as strategic location for finding orphan sources: metal scrap yards, metal scrap recycling facilities, conventional waste management facilities, borders/customs and airports. Detection equipment is available on a voluntary basis for metal scrap yards, metal recycling plants, metallurgical industries, conventional waste management facilities, borders/customs, transit hubs and airports. The danger of high financial costs in the case of returned load or goods encourages the use of detection equipment on a voluntary basis.

4.5.3.2. Campaign for orphan sources recovery

The regulatory framework does not ensure that campaigns are organised and thus campaigns have not taken place. There is no dedicated budget foreseen, with little available means (lack of budget and lack of competent staff). To possibly recover disused sources, systematic inspections of facilities in insolvency are performed, based on information provided by the Ministry of Justice.

The best method to recover orphan sources is using radiation detection equipment in strategic locations. The recovered radioactive material would be transferred to the waste treatment and storage facility or returned to supplier. There is no financial strategy covering intervention costs.

4.5.3.3. International cooperation and information exchanges

There have been two cases of discovery and ten cases of illicit trafficking within the last 10 years which have been communicated to the IAEA. The competent authority has been informed about distribution of contaminated steel by a foreign country. The Czech Republic is contributing to the IAEA Incident and Trafficking Database (ITDB) since 1993.

4.5.4. Preparedness and Response

4.5.4.1. Emergency plans and procedures

The Czech Republic has no emergency response plan in operation specifically applicable in the case of orphan sources and HASS.

An emergency team is available 24/7. Available equipment is: communication devices, measurement devices, individual protection equipment, shielded containers and detection material.

There are compulsory emergency preparedness and response requirements for HASS holders and the emergency response plans and/or procedures have to be approved by the authority. There are no compulsory emergency preparedness and response requirements for the institutions where orphan sources are more likely to be found. There is a unique contact point designed in case of detection of an orphan source, which is the general emergency call number.

Contamination control of the site after source removal is outsourced to an accredited technical support organisation. They have to report to SÚJB.

4.5.4.2. Training and information of persons potentially confronted with an orphan source

Personnel potentially confronted with an orphan source are trained. Training is given in the field of emergency to first responders (police, firemen and medical staff) and in the field of transport to customs officers and airport personnel. The content of the training courses in the field of emergency includes: information concerning the potential confrontation with a source, radiation protection principles, specific requirements for safe management of sources, procedures for prompt notification to competent authorities and emergency responses in case of (potential) detection/accident and actions to be taken on site in the event of the detection or suspected detection of a source. No training is foreseen for the fields transport, facilities and for others. These training courses are voluntary and are not documented, they are not regularly repeated and there is no comprehensive test organized.

4.6. Denmark

4.6.1. Regulatory framework with respect to HASS

4.6.1.1. Regulatory authority

The competent nuclear authority is the National Institute for Radiation Protection (NIRP), which is administratively part of the National Board of Health. The NIRP is responsible for all the requirements of the HASS Directive except for the financial security matter, which is a responsibility of the State.

4.6.1.2. Legislative framework

The legislative framework in the country is based upon:

- *Order no. 985 of 11 July 2007 on the Use of sealed radioactive sources*, which transposes the HASS Directive and used the same definition for a high-active source as the one from the HASS Directive. This law is applicable either for HASS and non-HASS. A HASS falling below the defined high-activity levels is still covered by this law. A source is always kept under regulatory control regardless the activity level.
- Before this law, *the Orders no. 308 of 24 May 1984 and no. 918 of 4 December 1995* were in force and were dealing respectively with the gamma radiographic sources and the other sealed sources. The main differences between the old regulations and new one are to be found in transfers (Article 4), records keeping (Article 5) and identification and marking (Article 7).

A source whose activity would have defined it as a HASS but whose activity had fallen down below the high-activity levels when the HASS Directive was transposed is covered by the aforementioned two orders.

4.6.2. Prevention and Deterrence

4.6.2.1. Authorization for practice with HASS

Before issuing an authorisation for the use of a HASS, the justification of use, responsibilities, staff competencies, adequacy of the source and its associated device with respect to its use, available documentation and procedures for work and maintenance, emergency procedures and communication links, control measures implemented to prevent inadequate use, unauthorized access, loss, theft, fire, flooding, etc. are considered. Arrangements for long term management of disused sources and related financial security are not considered before issuing an authorisation. (Note that this information is contradictory with the one given in 2.9.). The NIRP has refused an authorisation for use of a HASS because of an unjustified use.

4.6.2.2. Records keeping and updating

Each HASS holder has the obligation to keep records of all HASS under his responsibility and to provide the NIRP with the recorded information at the acquisition time, annually, or when the holder no longer holds or uses the source or when he stops his activities. No delay time to provide the records is prescribed in the legislation. NIRP keeps an electronic database of all authorized HASS holders and sources including all information requested in the standard record sheet given in Annex II of the HASS Directive. The non-HASS are recorded in the same database.

4.6.2.3. National inventory

According to NIRP there are no HASS in the country which are not recorded in the national database or identified in the holder's record. The register of authorized sources holders and of HASS is available to customs organisations and to police via request to NIRP.

4.6.2.4. Inspections and penalties

During inspections, the authority (NIRP) has access to the holder's records and check randomly the match between them and actual situation. Inspection looks at safety, security and non-proliferation fields and are organized both announced and unannounced. Inspections are funded by the State and through an annual tax linked to the authorization. Inspectors are staff from NIRP. They are equipped with all necessary equipment (individual dosimeter, contamination detectors, list and pictures of typical sources and containers, specific tools if needed).

Penalties are foreseen and have already been applied in case of breach of the national provisions pursuant to the HASS Directive.

4.6.2.5. Control of HASS by the holder

Tests carried out by the Holder to ensure the good conditions of each HASS are visual verification and dose rate measurement (no leak tests). They are performed annually and the results are communicated to the competent Authority. Their performance is also checked during inspections.

The security measures are examined during the authorization process and during inspections.

4.6.2.6. Sources holders' training

The Holder is responsible for defining the content of the training programme of its staff and the preparation of training material. The training courses are given to the radiation protection officer and exposed workers by the Holder itself. Non-exposed workers receive a basic training on radiation protection principles. Training sessions occur every 5 years. They are recorded but no comprehension test is organized. The records of training are checked by the Authority during inspections.

4.6.2.7. Identification and marking of HASS

HASS is systematically accompanied by the necessary relevant documentation. No cases of HASS without identification or information on its nature are known to the Regulatory Authority.

4.6.2.8. Transfers of HASS

In case of a national transfer of HASS, the Regulatory authority is informed of this transfer because a license needs to be requested by the Recipient of the source. In case of an international transfer, the Competent Authority will be contacted by their counterparts of the country of the Recipient. The records of the Holder give also indication of the transfer. The Holder transferring a HASS does not check that the Recipient holds a valid authorization for the possession of the source.

No cases where HASS went out of control during transfer are known to the Regulatory Authority.

4.6.2.9. Long-term management of disused HASS

Concerning the long-term management of HASS, no limited working life is defined in the national regulatory framework. An authorization is only granted if the long-term management route is already specified and planned. Similarly the import of a new source is conditioned on its re-export.

The country's policy on disused sources gives priority to returning the disused source to the supplier. If this would not be possible, the disused sources should be considered as radioactive waste and be transferred to an authorized waste treatment or storage facility. The re-use of the source for another application is only considered as last possibility.

The transfer of disused HASS for long-term management has to be arranged as soon as possible after termination of its use. No cases of disused source without long-term management solution are known to the Authority.

A national authorized storage facility for radioactive waste and accepting disused HASS is available in the country. Its capacity is considered as adapted to the potential amount of disused sources. Currently the long-term management of disused HASS is funded through take-back provisions incorporated in the supply contracts and through a State guarantee.

4.6.2.10. Security measures

Only locking mechanism is required for the Holder's premises (both during use and storage). The radwaste storage facility is secured through fences, access control and locks. For mobile use, locks on the source container are used. The security measures are examined during the authorization process and during inspections.

4.6.3. Detection

4.6.3.1. Detection of orphan sources

No threat assessment regarding orphan sources has been performed by the Regulatory Authority. Detection equipment at strategic locations for finding sources is present on voluntary basis. In that context, metal scrap yards and metal recycling plants are equipped with portal and portable equipment whereas border crossings, harbours and airports are equipped with portable equipment. Nothing is planned for metallurgic industries, conventional waste management facilities and transit hubs.

4.6.3.2. Campaign for orphan sources recovery

Registries follow-up (analysis of available historical records) and specific campaigns in scrap yards and metal recycling facilities have been realized by the Authority as recovery campaigns for orphan sources. No orphan sources have so far been discovered.

No specific budget is dedicated for this topic and no financial strategy is in place for dealing with recovery and long-term management of orphan sources.

4.6.3.3. International cooperation and information exchanges

Denmark is participating in international cooperation and information exchange mainly through the established IAEA channels. The country is contributing to the IAEA Incident and Trafficking Database (ITDB). It also uses this database as an international information source.

4.6.4. Preparedness and Response

4.6.4.1. Emergency plans and procedures

Denmark does not specifically have a national emergency response plan dedicated to orphan sources or HASS. But the Danish Emergency Management Agency (DEMA) is in charge of the national nuclear emergency preparedness planning and has prepared a national nuclear emergency management plan.

The NIRP has an emergency team ready to intervene 24/7 in case of emergency with an orphan sources or HASS. The team is composed of the NIRP staff and has all necessary equipment except mobile laboratories in dedicated vehicles. Up to now, the emergency plan has never been triggered because of orphan sources detection or incident with HASS.

Also the HASS Holders are required to have emergency preparedness and response plans which have to be approved by the Authority. No such requirement applies to institutions where orphan sources are more likely to be found.

Within the emergency plans, first actions such as first instructions to public, mobilization of responders, ensuring the security of the site and source are attributed to the emergency services. The Authority is responsible for ensuring the security of the source and additionally for the radiological assessment, transport of the source and contamination control of the site after source removal.

4.6.4.2. Training and information of persons potentially confronted with an orphan source

Managers of emergency services, scrap yards, metal recycling plants, customs and waste management facilities are trained on orphan source situations. Staffs from transit hubs, harbours, airport and metallurgical industries are not trained. The training sessions address the procedures and actions to be taken in case of detection, accident or suspicion for each activity sector.

There are no requirements to have such training according to the regulations. Trainings are neither documented nor repeated, no comprehension test is organized and no practical exercises are made.

The National Board of Health has sent out guidelines, primarily aimed at the recovery industry, concerning measures relating to the discovery of radioactive substances in scrap. The guidelines include help in identifying equipment with radioactive sources and instructions on measures to take following discovery of the type of equipment concerned. The guidelines are used for training purposes by the police, firefighters, and emergency staff, etc.

4.7. Estonia

4.7.1. Regulatory framework with respect to HASS

4.7.1.1. Regulatory authority

The competent authorities in accordance with the HASS Directive are the Ministry of Environment through the Environmental Board, the Environmental Inspectorate and the Estonian Rescue Board. The responsibilities are divided among these organisations, e.g. the Environmental Board deals with authorisation, transfers, records, orphan sources and International cooperation. The Ministry of Environment deals with orphan sources, financial security for orphan sources, report on experience and transposition. The Rescue Board is the designated contact point in case of detection of an orphan source

4.7.1.2. Legislative framework

The main legal instrument is the "*Radiation Act*" which entered into force on 01.05.2004. The principles of radiation and nuclear safety as well as the responsibilities of the licence holder are defined by this Act. Article 2 of the Act specifies that no radiation practice should be started without a radiation practice licence. There is no system for notification and registration. The Environmental Impact Assessment and Auditing Act states that the environmental impact shall be assessed upon application for if the proposed activity results in significant environmental impact.

According to the Article 14 of the Radiation Act, all radiation practices shall be performed only by licence holders. Article 18 establishes requirement for license holder to ensure finances for safe management of source after the end of its use. Article 18 (1) lists the documents, which the applicant for a radiation practice licence shall present, while Article 18 (3) defines the practices of low, moderate and high risk. All practices involving radioactive waste management and nuclear fuel cycle and the corresponding facilities, as well as practices using high-activity radiation sources are considered as practices of high radiation risk (Article 18 (3(1)). Article 19 establishes generic data and conditions common for all radiation practice licences and the additional ones, including public involvement (Article 20 and 21) in case of radioactive waste management and nuclear fuel cycle related activities as well as work activities within which the presence of natural radiation sources leads to a significant increase in the exposure which cannot be disregarded from the radiation protection point of view.

Fulfilments of conditions of the radiation practice licence as well as requirements of the Radiation Act are subject to inspection and control by the Environmental Inspectorate. The requirements for licence application are established with the Regulation No. 41 of 29 April 2004 "The Time Limits for Proceedings to Issue, Amend or Revoke Radiation Practice Licences, the Specific Requirements for and Format of Applications for Radiation Practice Licences, and the Format of Radiation Practice Licences". In Estonia radiation practice licence is valid up to 5 years.

The HASS Directive is fully transposed into the national regulatory framework; the date of enactment was 11 June 2006. The Regulation No. 113 of 7 September 2004, which entered into force on 19 September 2004 and was amended on 15 June 2006 deals with "*Activity Levels of Radionuclides, Requirements for the rooms where the Radiation Sources are situated, and for Labelling rooms and Radiation Sources*".

The regulation in force for sources with activity level below the high-activity level defined in the regulatory framework remains the one in force for all radioactive sources before the transposition of the HASS Directive, namely the Radiation Act and the Regulation of the Government No. 163 of 30 April 2004 concerning "*The Bases for Calculation of Exemption Values, and the Exemption Values for Radionuclides*" (entered into force 07.05.2004). Radiation Act, Article 30 sets the obligations for holder of radiation practice licence.

4.7.2. Prevention and Deterrence

4.7.2.1. Authorization for practice with HASS

The authorisation for practice with HASS is done according to the Radiation Act. All topics are being taken under consideration: justification of use; responsibilities; staff competencies; adequacy of the source with respect to its utilisation; available documentation and procedures for work and maintenance; emergency procedures and communication links; adequate arrangement for long term management of the disused sources; control measures to prevent inadequate use, unauthorised access, loss or theft of the HASS and control measures have been implemented to prevent damage of HASS by fire, flooding, etc.

Estonia has refused an authorisation for the use of HASS due to a failure in the justification of use.

4.7.2.2. Records keeping and updating

The holder of a radiation practice licence has the obligation to report an annual inventory of the radiation sources to the Environmental Board by 1 March of the following year (Radiation Act, Article 30). The recorded information is updated by the authority annually and when the holder no longer uses the source. There is no limited time delay authorised for providing the recorded information.

4.7.2.3. National inventory

With the information electronically provided by the HASS holder, the Environmental Board is in charge of maintaining a national inventory of authorized HASS holders and the HASS they hold. Entries shall be made either for the import or use of a radiation source based on the information contained in the radiation practice licence (Radiation Act, Article 37). The information recorded is the one requested in the standard record sheet given in Annex II of the HASS Directive. The sources not covered by the HASS Directive are recorded in the same database. The registry of licence holders is available to police organizations and only partially to customs organizations.

4.7.2.4. Inspections and penalties

Acting as an expert body, the Environmental Board is in charge of inspections of HASS holders in the field of Safety (Sf), Security (Sc) and Non-proliferation (Np) whilst the Environmental Inspectorate inspects on a routine basis both the Sf and Sc domains. A periodic inspection of authorised holders is announced and organised once per year for Sf and Sc. Random inspections are also organized and unannounced for Sc.

The inspectors are trained on visual detection of sources and containers; requirements for safe management of sources; possible consequences of loss, theft or inadequate use or damage of sources; procedures for prompt notification to the Authority and emergency responses in case of accident. The equipment of the inspectors consists of individual dosimeters; contamination detectors; pictures of typical sources and containers. The inspection is funded directly by the State.

Holders' records are available for inspection. During inspections and at least every 12 months for all the HASS, the Authority checks the match between the actual situation of the HASS and the information recorded by the Holder.

The penalties for breaches are as follows:

- Use of radiation source without radiation practice license: up to 300 fine units. The same act, if committed by a legal person, is punishable by a fine of up to 3200 euros.
- Violation of the requirements determined by a radiation practice license: up to 300 fine units. The same act, if committed by a legal person, is punishable by a fine of up to 3200 euros.
- Conveyance of radiation sources containing radioactive substances and conveyance of radioactive waste across the state border without an appropriate permit up to 300 fine units. The same act, if committed by a legal person, is punishable by a fine of up to 3200 Euros.
- Delivery of radiation sources containing radioactive substances and delivery of radioactive waste to a person who does not hold a radiation practice licence: up to 300 fine units. The same act, if committed by a legal person, is punishable by a fine of up to 3200 euros

4.7.2.5. Control of HASS by the holder

The control on the HASS and its associated device by the Holder is performed during inspections and by receiving the tests results, generally carried out once a year by visual verification and dose rate measurement.

4.7.2.6. Source Holders' training

According to the Regulation of the Minister of Environment N° 86 of 8 July 2004 – *Requirements for Exposed Workers Radiation Safety Training* – the HASS Holder defines the training program of its staff, prepares the training material and gives every 5 years the training sessions which concern the Radiation Protection Officer and the exposed workers. The programme includes the radiation protection principles, the safe management of sources, consequences of loss, theft and inadequate use of sources, emergency responses in case of accident, etc. The training sessions are recorded but no comprehension test is organized. The performance and efficiency of the training sessions is carried out by checking training records during authorisations and inspections.

4.7.2.7. Identification and marking of HASS

The documentation accompanying a HASS systematically includes the source identification, information and photographs of source, container, transport packaging device and equipment. To the knowledge of the authority, there are no HASS in the territory without identification number. There is no HASS manufacturer in Estonia as well as no recommended limited working life for the use of HASS.

4.7.2.8. Transfers of HASS

Before transferring a HASS, the Holder ascertains that the Recipient holds the appropriate authorisation by asking a copy of it, by direct contact with the Authority of the Holder's and Recipient's country. The Authority issues an authorisation/permit for the transport and issues an authorisation to the Recipient in case of a National transfer.

No lost or out of control of sources has been encountered because of unrecorded transfer

4.7.2.9. Long-term management of disused HASS

The national regulatory system does not define a limited useful life for HASS. The preferred and encouraged strategy for the long-term management of the disused sources is the return to the supplier. The solutions actually implemented are the return to the supplier, the transfer to authorized radioactive waste storage facility and in some case the storage at the holder's premises for a maximum period of 5 years (Radiation Act). The transfer for reuse to another authorised holder has never been implemented given the very limited HASS users in the country.

There is a national authorized storage facility for radioactive waste that accepts disused HASS on condition that radioactive waste package acceptance criteria should be followed by the Holder.

The authorisation for practice with HASS is issued only if the long-term management of the HASS after termination of its use is defined. The long-term management of disused HASS is funded by take-back provisions incorporated in the supply contract and in funds set by the Holder. One situation with a disused source without long-term management solution has been encountered. The source (Cs-137) was produced in the 70ties and stored in the Holder premises. The solution implemented was the transfer to the authorised waste storage facility.

4.7.2.10. Security measures

The minimum compulsory security requirements for the holder's premises - HP- (both during use and storage) and for the authorised radioactive storage facility –ARSF- concern fences and sources with locks (HP), Video surveillance, access control, locked premises, fire detection (HP+ARSF).

4.7.3. Detection

4.7.3.1. Detection of orphan sources

During the threat assessment carried out by the authority at national level, the strategic locations identified to detect orphan sources were metal scrap yards, borders/customs, harbours and airports. Metal recycling plants, metallurgical industries and conventional waste management facilities were not included.

The detection equipment available is of portable type and portals. The controls are voluntary at metal scrap yards and harbours with exception at the border/customs and airports where the controls are mandatory.

4.7.3.2. Campaign for orphan sources recovery

The regulatory framework does not ensure that campaigns to recover orphan sources are organised and no specific budget is assigned to that. Nevertheless recovery campaigns have been organised in 2009 and 2010 by the Ministry of Environment and the company A.L.A.R.A. Ltd. During those campaigns 214 sources were recovered and transferred to the A.L.A.R.A. storage facility.

The most effective type of recovery campaign was by means of public announcement.

The intervention costs related to recovery and long-term management of orphan sources were supported by the State.

4.7.3.3. International cooperation and information exchanges

In the last 10 years Estonia has informed 19 times of the discovery of orphan sources to the IAEA Incident and Trafficking Database and reported 3 times on cases of illicit trafficking. Estonia contributes to this database since 1997.

4.7.4. Preparedness and Response

4.7.4.1. Emergency plans and procedures

Estonia has a national radiological emergency response plan in place with relation to HASS and orphan sources. An emergency team is available to intervene 24/7 in case of emergency with an orphan source or HASS, namely the Rescue Board as first responder with a team of minimum 3 persons and the Environmental Board as second responder with 1 person. The Rescue Board is designated as unique contact point with a general emergency call number in case of detection of orphan sources. Its coordinates are broadcasted to potentially involved people through information campaigns to institutions likely to be confronted with orphan sources, emergency services (police, firemen, civil protection, etc.) and to general public.

Dedicated vehicle, Communication and measurement devices, individual protection equipment, shielded containers and decontamination materiel is the equipment available for the emergency team. Emergency services are in charge of ensuring the security of the site and of the source and transport of it.

There are also compulsory emergency preparedness and response requirements for the HASS holders which need to be approved by the Authority. No emergency response plans and procedures are however required for the facility operators where orphan sources could be found.

4.7.4.2. Training and information of persons potentially confronted with an orphan source

The personnel potentially confronted with an orphan source are trained. The training is addressed to both workers and managers of first responders, customs officers, personnel of scrap yards and waste management facilities. Only the emergency services get regular national training.

4.8. Finland

4.8.1. Regulatory framework with respect to HASS

4.8.1.1. Regulatory authority

Regulatory control of the use of radiation, including radioactive sources, is stipulated by the Radiation Act. According to this Act, the competent nuclear authority is the Radiation and Nuclear Safety Authority (STUK) which shall supervise the compliance with the Act and with the provisions and regulations issued pursuant thereto. Furthermore, the Radiation Act designates the police and customs authorities as responsible to furnish official assistance as necessary in supervising compliance with the provisions of the Radiation Act and with the regulations issued pursuant thereto. The role of customs authorities in import and export of radioactive substances is specified in the Radiation Decree.

STUK is responsible for all the requirements of the HASS Directive except for the transposition matter which is a responsibility of the State. Penalties are issued by the police or the court. STUK can set a conditional fine.

4.8.1.2. Legislative framework

The national legislative framework fully transposes the HASS Directive through amendments of *Radiation Act* (22.12.2005, n° 1178/2005, Chapter 8 A) and the *Radiation Decree* (29.12.2005, n° 1264/2005, Chapter 5 A).

These documents use the same definition for a high-active source as the HASS Directive. The law is applicable both to HASS and non-HASS. A HASS falling below the defined high-activity levels is still covered by this law. A source is excluded from regulatory control when its activity level is below the exemption levels specified in the Directive 96/29/EURATOM. The law was already in force for all radioactive sources before the transposition of the HASS Directive. The main differences between the old version and amended one are to be found in authorization (Article 3), records keeping (Article 5), requirements for holders (Article 6) and report on experience (Article 14).

A source whose activity would have defined it as a HASS but whose activity had fallen down below the high-activity levels when the HASS Directive was transposed is covered by the law.

According to a definition in the Directive, a source is classified as a high-activity source according to its activity at the time of manufacture. Therefore, a source that has ‘once been a high-activity source will always remain such’ irrespective of whether its activity has decreased to a very low level as a result of physical decay. This means that sources having the same level of activity are subject to different requirements depending on their history rather than on the actual risk from the source. The holders of a safety authorisation regard this as unfair. The regulatory authority shares this view: it does not seem justified to subject certain sources having the same risk level to stricter control than others solely because of their different history. The current situation does not correspond to the generally applicable principle that the control should be risk-based (i.e. a graded approach). They also pointed out the problem of the activity levels set out in the Directive which are not consistent with the classification of sources in the standards of the International Atomic Energy Agency (IAEA).

4.8.2. Prevention and Deterrence

4.8.2.1. Authorization for practice with HASS

Before issuing an authorisation for the use of a HASS, all relevant items are considered by the Regulatory Authority. The STUK has not yet refused an authorisation for use of a HASS.

4.8.2.2. Records keeping and updating

Each HASS holder has the obligation to keep records of all HASS under his responsibility and to provide STUK annually with the recorded information before the end of January of the following year. Next to these records, licensees have to notify all modification to the radiation sources and devices within a time frame of 2 weeks after the implementation of the modification.

Up to now, STUK receives complete information and in due time, except for the periodical (annual) transfer where some delay is encountered. STUK keeps an electronic database of all authorized HASS holders and sources including all information requested in the standard record sheet given in Annex II of the HASS Directive. The non-HASS are recorded in the same database. Thus information of all sources is in one database.

4.8.2.3. National inventory

According to STUK there are no HASS in the country which are not recorded in the national database or identified in the holder's record. The register of authorized source holders and of HASS is available to customs organisations and to police on request.

4.8.2.4. Inspections and penalties

During inspections, the authority (STUK) has access to the holder's records and checks the match between them and the actual situation for each HASS. Inspection looks at both safety and security. In Finland there are no HASS that belong to the non-proliferation regime. Generally, inspections are announced to the licensee and come at intervals of 3-5 years. Very few unannounced inspections have been made. Follow-up inspections in case of incidents or accidents are made only when this is judged necessary. Inspection scope covers all relevant items except contamination measurements. Inspections are paid by the licensees.

Inspectors are staff from STUK. All inspectors (safety, security and non-proliferation ones) are trained for each relevant field. Their equipment consists of individual dosimeter, contamination detectors, list and pictures of typical sources and containers and specific tools if needed.

Penalties (fine or imprisonment) are foreseen in case of violation of the Radiation Act or of the Criminal Act. They have never been applied up to now.

4.8.2.5. Control of HASS by the holder

Tests carried out by the Holder to ensure the good conditions of each HASS are visual verification and leak tests (no dose rate measurement). It is required to perform them at least once per year and the report of those shall be communicated to the competent Authority annually. Their performance is also checked during inspections. In the majority of the cases, these leak tests consists of swipe tests on the external surface of the source holder.

The security measures are examined during the authorization process and during inspections.

4.8.2.6. Sources holders' training

The content of Radiation Safety Officers' training is defined by the Authority. For other staff, the training is defined by the Holders. An organisation recognized by the Authority or the Holder itself may be involved in preparing the training material. Training courses are given to the radiation protection officer and exposed workers. Non-exposed workers receive a basic training on radiation protection principles. The management does not receive any training.

Training sessions occur at a rate of 5h every 5 years for workers and 10h every 5 years for radiation safety officers. They are recorded and a comprehension test is organized for Radiation Safety Officers. The training records are checked by the Authority during inspections. Verification is also included in the review and assessment of a new license application.

4.8.2.7. Identification and marking of HASS

HASS are systematically accompanied by the necessary relevant documentation as per the Radiation Decree. No cases of HASS without identification or information on its nature in the country are known to the Regulatory Authority.

4.8.2.8. Transfers of HASS

The Holder transferring a HASS has to check that the Recipient holds a valid authorization for the possession of the source by asking a copy of it to the Recipient and has to notify STUK within 2 weeks of the transfer, just like the receiver in case of a national transfer. In case of an international transfer (outside EU) of HASS, the prior approval of STUK shall be sought. STUK shall ensure from the regulatory authority of the destination that there is no impediment to the transfer of a HASS in the said country and that the recipient of the transfer is authorised to receive the source.

Furthermore, the Regulatory authority is informed of the transfer because a license needs to be requested by the Recipient of the source. The licenses detail the individual sealed sources (with activity above exemption levels) and in case of renewal or exchange of a sealed source, an amendment to the license is required.

No cases where HASS went out of control during transfer are known to the Regulatory Authority.

4.8.2.9. Long-term management of disused HASS

No limited working life is defined in the national regulatory framework. An authorization is only granted if the long-term management route is already specified and planned.

The country's policy on disused sources gives priority to returning the disused source to the supplier. The next preferred option is the transfer of the source for re-use in another application. If this would not be possible, the source should be considered as radioactive waste and be transferred to an authorized waste treatment or storage facility. The actual situation of disused HASS does not exactly reflect this policy because disused sources are transferred to storage facility rather than re-use in another application. Some disused sources are stored at the Holder's premises. This is the case for some older unused HASS sources which, for various reasons, cannot be returned to the manufacturer or stored in the national long-term storages.

Although storage at the user's premises of sources that have no foreseeable use is not allowed, the regulations do not define a specific time limit before which the transfer of disused HASS is mandatory. Compliance with this requirement is a particular point of attention to STUK, but it is not strictly enforced. This approach has drastically reduced the number of sources in this case and STUK is estimating that currently less than 10 disused sources are stored at users' premises.

Cases of disused sources without long-term management solution (or financial solution for it) are known to the Authority. These are historical sources whose manufacturer no longer exists. So far, these sources are stored at Holder's premises. A potential solution would be to extend the capacity of the radwaste storage facility. Other solutions are sending these sources to other recycling plants.

A national authorized storage facility for radioactive waste is available in the country. Currently it does not accept disused HASS but arrangements in that sense are ongoing (extension of the existing facility). Sending back of the HASS to the manufacturer and transfer for re-use to another authorised facility are the other foreseen options to help the management of the disused HASS.

Currently the long-term management of disused HASS is funded through take-back provisions incorporated in the supply contracts. For very high activity sealed sources (activity exceeding 100 times the activity limits for HASS), a fund needs to be set up by the Holder. As per the Radiation Act, this fund could be a bank guarantee (under the control of STUK), credit insurance or a security of comparable reliability prescribed by the Decree of the Council of State.

4.8.2.10. Security measures

At installations where HASS are present, access control, locked premises, locking mechanism for the source and fire detection are planned for the Holder's premises (both during use and storage). The radwaste storage facility is secured through the same devices except the lock on the source. Moreover video surveillance is required in premises if sources activity exceeds IAEA category 1.

Mobile HASS sources are mainly used in gammagraphy and in some cases also temporary stored at work sites. Locks are present on the source container and if storage at work site occurs then these sites are secured by access control and fire detection.

4.8.3. Detection

4.8.3.1. Detection of orphan sources

No comprehensive risk/threat assessment regarding orphan sources has been performed by the Regulatory authority but locations where orphan sources can be identified have been considered. These strategic locations are metal scrap yards, metal scrap recycling facilities, metallurgic industries, borders/customs, harbours and airports.

Detection equipment at strategic location for finding sources is present on a voluntary base. Such initiative is encouraged through information dissemination by leaflets, in seminars and at other training occasions. The equipment used does not have to be authorized by the competent authority. In that context, the major installations of this type are equipped with portal and portable equipment except metal scrap yards only equipped with portable one.

4.8.3.2. Campaign for orphan sources recovery

No recovery campaign has been organized in the country because no orphan sources from past or present activities are expected to be found. Consequently no specific budget is dedicated for this topic. The monitoring of scrap metal is considered as the best method to recover the greatest number of orphan sources. The recovered orphan sources are either returned to the supplier either transferred to the radwaste facility. There is a financial strategy in place for dealing with recovery and long-term management of orphan sources. These costs are supported by the State and the sources' Holders.

4.8.3.3. International cooperation and information exchanges

Finland is participating in international cooperation and information exchange mainly through the established IAEA channels. The country is contributing to the IAEA Incident and Trafficking Database (ITDB) since 1995. It uses this database as an international information source.

4.8.4. Preparedness and Response

4.8.4.1. Emergency plans and procedures

Finland has a national radiological emergency response plan dedicated to orphan sources or HASS. STUK's preparedness organisation is available on short notice. The team has all necessary equipment. The team can be reached through the general emergency call number or directly by phoning to STUK.

Also the HASS Holders are required to have procedures for abnormal events. These are checked during inspections and during review and assessment of new license applications. No such requirement applies to institutions where orphan sources are more likely to be found.

Within the emergency plans, the first instructions to public are made by the emergency services. In collaboration with the Authority, they are also responsible for the mobilization of responders, ensuring the security of the source and its transport. In collaboration with the Authority and the Radiation Protection Expert they perform the radiological assessment of the site. The licensee and the police have the responsibility to secure the site. Finally the contamination control of the site after source removal is performed by the licensee together with the Authority and the Radiation Protection Expert.

4.8.4.2. Training and information of persons potentially confronted with an orphan source

Training of persons potentially confronted with an orphan source is not prescribed in the regulations. Workers and managers of emergency services and of customs are trained on all the relevant items. Workers of metallurgic industries receive training only on potential confrontation with a source and procedures and actions in case of detection or accident. Staffs from other fields are not trained.

Record keeping of training courses is not mandatory but most organisations (e.g. emergency services, customs, etc.) have training databases where information is stored. They are not regularly repeated and no comprehension test is organized. The training sessions do include practical exercises dealing with portal detectors, hand-held instruments, list and pictures of typical sources and containers and specific area for safely locate and identify the source.

4.9. France

4.9.1. Regulatory framework with respect to HASS

4.9.1.1. Regulatory authority

While applying and insisting on the principle of the prime responsibility of the operators, the French regulatory framework foresees different actors involved in the control of radioactive sources and their transfer. These actors are the authorities and the Institute for Radiological Protection and Nuclear Safety (IRSN). The authorities are:

- ASN (Authority for Nuclear Safety), the independent administrative authority in charge of licensing and inspecting the holders, users and suppliers of radioactive sources (excluding defence activities).
- ASND (Nuclear Security Authority for Defence), in charge of all activities with radioactive sources and linked to defence of the French Territory.

However, in view of administrative procedure simplification, when the establishment is subject to an authorization from the States representative in the Department (prefecture) for activities different from the possession and use of radioactive sources, the detention and the use of such source is integrated in this authorisation and regulated by Prefect. In that specific case, the inspections are also conducted by the services of the prefecture. The aim of this simplified procedure was to have a single authorisation issued by one authority. However, this simplification is going to change in the near future thanks to a decree that will change the regime applicable to these installations. After the enactment of this decree,

all sealed radioactive sources will be under the authority of the ASN (and ASND) so that the ASN (and ASND) will be in charge of all HASS holders in the future.

The Institute for Radiological protection and Nuclear Safety (IRSN) is the technical support organisation of the ASN. The Institute also manages the national inventory of ionising radiation sources and the control of their movements/transfers for all users.

The authorities are responsible for the updating of the list of authorizations issued and declarations received for activities they are regulating. This list together with copies of authorizations and attestations of declarations issued are then transferred by the authorities to the IRSN. This list is also made available to labour and radiation protection inspectors by the IRSN.

The ASN with the technical support of IRSN is designated as the competent authority in accordance with the Council Directive 2003/122/Euratom on the control of high-activity sealed radioactive sources and orphan sources (HASS Directive). The ASN is responsible for the requirements of the HASS Directive dealing with the articles 3 (authorization), 5 (records), 8 (training and information), 9 (orphan sources), 10 (financial security for orphan sources), 11 (international cooperation), 12 (inspections), 14 (report on experience), 15 (penalties), and 16 (transposition) while the IRSN is responsible for the article 4 (transfers) but is also involved in the articles 5 (records), 8 (training and information) and 11 (international cooperation).

4.9.1.2. Legislative framework

The current French regulatory framework related to the protection of the population against ionizing radiations is resulting from the transposition of the EU Directives Euratom (in particular 90/641, 96/29, 97/43 and 2003/122) and is integrated into two coherent codes: the French labour code and the French public health code and different ministerial decrees and orders.

The requirements of the HASS directive are transposed into the French public health code and the French labour code but also in the French environment code and different ministerial decrees.

The same definition and related activity levels as those specified in the HASS directive are being used for defining HASS in the French legal framework. The provisions regulating the management system apply to all sealed radioactive sources with activity above the exemption levels. Nevertheless, some additional provisions are specifically required for HASS. The main differences in requirements for the management of HASS and non HASS are to be found in the system of transfer recording, training of users and the identification and marking. In particular, the requirements of HASS directive concerning articles 5 (transfers) and 7 (identification and marking) will be transposed in an ASN Resolution shortly (official consultation in progress).

A source defined as a HASS remains regulated by the requirements for HASS when its activity level falls below the high-activity levels. Similarly, a source whose activity had fallen down below the high-activity levels when the HASS directive was transposed is regulated by the HASS regulation. A source is not subject to authorization (exempted from the regulatory control) when its activity level is below the exemption levels specified in the Directive 96/29/Euratom as long as this activity level has never been higher than this exemption level. In other words, decay is not taken into account to change the applicable regime.

4.9.2. Prevention and Deterrence

4.9.2.1. Authorization for practice with HASS

Before issuing an authorization for the use (or supply) of HASS, the ASN ensures that all arrangement and provisions of article 3 of the HASS Directive are met, namely justification of use, responsibilities, competencies, procedure for work and maintenance, emergency procedures, long term management and financial security, control measures to prevent external accidents (fire, flooding …). The security

measures implemented to prevent inadequate use, unauthorised access, loss or theft are not major issues in the licensing process until now. Since the ASN is currently not yet officially in charge of the security issues, safety concerns are considered more in details than security. The security aspects are only partially covered in that frame by the potential impact theft and fire could have on the radiation protection. However, ASN should be entrusted as the regulatory authority for security issues for most of French HASS and the assessment of these issues will then be integral part of the licensing process.

Authorization is only granted after all relevant information is received and has been judged as being adequate by the regulatory authority. The ASN has already refused authorization for the use of HASS because the applicant was not able to confirm the level of safety.

4.9.2.2. Records keeping and updating

All HASS and non-HASS holders are required to keep up to date records of the activity and location of radioactive substances under their responsibility. The records are kept at the workplace and have to be readily available for inspection.

The inventory of ionizing radiation sources requested by the regulation is made of two components: the national file of radioactive sources and the list of declared and authorised activities. The national file allows individually monitoring of each sealed radioactive source whose activity is higher than the exemption levels when the source is held by a holder or user. Moreover, the national file of sources allows knowing the responsible body for each radioactive source. The update of this file is made by:

- The pre-registration of the transfers;
- The cross-check between the pre-registration of movements, the periodical reports for holders (yearly) and suppliers (quarterly), and the list of authorized activities;
- The recovery certificates issued by suppliers when sources are taken back.

The authorisation for a transfer of a sealed radioactive source (including HASS) must be obtained before the actual movement of the source (prior authorisation). The suppliers have to provide their inventory of the distributed sources each 3 months. The holders have to provide their inventory directly to the IRSN in a written or electronic form every year with a tolerated delay of 3 months.

In the future the holders of HASS will be requested confirm the reception of a HASS to the consignor within 48 hours (for cat. 1 & 2) or a month (cat. 3) while the source certificate must be sent to the IRSN within the month for all sources.

The IRSN crosschecks the stock declared by the holders every year with the inventory recorded on the basis of pre-registration of the transfers and the quarterly supplier’s declarations. In case of discrepancy, questions are asked to the holder in order to correct the data of the national inventory. (But the inventory recorded in the national register is never sent to the user.)

All sources covered and non-covered by the HASS directive and their holders (or suppliers) are then recorded at the national level in the same electronic database used to establish a national inventory of radioactive sources. The following data are recorded: holder’s details, isotope, activity at a reference date, type of source, type of equipment/container, manufacturer details, location of sources, mobile or fixed source. The updating of the national inventory is ensured and controlled by the recording and the comparison of the periodical information provided by holders, users and suppliers.

The access to this inventory is eased by the use of the SIGIS system (system of information and management of the inventory of ionising radiation sources). All these data and the national inventory are managed by the IRSN and the records are available to ASN and radiation protection inspectors but also to police and customs organizations for some specific cases.

To the knowledge of the authority, there are no HASS presently used in France which are not recorded in the national inventory.

4.9.2.3. National inventory

From the authorised holders, the vast majority is from the industry sector. Several hundred HASS are used in mobile devices (gammagraphy) and have a special form certificate. Several thousand HASS for fixed use have also a special form certificate (medical sector and industry, research and education). During inspections, a systematic verification between the records of the national inventory and the actual situation at the licensee is performed.

4.9.2.4. Inspections and penalties

In France, three levels of inspection exist:

- Internal controls performed by the Radiation Protection Officer
- External control performed by the IRSN or recognised organisations
- Inspections by the ASN on the basis of regulation requirements.

Inspectors of the ASN are in charge of radiation protection and safety inspections for HASS holders. The inspections are directly funded by the State.

In the safety field, the inspections are carried out either periodically (every year to every 3 years), or randomly or as follow-up actions in case of incident. The scope of inspections related to safety concerns the documentation, a visual inspection of HASS, dose rate measurements of leakage radiation, contamination checks and a check of the inventory at the holder. For each inspection, an extract of the national inventory is compared to the holder's one. Otherwise, technical visits are currently performed by ASN inspectors in order to anticipate the future requirements when they will be officially in charge of the security aspects. The answers are given by the holders on a voluntary basis.

The practical training of the inspectors concerns information regarding radiation protection, their potential confrontation with a source, the visual detection of sources and containers and the specific requirements for their safe management. Inspectors dealing with security aspects receive training about the possible consequences of loss, theft or inadequate use of sources and procedures/responses to be followed in case of an emergency situation. Their standard equipment is composed of individual dosimeters and radiation detectors. Inspectors do not receive practical training in nuclear metrology.

In case of breaches of the national provisions a system of penalties is in place with a maximum penalty of 15 000 € and 1 year imprisonment. Penalties have already been applied for lack of authorization or serious risks.

4.9.2.5. Control of HASS by the holder

The ASN also checks during inspections the regular performance of suitable tests by the holder to control the good conditions of each HASS and associated device (integrity, place of use or storage). The checks generally performed by the holder are visual inspections, test of good operation of the device, dose rate measurements and test of non-contamination (smear test) as close as possible to the HASS. These tests, as specified in an ASN Resolution, take place every 3 months.

4.9.2.6. Sources holders' training

Training and information must be provided to the workers likely to be exposed to ionizing radiation. The content of the training programme for the source holder's staff is defined and given by the holder. The holder is responsible for the training for all the workers while only the Radiation Protection Officer (RPO) is trained by the IRSN or by one of the organizations recognized by the ASN. The training sessions are recorded. A comprehension test is organized at the end of the training session of the RPO. It is worthwhile to note that more training is required for some specific activities such as industrial radiography and a certificate (CAMARI) is issued after written and oral examinations.

The training sessions are given at least every 3 years for the staff and every 5 years for the RPO. A reinforced training is required by the regulation for the workers likely to be exposed to HASS. The content of the training programme concerns radiation protection principles, specific requirements for safe management of sources, consequences of loss, theft or damage of sources and emergency response in case of accident. The authority verifies the performance and efficiency of the training sessions by checking the training records during inspections.

4.9.2.7. Identification and marking of HASS

Currently, there is no HASS manufacturer in France. The HASS used in France come from the USA, Canada, Russia and EU Member States. Limited working life recommended for HASS by the manufacturers supplying France is not considered in the French regulation. The documentation accompanying a HASS systematically includes the source identification on the source or on the container. To the knowledge of the authority, there are no HASS in the territory without identification number.

Information and photographs of the source design type, typical source container, transport packaging, device and equipment are not included in the document accompanying the HASS. Indeed, the correct identification and marking of the HASS is not currently verified because the transposition of the article 7 of the HASS Directive is currently being revised.

4.9.2.8. Transfers of HASS

Any transfer of radioactive sources is managed by a registration system with prior declaration and authorisation. Before each transfer, a special form has to be filled in and sent to the IRSN (Public health code articles R. 1333-47 to 49). For all sealed sources, the form is recorded by the IRSN when the cross-checking between the authorization, the sources already held by the holder and information from the form are coherent.

The IRSN, manager of the national inventory, is in charge of the control of any transfers of radioactive sources. The comparison of the periodical information and records provided by holders, users, and suppliers with the request for transfer allows the IRSN to be informed of any individual transfer of HASS. This control is performed by the IRSN that informs the ASN which can take the necessary actions in case of unauthorised transfer or undeclared transfer.

In case of national transfer and as already mentioned, the transfer is recorded in the national inventory prior to the physical transfer. To ensure that the transfer is still authorized at the moment the source is physically delivered, the holder needs to be confirmed at the moment of the transfer that the recipient holds the appropriate authorization by asking a copy of the authorization. In their records, both the new recipient and the former holder have to mention the new situation and location of the HASS. The holder must be able to justify the origin and the destination for each source held on site.

From his side, the supplier has to send every 3 months a report to the IRSN giving information on all the sources delivered and received during the period. In case of EU transfer, according to the articles 4 and 6 of the Directive EURATOM 1493/43, the transfer must be declared to the IRSN and an inventory from the European suppliers is supposed to be sent to IRSN every 3 months.

In case of international transfer, the holder must ascertain that the recipient holds the appropriate authorisation. If the laws in the recipient’s country are not similar with the French ones, he can also contact the national competent authority of the recipient’s country to ensure it.

No cases where HASS went out of control during transfer are known to the regulatory authority.

4.9.2.9. Long-term management of disused HASS

The French Public health code defines a limited useful life of 10 years for all sealed sources, including HASS. Once this period is expired or once the source is no more used before the period of 10 years, the source must be either sent back to the supplier/manufacturer or re-tested for a new working period of 5 years, renewable once. In this case, the holder must submit an authorization request, including an advice from his supplier.

The aim of this policy is to avoid the storage of disused sources at the user's premises. In this regulatory regime the user is required to ensure the taking back of the source; the supplier has the obligation to recover any source he has distributed, ensure the taking-back of the source delivered and must provide a financial guarantee in this regard.

The ASN requests at the time of source delivery the commitment of the foreign manufacturer to take back the source. The commitment of the manufacturer towards the French supplier is contractual while the taking-back of the source by the French supplier is a regulatory obligation.

Currently an authorization for using HASS is issued only if the long term management route is specified and planned in the request for authorization. By order of preference, the strategies nationally encouraged for the long term management of the disused sources are (i) return to the supplier, (ii) transfer to a producer for recycling (iii) transfer for reuse to another authorized holder (in France for less than 10 years old sources, abroad for others) and (iv) transfer to authorized radioactive waste treatment/storage facility. The capacity of the authorized national storage facility of ANDRA would not be adapted if the sources are not returned to the suppliers. However, in some case and depending on the origin of the sources, the authorized national storage facility of ANDRA may accept disused HASS. Some concerns were encountered with the long-term management of old sources for which the suppliers do not exist anymore. In that case, the sources were returned to other suppliers or stored on site, or recovered by ANDRA.

Long-term management of HASS is funded by the suppliers, and sometimes included in the cost of their contracts with holders. Since 1990 this funding is secured by a guarantee fund. A financial warranty is paid by the supplier for each source delivered. Suppliers can either pay a guarantee to ANDRA or contribute to a common fund with an annual fee to cover the working costs of the association. This fund is used for the management of sources that have to be taken back if the supplier does not exist anymore. For all the sources concerned since the implementation of the financial guarantee in 1990, the costs of recovering these sources would be covered by this system. For older sources uncovered by a financial guarantee, a fund dedicated to the recovery of orphan sources in case of failure of the supplier/manufacturer exists and its management is ensured by ANDRA.

4.9.2.10. Security measures

The regulatory requirements regarding the security of HASS are under parliament approval. A graded approach is considered.

4.9.3. Detection

4.9.3.1. Detection of orphan sources

A threat assessment concerning the orphan sources has been performed at national level by the authority, giving as strategic location for finding orphan sources, conventional waste management facilities, harbours and transit hubs. Most of these sites are currently equipped with portal detection means. The installation of detection equipment is compulsory for metal scrap yards, metal scrap recycling facility and conventional waste management facilities. Nevertheless, the type of equipment is not imposed by the authority and the equipment must not be authorised. Moreover portable equipment is used on voluntary basis in harbours and transit hubs.

4.9.3.2. Campaign for orphan sources recovery

Campaigns for orphan sources recovery have been organized in France although it is not required by the regulatory framework. The campaigns are selectively organised based on the type of sources but not on a regular frequency. A specific budget is dedicated to the recovery campaigns and the means available are considered as sufficient. The radionuclides mainly collected were radium and tritium under the form of needles, watches, radium fountains, etc. These were organized by ANDRA on a voluntary basis. The recovered sources were returned to suppliers/manufacturers when identified or transferred to authorized storage facility.

Review of historical records of sources available at the authorities, the suppliers, the manufacturers and the licensees and systematic inspections of facilities are performed to recover orphan sources. National recovery campaigns have been organized by ANDRA to recover tritium and radium sources, objects containing uranium, lightning rods, ionizing smoke detectors, etc. These campaigns aim at informing the public on how to identify these items and the procedure to declare and dispose them off.

4.9.3.3. International cooperation and information exchanges

Over the last 10 years, the ASN has not been informed directly on HASS recovery or malicious acts but obtains some information mainly through the channel of the ECURIE database. The Direction of International Relation of the CEA (CEA/DRI) is the official contact for ITDB in France.

4.9.4. Preparedness and Response

4.9.4.1. Emergency plans and procedures

France has no national radiological emergency plan in relation with orphan sources or HASS since the emergency response plan is organized at department level. Each department shall have its own emergency response plan which could be different from one to another department. In case of an accident/incident with HASS in a facility licensed by the ASN, the decision and the implementation of protection measures with respect to the safety of persons within the site belongs to the head of facility (hospital, laboratory, industry) in conformity with an internal emergency plan under article L.1333-6 of the Public health code. The prefect is concerned with the safety of persons on the public domain.

In case of an accident occurring in a place where there is no responsible person identified (orphan source discovery), the responsible body of the radiation protection intervention is the prefect of the department depending on the magnitude of the accident.

Up to now, no emergency plan has already been initiated for HASS. There are contact points designated in case of detection of an orphan source.

4.9.4.2. Training and information of persons potentially confronted with an orphan source

The French labour code obliges the employer to train his workers in facilities where orphan sources are likely to be found. The training and its content is organized and defined under the responsibilities of the employers. It is addressed to workers and managers of the emergency services (police, fire fighters, and medical staff), and to workers of scrap yards, metal recycling plants and waste management facilities. For people who could be confronted to orphan sources, the training required in the labour code must contain information and advice about how to visually detect a source or its packaging, about radiation and their effects, and about the measures to be undertaken on site in case of detection or suspicion of detection of such a source.

4.10. Germany

4.10.1. Regulatory framework with respect to HASS

4.10.1.1. Regulatory authority

Germany has a federal system with 16 independent Federal States. Each federal state is responsible for the licensing procedure of HASS. In every federal state exists one or more competent authorities (approx. 60 competent authorities in Germany) for licensing and control of HASS. The register for HASS is operated by the Federal Office for Radiation Protection, BfS. All competent authorities have read-access to the register. The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety is responsible for the transposition of the HASS-Directive into national law, international cooperation and report on experience.

4.10.1.2. Legislative framework

Germany has fully implemented the HASS Directive into its national legal framework with the following instruments:

- *Gesetz zur Kontrolle hochradioaktiver Strahlenquellen. Enacting Modification of the Atomgesetz, issued 15 July 1985 (BGBl I, page 1565), last amendment from 24 February 2012 (BGBl I, page 212);*
- *Strahlenschutzverordnung (Radiation Protection Ordinance), issued 13 October 1976 (BGBl I, page 2905), last amendment from 18 August 1997 (BGBl I, page 2113);*
- *Atomrechtliche Deckungsvorsorge-Verordnung, issued 25 January 1977 (BGBl I, page 220), last amendment from 23 November 2007 (BGBl I, page 2631) and Atomrechtliche Abfallverbringungsverordnung issued 30. April 2009 (BGBl I, page 1000).*

The activity levels in the German legislation follow Annex 1 of the HASS Directive. All sources with activity levels below the high-activity levels but above the clearance levels are covered also by the Radiation Protection Ordinance, these requirements have been in force before the transposition of the HASS Directive. A HASS decayed below the defined high activity levels is covered by the provisions for non-HASS. Existing sources which would have been declared as HASS before the transposition of the HASS Directive are also covered by the provisions for HASS. A source can leave regulatory control when its activity is below clearance levels.

4.10.2. Prevention and Deterrence

4.10.2.1. Authorisation for practice with HASS

Before granting an authorisation for the use of HASS, all relevant issues are considered by the Regulatory Authority, including external accidents (fire, flooding …), emergency procedures and the long-term management of the disused source. Authorisation by local competent authorities is only granted after all relevant information is received and has been judged as being adequate.

4.10.2.2. Records keeping and updating

All HASS holders are required to maintain records of the HASS under their responsibility. Furthermore, every HASS holder is obliged to send electronic notifications about receipt, transfer, location change, control, loss, theft or finding of a HASS to a central database, the national HASS registry, which is operated by the BfS. The notifications are done electronically via secure internet connections. The data, which have to be submitted in a notification, correspond to the required information of the standard record sheet of the HASS Directive, which has been adopted in detail by the German Radiation Protection Ordinance. The local competent authorities verify if all notifications are in compliance with the licence granted. All notifications to the HASS registry have to be done

immediately except notifications about regular inspections, which have to be done within one month. No information to the authority is requested when the holder no longer uses the source or no longer uses any source, but the HASS holder is generally obliged to return the HASS to the supplier or manufacturer, when the use of the HASS is no longer intended.

4.10.2.3. National inventory

The recorded information in the database of the HASS registry establishes a national inventory of all HASS used in Germany, their history and respective holders to allow federal as well as local authorities and task force/police organisations to trace back HASS within Germany. The registration of sources below the HASS levels falls within the competences of the local authorities.

4.10.2.4. Inspections and penalties

The holder's records are available for inspection by the competent authorities. During these inspections, a systematic verification between the records in possession of the regulatory authority and the actual situation at the licensee is performed for all HASS. Verification is realized for each HASS. All competent authorities are responsible for inspections of HASS holders. The main focus of these inspections lays on the safety, but covers security aspects as well.

Inspections are usually announced to the licensee, but unannounced inspections are possible if appropriate in specific cases. Inspectors receive training in all relevant fields, including practical experience in metrology and the necessary equipment (individual dosimeters and contamination detectors but no dose rate survey meters) is available. The scope of an inspection covers all relevant fields of safety. In case of non-respect of regulations, penalties are foreseen. The system of penalties has not been applied up to now.

4.10.2.5. Control of HASS by the holder

The competent authority verifies regular performance of suitable tests by the holder during the inspections; this includes usually visual verification and leak tests. These tests are done by external accredited radiation protection experts.

The competent authority requests all information on the control measures implemented to prevent inadequate use, unauthorized access, loss or theft, fire protection etc., during the authorisation process, and verifies it during inspections. All controls of HASS have to be notified to the HASS registry.

4.10.2.6. Sources holders' training

The content of the training programme of HASS holders' staff is defined by the authority. The holder and the radiation protection officer (RPO) are responsible for an adequate training. The training programme is prepared by the holder and organisations recognised by the authority. For occupationally exposed personnel the period is 12 months. Management staff and non-exposed workers are not trained. Training sessions are recorded, but there is no comprehension test. The performance and efficiency of the training sessions is verified through regular reporting by the holder, as required by the competent authority.

Both radiation protection officers and exposed workers are trained in radiation protection principles, specific requirements of safe management of sources, possible consequences of loss, theft or inadequate use or damage of sources, and notification to the competent authorities and emergency responses in case of accident.

4.10.2.7. Identification and marking of HASS

Usually the documentation accompanying the HASS includes source identification, information and photographs of source design type, information and photographs of typical source container &

information and photographs of transport packaging. In a few cases, where HASS without an ID had to be registered, the BfS issued a registration number for the HASS registry. There are HASS with non-unique ID's or ID's which re-appear in a certain time interval for nuclides with a short half-life depending on the manufacturer. Therefore, it would be desirable to establish a system of unique HASS-ID's among the manufacturers and suppliers.

4.10.2.8. Transfers of HASS

In Germany, the Bundesamt für Wirtschaft und Ausfuhrkontrolle (BAFA) is responsible for import and export of radioactive sources. The BfS maintains the central register for HASS, while all other sources are registered by the federal states. Inspections provided by the authorities of the federal states are carried out once a year and registered, as is the case for any transfer of sources.

Before the transfer of a HASS, the holder has to ascertain that the recipient holds an appropriate authorisation. This is a legal obligation, but various procedures are in place. The competent authority is informed of individual transfer of HASS from the holder's records, by issuing an authorisation/permit to the holder for the transfer, by issuing an authorisation/ permit for the transport and by issuing an authorisation to the recipient in case of a national transfer. There is no evidence of loss or out of control because of an unrecorded transfer.

4.10.2.9. Long-term management of disused HASS

The working life of a HASS is not defined by the national regulatory framework. The country's policy on disused sources gives priority to returning the disused source to the supplier or manufacturer. Another possibility is the transfer to another authorised user. If this would not be possible, the disused source should be considered as radioactive waste and be transferred to the national authorised waste treatment and storage facility. The national waste treatment and storage facility accepts disused sources. If the capacity of the facility is not adapted to the potential of disused source the source has to be sent back to the manufacturer. The current management situation of disused HASS corresponds to this policy. Storage of disused sources at the holder's premises is possible. The holder can be authorised to store the HASS after termination of the use on his premises; this depends on the requirements in the license. The holder is forced to make arrangements for a safe and secure long-term management after termination of use because authorisation is issued only if the long-term management route is already specified and planned. Up to now no situations dealing with disused sources without any long-term management solution have occurred.

The long-term management of disused HASS is funded by "take back" provisions incorporated into the supply contract and/or by a fund set by the holder. There has been no situation without any financial solution for long-term storage of a disused HASS.

4.10.2.10. Security measures

According to the German radiation protection ordinance, the licensee is obliged to fulfil the requirements for the use of HASS, which also cover security requirements. Detailed security measures are laid down in the German Industry Standards (DIN). Every competent authority can decree special conditions for security measures within a single licence by a case to case decision. A guideline for competent authorities dealing with general security requirements is currently being drafted.

4.10.3. Detection

4.10.3.1. Detection of orphan sources

A threat assessment regarding orphan sources has been performed by the Regulatory Authority. Metal scrap yards, metal scrap recycling facilities, metallurgic industry, conventional waste management facilities, borders/customs, harbours, transit hubs and airports were identified as strategic locations to detect orphan sources. Portal and portable detection equipment is available at these strategic locations

on a voluntary basis, except for borders/customs, where they are compulsory. The equipment does not need to be authorised by the Regulatory Authority, nor is its type imposed by the Regulatory Authority. To encourage the use of detection equipment on a voluntary basis a commitment by the industry has been agreed upon.

4.10.3.2. Campaigns for orphan sources recovery

The regulatory framework does not foresee that campaigns are organized, but the competent authority can initiate campaigns if necessary. There is no special budget dedicated for this.

After the reunification of Germany, campaigns to recover orphan sources were conducted. Currently no further campaigns exist or are planned. It is assumed that most orphan sources have been found and taken care of. Nevertheless, it is to be noted that strategic transportation routes, recycling centres and metal facilities are checked regularly and the facilities carry out voluntary measurements.

The following actions have been realized: systematic analysis of the historical records at the authority, investigation in the former holder's records, systematic inspection of facilities, aerial surveys and specific campaigns in former military sites. The radionuclides mainly collected are Co-60 and Cs-137. The scope of the recovery campaigns was based on the use of mobile sources and geographical area. The recovered radioactive material has been returned to the supplier/manufacturer or has been transferred to the waste treatment and storage facility. There is no financial strategy covering intervention costs but in any case the federal states take care of safe and secure disposal.

4.10.3.3. International cooperation and information exchanges

There have been more than ten cases of theft, more than ten cases of loss and more than ten cases of discovery of sources within the last 10 years. The information has been communicated to the IAEA Incident and Trafficking Database (ITDB). Germany has been contributing to the IAEA Incident and Trafficking Database (ITDB) since its establishment.

4.10.4. Preparedness and Response

4.10.4.1. Emergency plans and procedures

Germany has a general emergency response plan in operation, also applicable in the case of orphan sources and HASS. In every federal state the competent authorities have appropriate measures in case of discovery of orphan sources. Additionally, the Federal Office for Radiation Protection has the capability to provide support in case of important radiological incidents. Available equipment is: dedicated vehicles (mobile laboratory), communication devices, measurement devices, individual protection equipment, shielded containers and detection material. The emergency plan has not been initiated because of orphan sources or an incident with HASS.

There are compulsory emergency preparedness and response requirements for HASS holders. For institutions where orphan sources are more likely found, these are in general not required. This depends on the decision of the competent authorities on case by case basis. The contact points in case of detection of an orphan source are the local competent authorities.

4.10.4.2. Training and information of persons potentially confronted with an orphan source

A quite extensive and adequate training and information plan is offered on a voluntary basis for all people who could potentially be confronted to orphan sources, but only at the level of the workers. There is no training foreseen for the management and also no training for other people. Training sessions are not documented and are repeated periodically on a voluntary basis. There are companies which offer these courses. A comprehension test is encouraged but not mandatory. However, the people that require this type of training in order to carry out their official work duties in case of emergencies do get a comprehension test.

4.11. Greece

4.11.1. Regulatory framework with respect to HASS

4.11.1.1. Regulatory authority

The competent Authority in accordance with the HASS Directive is the Greek Atomic Energy Commission (GAEC). It deals with all articles of the HASS Directive.

4.11.1.2. Legislative framework

The Greek framework for safety is set out primarily in a number of laws, decrees and common ministerial decisions. In particular:

- *Legislative Decree 181/1974 "Protection against Ionising Radiation"*
- *Law No. 1733/1987 "Transfer of Technology, inventions, technological innovation and establishment of the Greek Atomic Energy Commission"*
- *Ministerial Decision No. 17176 "Powers and competences of GAEC Administration Board"*
- *Presidential Decree No. 404/1993 "Organisation of the Greek Atomic Energy Commission"*

These legislative measures provide for the initial establishment of an authorisation procedure for the use of ionising radiation in Greece, the issuance of regulatory decisions, compliance, monitoring and penalties. In addition, they provide for the establishment of the Greek Atomic Energy Commission (GAEC) as an autonomous legal entity within the public sector and for the powers and competencies of the GAEC Board. More detailed regulations are set out in a suite of legislative measures based primarily on the transposition of EURATOM directives concerning radiation protection and nuclear safety.

The HASS Directive is fully transposed in the national regulatory framework and the date of enactment was the 31st May 2006 through the publication in the Government Gazette of the Ministerial Decision No. 10828/(EFA)1897 "Control of high-activity sealed radioactive sources and orphan sources".

The definition of a HASS in the national regulatory framework is the same as the one of the HASS Directive. The same activity levels are used. GAEC applies in practice the HASS MD (and consequently the HASS Directive) to all radioactive sources – in a graded approach – irrespective of their form and activity.

In practice, all sources are kept under regulatory control regardless the activity. However, GAEC may exclude a source from regulatory control if the source holder/user/operator declares and proves that the source activity is below exemption levels.

4.11.2. Prevention and Deterrence

4.11.2.1. Authorization for practice with HASS

All topics are being taken under consideration: justification of use; responsibilities; staff competencies; adequacy of the source with respect to its utilisation; available documentation and procedures for work and maintenance; emergency procedures and communication links; adequate arrangement for long term management of the disused sources; control measures to prevent inadequate use, unauthorised access, loss or theft of the HASS and control measures have been implemented to prevent damage of HASS by fire, flooding, etc.

Prior to import of every radiation source - irrespective of the activity, type and isotope -, a legal written declaration from the source manufacturer, stating that the manufacturer will take back the source after its useful life is necessary. Also, a legal written declaration from the source user stating

that he/she will undertake all financial and administrative provisions to export the source back to manufacturer or other licensed storage/recycling facility abroad.

GAEC has never refused an authorization for the use of a HASS.

4.11.2.2. Records keeping and updating

HASS records are kept by the holder and are subjected to GAEC inspections periodically (during operation licence renewals or earlier). According to HASS MD, the holder must provide to GAEC the records at least once a year. In case of minor or major changes to the facility, the holder submits the relevant records to GAEC without delay. GAEC performs announced and unannounced inspections periodically, at least once a year – regardless the license validity period – and assesses HASS records.

The information is sent by the HASS holder to the GAEC in written form. The records kept by the holder include sufficient information. However the detailed points of Annex II are difficult to be followed and sometimes there is missing information.

4.11.2.3. National inventory

GAEC maintains the national registry of radiation sources irrespective of their activity, type and isotope. GAEC maintains a National Radiation Protection Database which is regularly updated by the GAEC staff. The electronic database includes: facilities, licensing details, inventory of radiation sources, inspection results, dose registry, and education level of the occupationally exposed workers, radioisotopes distribution/supply and transport. The database provides for an automatic notification prior to the expiry of licenses/or certificates of compliance. GAEC will inform the licensee accordingly to avoid the delays in the renewal of the license.

The register of authorised sources Holders is available for inspection to police organisations and to customs under request. During inspections, the Authority checks the match between the actual situation of the HASS and the information recorded by the Holder.

4.11.2.4. Inspections and penalties

The GAEC is in charge of the inspection of HASS holders for Safety (Sf), Security (Sc) and Non-proliferation (NP). The planning is organised once per year on Sf and Sc (announced) and randomly (unannounced) for both. The inspections cover NP only as follow-up action in case of an incident or any other suspicious situation and also once before the first licensing of the facility.

The inspectors are trained on Sf and Sc issues on the following fields: visual detection of sources and containers; requirements for safe management of sources; possible consequences of loss, theft or inadequate use or damage of sources; procedures for prompt notification to the Authority and emergency responses in case of accident.

The training on NP regards the possible consequences of loss, theft or inadequate use or damage of sources and the procedures for prompt notification to the Authority and emergency responses in case of accident. The inspectors' equipment consists of individual dosimeters; contamination detectors; portable survey meters, spectrometers. For the Sc, no instruments are used; for Sc tests on security measures and visual inspections are performed; for NP no tests are performed.

The inspections are paid by the licensees and funded directly by the State. GAEC charges the licensees, however if needed, GAEC covers the expenses by its own budget.

There are penalties applicable to breaches. In addition to any penal sanctions, infringement of the provisions of this Joint Ministerial Decision shall entail administrative sanctions. The foreseen penalties have not yet been applied in practice. In a few cases the operation license has been suspended.

4.11.2.5. Control of HASS by the holder

The competent Authority verifies the regular performance of suitable tests on the HASS and its associated device during inspections. The tests, generally carried out yearly, are visual verification and dose rate measurement. The competent Authority is informed on the control measures implemented during the authorization process, by regular reporting by the holder and during inspections.

4.11.2.6. Sources holders' training

The definition of the training program of the HASS holder staff is done by both the GAEC and the Holder. The training material is prepared by the Holder and approved by GAEC. The training sessions are not recorded and no comprehension test is organized. Training is given at the start of the job but no frequency is defined to repeat it. The Authority verifies the performance and efficiency of the training sessions through regular reporting by the Holder: in fact, during inspections, staff (ad hoc) is interviewed by GAEC, while the RPO of the facility provides relevant information (in oral in most cases). The categories subjected to training are the radiation protection officer and the exposed workers.

4.11.2.7. Identification and marking of HASS

All HASS are accompanied by their certificate from manufacturer and all documentation necessary (drawings-design in place of photographs in most cases). The correct identification of the HASS is checked by the Regulatory authority only by the source certificate. Operators perform measurements of the dose rates (radiation output) for the purpose of their job. Recently, the suppliers of HASS have recommended a limited working life, which is generally 10 years.

4.11.2.8. Transfers of HASS

For transfers of HASS between facilities from different countries, documents which have been approved by the competent authorities of the recipient country must be granted prior the shipment. These, validate that the recipient is capable for the safe and secure management of the HASS. Additionally the import or export license must be issued by GAEC in advance; its issue is possible only if the holder (in case of export) or the recipient (in case of import) has been authorized. For transfers between facilities within Greece, the recipient has to obtain the authorization in advance.

Additionally, in both cases mentioned above, the transport license has to be issued either to the holder (for export) or the recipient (for import) prior the transfer.

4.11.2.9. Long-term management of disused HASS

The national regulatory system does not define a limited useful life for HASS. The disused source must be sent back to supplier/manufacturer. There is also the possibility to ask from the manufacturer to renew - update (if possible) the working life. The preferred strategy is the transfer for reuse to another authorised holder, then the return to supplier then transfer to storage facility.

There is a national authorized storage facility for radioactive waste that accepts disused HASS, for short-term storage and then exporting for recycling to an authorised facility abroad. Long-term management of disused HASS is funded by take-back provisions incorporated in the supply contract and by funds set by the Holder. Another alternative is that prior to import of HASS, the holder declares to undertake all costs for the back-end solution.

Up to now, the long-term management of disused HASS are not hindered due to financial reasons. However, the finance for the export of disused HASS for recycling may become a significant problem.

4.11.2.10. Security measures

Security measures required at Holder’s premises during use and storage of the HASS are: video surveillance, recorded control access, locked premises, security staff, lock on the source, fire detection and others means such as motion detection systems, sirens and visual alarm panels. Nothing is required at places of mobile use and in storage facilities.

4.11.3. Detection

4.11.3.1. Detection of orphan sources

A threat assessment has not been performed on a rigid and "real life" basis. The strategic locations identified to detect orphan sources are metal scrap yards, metal recycling facilities, metallurgical industries, conventional waste management facilities, borders/customs, harbours and airports. Portal and portable are available in all these locations and are compulsory for metal scrap yards, metal recycling facilities, metallurgical industries and borders/customs. Only major metal scrap yards operate portals. The availability of detection equipment is voluntary for conventional waste management facilities, harbours and airports.

The detection equipment applied does not need to be authorised by GAEC. GAEC performs inspections, provides advices on the use and is always informed in case of alarms (true, innocent or false). The use of detection equipment on a voluntary basis is encouraged through the national policy on illicit trafficking of radioactive material. Telemetric monitoring is also available.

4.11.3.2. Campaign for orphan sources recovery

The regulatory framework ensures that campaigns are organised to recover orphan sources from past activities, through the production and distribution of leaflets and through informing relevant organizations, bodies and professions. GAEC has an appropriate dedicated budget of 100 000 € to recover and manage orphan sources. One recovery campaign has been organised. The recovered sources are transferred to the storage or to a recycling facility.

4.11.3.3. International cooperation and information exchanges

Greece contributes to the IAEA Incident and Trafficking Database since 2000.

4.11.4. Preparedness and Response

4.11.4.1. Emergency plans and procedures

Greece has a national radiological emergency response plan in place with relation to HASS and orphan sources. There is an emergency team available to intervene 24/7 in case of emergency. The team of about 30 is composed of GAEC scientific and technical personnel. The equipment available is composed of dedicated vehicles, communication and measurement devices, individual protection equipment, shielded containers and decontamination material.

There is compulsory emergency preparedness and response requirements for HASS holders and the procedures have to be approved by the Authority. There are also compulsory emergency preparedness and response requirements for the facility operator of institutions where orphan sources are more likely to be found. These procedures should also be approved by the Authority.

There is a unique contact point designated in case of detection of an orphan source (GAEC – Licensing and Inspection Division).

4.11.4.2. Training and information of persons potentially confronted with an orphan source

The personnel potentially confronted with an orphan source are not specifically trained. Specific training is addressed only to workers of the different categories (emergency, transport, facilities). Training courses are obligatory according to the regulations, but they are not regularly repeated and not all are documented. Comprehension tests are not always organised.

4.12. Hungary

4.12.1. Regulatory framework with respect to HASS

4.12.1.1. Regulatory authority

The nuclear regulatory authority having the prime responsibility in the field of safety and security of ionizing radiation sources is the Hungarian Atomic Energy Authority (HAEA). However, Radiation Health Centres of Government Offices share the responsibility for most of the requirements of the HASS Directive: authorisation, transfers, records, training and information, orphan sources, inspections, report on experience, penalties and also transposition.

The HAEA is the sole authority dealing with the financial security of orphan sources as well as with international cooperation. In addition to HAEA and Radiation Health Centres, the Office of the Chief Medical Officer has also responsibility in the authorisation process. This Office is also involved in the report on experience and penalties.

The Police has several responsibilities linked to the implementation of the HASS directive such as inspections, report on experience and penalties.

4.12.1.2. Legislative framework

The legislative framework in the country is based upon:

- *Act on Atomic Energy (Act CXVI) which was approved by the Hungarian Parliament in December 1996 and entered into force on July 1st, 1997*
- *Act on Public Health (Act CLIV) promulgated on December 1997.*

Both Acts and the governmental and ministerial decrees based on them already covered several provisions of the HASS Directive when it entered into force on 31/12/2003. Other provisions of the HASS Directive were afterwards implemented by amending the existing decrees.

The HASS Directive is fully transposed in the national framework through the following documents:

- *Act CXVI of 1996 on atomic energy*
- *Act CLIV of 1997 on public health*
- *Decree of the Minister of Health 16/2000 (VI.8.) on the execution of certain provisions of Act CXVI of 1996 on Atomic Energy associated with radiation protection*
- *Decree of the Minister of Transportation, Communication and Energy 11/2010 (III.4.) on the order of registration and inspection of radioactive materials and related data supply*
- *Government Decree 112/2011 (VII. 4) on the scope of activities of the Hungarian Atomic Energy Authority in connection with its international obligations including the European Union, its authority and penalizing rights, the assignments of its co-authorities and on the Scientific Committee assisting the HAEA`s activity*
- *Governmental Decree 17/1996 (I.31.) on the actions in connection with the found or confiscated radioactive or nuclear materials*
- *Governmental Decree 72/2000 (V.19.) on the special conditions of acquiring the possession rights of certain materials, equipment and facilities belonging in the scope of application of atomic energy, as well as on the procedure for reporting their possession and operation*

- *Decree of the Minister of the Interior 47/2012 (X. 4.) on the tasks of the police in connection with the application of atomic energy.*

This framework regulates the use of all types of radiation sources, including HASS. Requirements for authorization regime, holders, identification and marking, training, orphan sources, financial security, penalties are similar for HASS and non-HASS. However, requirements related to transfers, records and inspections are different for HASS.

A source is excluded from the aforementioned regulatory framework when its activity level is below the exemption levels specified in the Directive 96/29 Euratom.

4.12.2. Prevention and Deterrence

4.12.2.1. Authorization for practice with HASS

Before issuing an authorisation for the use of HASS, all relevant issues are considered by the regulatory authorities (both HAEA and Radiation Health Centres): justification of use, assignment of responsibilities, user's competencies, adequacy of the HASS with respect to its use, available documentation, measures to prevent external accidents (fire, flooding …), physical protection, financial security and emergency procedures. However, the adequate arrangement for the long term management of the disused HASS is not a prerequisite for the authorisation granting. The source remains under the holder responsibility until the final disposal.

An authorization for using a HASS has been refused because the authorization request was not in compliance with the requirements.

4.12.2.2. Records keeping and updating

All sealed radioactive sources are recorded in a central registry, operated by the HAEA. The central registry system has been in operation since the end of the 1960s and it provides for the regulatory control of radioactive sources throughout their full life-time. The HASS holders are required to keep records of HASS under their responsibility. The recorded information is supplied electronically. The unified computerised central registry system is based on regular electronic reports of inventory changes and annual inventories, and a passport identifying each sealed source that contains all relevant technical data as well as details of the owner of the source.

The information recorded by the holders is considered as complete by the HAEA and cover all the information requested by the standard record sheet given in annex II of the HASS Directive. Non-HASS are recorded in the same database

In addition to the records kept by the holders, the owners of sealed radioactive sources must obtain official certificates by HAEA which confirm the ownership of the sealed radioactive source and identify individually the sealed radioactive source.

4.12.2.3. National inventory

The national inventory of HASS holders and the HASS they hold established by HAEA is based on the information recorded and provided by the holder. The register of HASS is available to the Police but also to customs on request.

HAEA regularly controls local records of holders. During inspections, a systematic verification between the records in possession of the HAEA and the actual situation at the licensee is performed for all HASS. The verification is made randomly at the holder's premises but at least for all HASS every 48 months.

4.12.2.4. Inspections and penalties

The inspections are directly funded by the State. They are based on risk informed approach; frequency is adapted with the category of the source and laid down in the inspection plan. Inspections are either announced or unannounced or conducted as a follow-up action in case of suspicious situation.

The inspection scope encompasses safety, security and non-proliferation issues. The 10 HAEA's inspectors are in charge of inspections in the fields of security and non-proliferation while the 7 Radiation Health Centres inspectors are responsible for safety issues.

In addition to the HAEA's inspection activities, the special authorities (Radiation Health Centres of Government Office, the Police) taking part in the licensing procedure may also carry out separate official inspections.

Inspectors receive training in all relevant fields: practical experience in metrology information related to potential confrontation with a source, visual detection of sources, safe management of sources, procedures in case of emergency and possible consequences of loss, theft, inadequate use or damage to sources. All inspectors have individual dosimeter, dose rate survey meter and contamination detector.

In case of non-respect of regulations, a system of administrative penalties is in place. These administrative penalties depend on the type of infraction and range from 170 € to 10 500 € for the company and to 5 years of imprisonment for the person. The system of penalties has never been applied so far.

4.12.2.5. Control of HASS by the holder

Regular testing of the good conditions of each HASS and associated device by the HASS holder are required according to the legislation. Safety tests of HASS include dose rate measurements and leak tests. Only those holders who have appropriate technical background are able to carry out leak tests not only for themselves but for other holders as well. The HAEA verifies the regular performance of these tests during inspections. The control measures implemented by the holder to prevent inadequate use, unauthorised access, loss or theft of the HASS and the damage by fire and flooding are also part of the inspection.

4.12.2.6. Sources holders' training

HASS holder's staff requires training, which is defined by the authority (the Office of the Chief Medical Officer) and training organisations recognised by the authority for this purpose. The training sessions are recorded but no comprehension test is performed. The sessions are organised annually for security awareness and every five years for safety aspects. Training concerns safety, security, transport and radiation protection. Radiation protection officer and exposed workers receive training on radiation protection principles, specific requirements for the safe management for sources, possible consequences of loss, theft or inadequate use or damage of sources, prompt notification and emergency response. The management staff receives the same training session except about the specific requirements for the safe management of sources. Non-exposed workers only receive information about radiation protection principles.

4.12.2.7. Identification and marking of HASS

HASS need to be systematically accompanied by the necessary documentation. This documentation contains the source identification number together with information and photographs of source design type. Some old sources produced in Russia are in the territory without a readable identification number.

The manufacturers supplying HASS in Hungary recommend a limited working life which depends on production technologies of the HASS and the field of application. When not set by the manufacturer, national authorities define a recommended working life of 15 years as a first step.

4.12.2.8. Transfers of HASS

In case of transfer of HASS, the HASS holder must ask a copy of the recipient authorisation before the transfer is made. In the cases of international transfers, Euratom rules are followed for transfer within EU countries while the Code of Conduct requirements apply for transfer in non-EU countries. The HAEA is informed of the transfer from the records of the holder via electronic reports, which are required to be sent to the Central Registry of the HAEA No cases where HASS went out of control during transfer are known to the Regulatory Authority.

4.12.2.9. Long-term management of disused HASS

No enforcement exists to force the HASS holder to make adequate arrangement for the long term management of disused HASS. The country's policy on disused sources gives priority to returning the disused source to the supplier although take-back provisions must not be legally included in the supply contract.

Once the recommended working life expires, storage in safe and secure manner at the user premise is the alternative if not take-back provisions are included in the contract. The holder is authorised to store the HASS after termination of its use on his premises until the expiry of the license for storage. Radiation Health Centres of Government Office give specific licenses for temporary storage upon request of the holder. In that case, the disused HASS should be considered as radioactive waste and be transferred to the Radioactive Waste Treatment and Disposal Facility at Püspökszilágy prior to the expiry date of the corresponding storage license. The facility has sufficient space and infrastructure to handle the spent sources safely. The fees charged for disposal are sufficiently low in order to ensure that the lack of financial resources on the side of users should not be an obstacle to safe disposal.

Today, the long-term management of HASS is funded through take-back provisions incorporated in the supply contracts and by the Central State Financial Fund. The source of this fund is provided from the payments of nuclear power plant. No cases of disused HASS without long-term management have been encountered.

4.12.2.10. Security measures

The minimum compulsory security requirements depend on the ratio of the isotope specific activities. HASS manufacturers, the Radioactive Waste Treatment and Disposal Facility, and all holders of radioactive sources (not only HASS) - both in fix and mobile use - are required to implement a physical protection (security) system corresponding to the security level of their radioactive sources. Such system should include fences, video surveillance, recorded control access, locked premises, security staff, and sources with lock according to the legislation.

4.12.3. Detection

4.12.3.1. Detection of orphan sources

A threat assessment regarding orphan sources has been performed by the HAEA, yielding as strategic location for finding orphan sources metal scrap yards, metal scrap recycling facilities, metallurgical industries, border crossings, and airports. However, conventional waste management facilities are excluded. At all of these locations, detection equipment is mandatory. They are required to be all equipped with portal monitors as well as portable radiation detectors at border crossings and airports. Although the use of detection equipment is compulsory by the law, HAEA does not impose the type of equipment to be installed. However, the detection equipment must be authorised by the HAEA.

Schengen borders are equipped with portal detectors and special shielded parking places to park suspicious transports.

4.12.3.2. Campaign for orphan sources recovery

So far, no specific recovery campaigns of orphan sources have been organised in the country.

4.12.3.3. International cooperation and information exchanges

Hungary is actively participating in international cooperation and information exchange, mainly through the established IAEA channels. The country is contributing to the IAEA Incident and Trafficking Database (ITDB) since 1994.

4.12.4. Preparedness and Response

4.12.4.1. Emergency plans and procedures

Hungary has a national radiological emergency response plan in operation. However, HASS or orphan sources are not specifically addressed in the plan which covers all kind of radiological incidents/accidents. HASS holders on the other hand are required to establish an on-site emergency response plan, which needs to be approved by the HAEA. The same requirement applies for facility operators where orphan sources are more likely to be found. The establishment of such on-site emergency response plan is part of the authorisation documentation.

In case of emergencies involving HASS or orphan sources, the Regulatory authority has an emergency team available to intervene 24/7. This team has full radiological intervention equipment available (mobile laboratories, measurements devices, protection equipment. etc.). No dedicated phone number exists for HASS or orphan sources and the emergency team is reached through the general emergency phone number.

Within the national emergency plan all required actions are attributed to responsible organisations.

Based on the Hungarian experience, the best follow-up actions after the detection of an orphan source are fast alerting, secure of the zone, radiation protection check followed by a safe and secure transport and storage of the source.

4.12.4.2. Training and information of persons potentially confronted with an orphan source

A quite extensive and adequate training and information plan is mandatory by regulation for all people who could potentially be confronted to orphan sources (emergency services, custom officers and facilities such as scrap yards, metallurgical industries, etc.) but mainly at the level of the workers. The content of the training covers information concerning potential confrontation with a source, visual detection of sources and containers, radiation protection principles, possible consequences, procedures for prompt notification and actions to be taken.

These training sessions are documented and repeated every 2-5 years depending on the level. There is a comprehension test organised. The emergency trainings include also table top exercises, practical exercises on identification of real sources of ionising radiation.

4.13. Ireland

4.13.1. Regulatory framework with respect to HASS

4.13.1.1. Regulatory authority

The Radiological Protection Institute of Ireland (RPII) is the competent national authority with responsibility for ensuring that Irish people and the environment are adequately protected from the harmful effects of ionising radiation. The RPII being the only one named competent authority in Ireland with regard to the HASS Directive; it deals with all the requirements of the articles of the HASS Directive.

4.13.1.2. Legislative framework

The legislative framework in the country is based on the *Radiological Protection Act, 1991 as amended.* Statutory Instruments (SI) principally take the form of Regulations or Orders and they are referred to as being secondary legislation. The SI N° 875 of 2005 also called "Control of High Activity Sealed Radioactive Source Order" enacted 31st December 2005 fully transposes the HASS Directive requirements in the Irish regulatory regime. Report on the experience gained from the implementation of the HASS Directive was sent to the EC on January 2011. The same definition and related radiological criteria are being used for defining HASS as those used in the Directive. Under the Irish legislation a HASS is always a HASS until it decays below the exemption values listed in Directive 96/29/EURATOM.

The Regulation in force for sources with activity levels below those defined by HASS is the SI N° 125 of 2000 (*Ionising Radiation Order*, 2000). Although many of the provisions required by the HASS Directive were already implemented in Irish legislation by S.I. No. 125 of 2000 and the Radiological Protection Act 1991, the main differences in the requirements for HASS and non-HASS are to be found in identification and marking (art.7), training and information (art.8), orphan sources and financial security for orphan sources (art. 9 &10) and report on experience (art. 14).

4.13.2. Prevention and Deterrence

4.13.2.1. Authorization for practice with HASS

Under Irish regulatory system a licence is required for all practices involving radioactive sources, materials or irradiating apparatus and must be obtained in advance of conducting any of the practices. Licences for HASS are a part of the normal licensing system. Under Article 5(1) of S.I. No. 875 of 2005 a licence must be obtained from the RPII in advance for any practice involving HASS and all such licenses are issued under, and in accordance with Article 4 of S.I. No. 125 of 2000. Licences are issued for fixed periods ranging from 1-4 years and all licence amendments must be authorised in advance by the RPII.

Before issuing an authorisation, all topics are being taken under consideration: justification of use; responsibilities; staff competencies; adequacy of the source with respect to its utilisation; available documentation and procedures for work and maintenance; emergency procedures and communication links; control measures to prevent inadequate use, unauthorised access, loss or theft of the HASS and control measures have been implemented to prevent damage of HASS by fire, flooding, etc. The long-term management of the HASS must be specified prior to authorisation. The conditions of licences for HASS have annual requirements in relation to the upkeep of take-back agreements and the provision of adequate financial arrangements for ultimate disposal in the event of bankruptcy.

An authorisation for the use of a HASS was never refused in Ireland.

4.13.2.2. Records keeping and updating

HASS holders are required to keep records of all HASS under their responsibility. The HASS holder provides the RPII with the recorded information as soon as possible after acquisition and following transfer/return to the manufacturer. The information is provided either electronically or as paper copy.

4.13.2.3. National inventory

The recorded information is used to establish a national inventory of authorised HASS holders and the HASS they hold. The national database contains information about all licensees and all sources, not just HASS licensees and HASS sources. The information recorded for HASS in the database is in compliance with the data given in the standard record sheet of the Annex II of the HASS directive.

Access to the database of radioactive sources is not available to the police but information is made available to them. The records kept by the holders are routinely inspected during regulatory inspections and the licensee inventory should match the HASS sources found on-site. The verification is realised for each HASS.

4.13.2.4. Inspections and penalties

The RPII is in charge of the inspections of HASS holders. Routine regulatory inspections of HASS licensees are part of the RPIIs annual inspection programme. The inspection is funded by means of an annual tax linked to the authorisation. RPII inspectors are warranted to undertake inspections at any time and can carry out unannounced inspections if deemed warrant. Regulatory inspections of licensees with HASS are conducted at frequencies consistent with IAEA recommendations. All licensees with mobile HASS and industrial irradiators are inspected annually and others are inspected from 1-3 years depending on the category of licensee.

Inspectors are technically qualified and competent and receive in-house and on-the-job training in addition to attending external courses. Inspectors are also accredited as part of ISO 17020-accreditation scheme. Inspectors in Ireland are familiar with all licensed HASS sources in the country as well as the container. The scope of inspection covers documentation, inventory, visual inspection of HASS and their environment, dose rate measurements and security measures. The inspections cover also risk assessment, radiation safety procedure and emergency plans. RPII inspectors do not routinely take wipe tests during inspections, but they request to see all relevant wipe test certificates not just for HASS but for all sealed sources.

Security audits of HASS licensees are conducted by the National Crime Prevention Unit before issuing a licence and the findings are forwarded to the RPII for action during RPII regulatory inspection. Breach of conducting an unlicensed practice as well as failure to comply with licence conditions are penalised with a fine not exceeding € 1200 per offence or imprisonment for a term not exceeding 12 months or both. These breaches and penalties have been tested in the Courts with licensees but no cases involving HASS licensees have yet come before the courts.

4.13.2.5. Control of HASS by the holder

Visual inspections by the HASS holders are required monthly while leak tests are required every 2 years unless an incident warrants more frequent testing. Dose rate measurements are generally taken during use of the HASS. The regular performance of tests by the holder is verified during inspections as the regulatory inspectors will look at all relevant information and take copies of all relevant test results. The control measures implemented to prevent inadequate use, unauthorized access, loss or theft of the sources or their damage by fire or flooding is part of the licensing process and is also routinely checked during inspections.

4.13.2.6. Sources holders' training

The content and the preparation of the training program of the HASS holder staff is defined by the holder. The RPII Inspectorate would expect the training to cover radiation protection, risk assessments, safety procedures and emergency planning. Under the Irish legislation, the training must be repeated at regular intervals but no time period is specified. The training sessions are recorded; all such training must be documented by the holder and go onto the staff training record. However, no comprehension test is organized. The performance and efficiency of the training sessions is verified by checking training records and looking over the course content during inspections.

All the categories of workers (management staff, exposed and non-exposed workers) receive the same training covering radiation protection, specific requirements for safe management of source, possible consequences of loss, theft, inadequate use or damage of sources and prompt notification.

4.13.2.7. Identification and marking of HASS

The documentation accompanying the HASS systematically complies with the requirements of the article 7 of the HASS Directive. Licensees forward the relevant documentation at licensing stage and at subsequent renewals and amendments. During inspections the relevant paperwork is checked against the HASS sources found on-site and source number/pig-tail numbers are physically checked on-site. To the RPII's knowledge, there is no HASS in Ireland without identification number.

Ireland having no national HASS manufacturer, all the HASS are imported. Co-60 sources used in industrial irradiators in Ireland come with a 20 year working life. Other HASS sources don't have a recommended working life.

4.13.2.8. Transfers of HASS

Source transfers can only take place following approval being granted by the RPII in Ireland. It is an offence to transfer a source without prior authorisation from the RPII. In case of international transfer, the authority is informed by national competent authority of the recipient country. No situation with a source lost or out of control due to unrecorded transfer has been encountered in Ireland.

4.13.2.9. Long-term management of disused HASS

The national regulatory framework does not define a limited use life for HASS. Under the Irish regulatory system a licence condition states that once a source becomes disused it is either returned to the supplier or placed in a recognized installation or transferred to another licensed user without undue delay. This condition applies to all sources including HASS, but HASS are also covered by additional licence conditions in relation to upkeep of take-back agreements and the provision of adequate finances for ultimate disposal in the event of bankruptcy. These latter conditions do not apply to all sealed sources.

The preferred national strategy for the long-term management of HASS is the return to the supplier. At the end of their useful working life all HASS sources are returned to the manufacturers in accordance with take-back agreements. HASS licensees as part of the licensing process must forward a copy of the take-back agreement and the financial arrangements that are in place to deal with the HASS sources. This take-back agreement and financial arrangement must be confirmed annually by the licensee to the RPII and any changes highlighted. Compliance with these conditions is checked annually by the inspectors.

4.13.2.10. Security measures

As part of the implementation programme, the RPII, in conjunction with the National Crime Prevention Unit of An Garda Síochána (the Irish Police Force), have undertaken security audits of all HASS licensees and have overseen improvements in security where required. The security

requirements foresee fences, recorded control access, locked premises and locked source as well as fire detection. Video surveillance is available only at holder's premises during storage.

4.13.3. Detection

4.13.3.1. Detection of orphan sources

A threat assessment considering orphan sources identifies strategic locations where orphan sources are likely to be found: metal scrap yards and harbours. In those locations, detection equipment is available but on a voluntary basis only. The equipment includes either portal or portable monitors at metal scrap yards and portal monitors at harbours. Revenue and Customs have two truck mounted mobile scanning units with radiation detection capabilities which move from port to port. The equipment used does not need to be authorised by the RPII.

4.13.3.2. Campaign for orphan sources recovery

The regulatory framework allows for such recovery programmes but to date no campaigns have been organised. No orphan sources have been discovered in Ireland to date and all legacy sources are still under licence. Source inventories are checked routinely during regulatory inspections to confirm the continued presence of sources.

4.13.3.3. International cooperation and information exchanges

Ireland contributes to the IAEA Incident and Trafficking Database since 2002. Ireland has reported to the IAEA Incident and Trafficking Database three incidents.

4.13.4. Preparedness and Response

4.13.4.1. Emergency plans and procedures

In 2010 the Irish Government agreed a Temporary Operational Protocol for seized and orphan sources which sets out responsibilities for RPII, Government departments and key stakeholders to ensure that these sources are dealt with in a safe and secure manner. The staff of the RPII constitutes a team if/when required, composed of max 7-10 persons equipped with communication means, measurement devices, individual protection equipment, shielded containers and decontamination material. The RPII operates an on-call duty officer system 24/7, where necessary to activate the emergency response. The emergency plan has not been initiated because no orphan sources detection or incidents has occurred.

As part of the licensing process HASS licensees must submit risk assessments, radiation safety procedures and emergency/intervention plans which must be approved by the RPII. However, there are no compulsory emergency preparedness and response requirements for the operators of institutions where orphan sources are more likely to be found. RPII can only recommend to such organisations that emergency plans are put in place.

4.13.4.2. Training and information of persons potentially confronted with an orphan source

The personnel potentially confronted with an orphan source are not trained. Under the Irish legislation the training is only obligatory to licensees.

4.14. Italy

4.14.1. Regulatory framework with respect to HASS

4.14.1.1. Regulatory authority

The Italian legislation covers all activities related to import and export, handling, use, storage, transport, disposal of radioactive materials, products, apparatus and any other devices containing radioactive substances. The main legislation is:

- *Act no. 1860 of 31st December 1962, governing radiation sources, nuclear installations and third party liability;*
- *Legislative Decree no. 230 of 17th March 1995 (as amended by successive legislative decrees), governing radiation sources, nuclear installations as well as the radiation protection provisions for workers and the member of the public; the Legislative Decree replaced the Presidential Decree no. 185 of 13th February 1964;*
- *Legislative Decree no. 52 of 6th February 2007, which transposes the European Union directive 2003/122/Euratom on the control of high-activity sealed radioactive sources and orphan sources.*

An important feature of legally binding rules concerning safety and radiation protection in Italy is that contravention to obligations by operators and/or users constitutes a misdemeanour and entails a penal sanction; compliance can be enforced by means of criminal proceedings after due process of law.

With regard to the licensing process, central authorizations (Cat. A) are granted with interministerial decree issued by Ministry Economic Development, acting in accordance with Ministry of Environment, Ministry of Interior, Ministry of Health and Ministry of Labour, and based upon binding technical advice of ISPRA, which entitled by the Italian legislation with the role of regulatory body for nuclear safety and radiation protection. Coordination of licensing process is performed by Ministry Economic Development.

Local authorizations (Cat. B) are granted by the Prefect, for industrial and research use of radioactive sources or by local health authority, as identified by the Region law for medical use of radiation sources.

Inspection activities are performed by ISPRA and other authorities such as Labour Inspectorate or local Health bodies.

Ministry of Economic Development / ISPRA is the organization designated as the main competent authority in accordance with the HASS Directive. They are responsible for authorization, transfers, records, inspections and report on experience.

The following authorities have also competences:

- Prefectures (Ministry of Interior) / Local Health Authorities. They are responsible for authorization, transfers, records and inspections.
- Prefectures (Ministry of Interior). They are responsible to issue the local radiological emergency preparedness and response plan in relation to radioactive (also non HASS) and orphan sources.
- Ministry of Environment (together with Ministry of Economic Development). They are responsible for report on experience.
- Ministry of Foreign Affairs in coordination with Ministry of Interior. They are responsible for orphan sources and international cooperation.
- Ministry of Foreign Affairs. It is responsible for international cooperation and information exchange.

4.14.1.2. Legislative framework

The HASS directive has been transposed into national legislation in Italy by Legislative Decree no. 52/2007, on 6 February 2007. Financial security provisions for orphan sources are not transposed because of lack of economic resources.

Italian legislation follows the activity levels in the Annex 1 of HASS directive. If the activity of a HASS falls below HASS directive level it is covered by provisions of non-HASS established in the Italian legislation. Existing high activity sources at time of transposition of HASS directive are also covered by provisions of Legislative Decree no. 52/2007. A source is excluded from regulatory control when its activity is below the exemption levels laid down in Legislative Decree no. 230/1995.

4.14.2. Prevention and Deterrence

4.14.2.1. Authorization for practice with HASS

All relevant topics are being taken under consideration for giving the authorisation in Italy: justification of use; responsibilities; staff competencies; adequacy of the source with respect to its utilisation; available documentation and procedures for work and maintenance; emergency procedures and communication links; adequate arrangement for long term management of the disused sources; control measures to prevent inadequate use, unauthorised access, loss or theft of the HASS and control measures that have been implemented to prevent damage of HASS by fire, flooding, etc.

It has happened that authorization of a HASS has been refused because of missing authorization of the facility.

4.14.2.2. Records keeping and updating

HASS holders are required to keep records of all HASS under their responsibility. The HASS holder provides the authority with the recorded information at the acquisition time, when the holder no longer holds the source and periodically (each 3 months). In addition specific provision of the Italian legislation prescribes that a report of all sources hold during the year shall be sent to the competent authority at the end of the year. The maximum delay to provide the information is 90 days.

4.14.2.3. National inventory

The recorded information is used to establish a national inventory of authorised HASS holders and the HASS they hold. Up to now the information was provided to the authority only in written copy. Data (all information requested in the standard record sheet given in Annex II of the HASS Directive) will be processed into a national electronic database (national register).

Sources not covered by the HASS directive are also included in the national register, but in a separate database. The register of authorized source holders is not available directly to customs or to police organizations.

During inspections, the authority checks the match between the actual situation of HASS and the information by the holder for each source.

4.14.2.4. Inspections and penalties

Inspections are executed by ISPRA for Category A facilities, in the fields of safety, security and non-proliferation. Local authorities execute inspections only in the field of safety. Unannounced inspections as well as follow-up actions in case of an incident or any other suspicious situation are organized for safety.

The inspectors dealing with HASS are trained in their specific field, meaning in security, safety and non-proliferation and have experience in nuclear technology. Training regarding information concerning their potential confrontation with a source, visual detection of sources and containers, specific requirements for safe management of sources, possible consequences of loss, theft or inadequate use or damage of sources and procedures for prompt notification to the Authority and emergency responses in case of (potential) detection/accident is provided in the field safety.

The scope of an inspection related to HASS is related to safety and includes documentation, inventory, contamination measurements and dose rate measurements of leakage radiation. Special security measures are not covered. The inspections are directly funded by the State.

In case of breaches of the national provisions pursuant to the HASS Directive penalties of 1 to 3 month imprisonment or fines ranging from 5000 to 20000 Euro are applicable.

4.14.2.5. Control of HASS by the holder

The competent Authority verifies the regular performance of suitable tests by the Holder to control the good conditions (integrity, place of use or storage etc.) of each HASS and associated device during inspections. Leak tests are carried out by the supplier.

The competent Authority is informed on the control measures implemented during authorization process and during inspection.

4.14.2.6. Sources holders' training

The definition of the training program of the HASS holder staff is done by the holder itself following the Italian legislation. The training material is prepared by the holder with the qualified experts' support. The training sessions are recorded; verification of training is done by the holder who then usually checks through tests/exams. However tests are not mandatory by legislation.

Training records are checked by the Authority during inspections. The categories subjected to training are in general terms the management staff, the radiation protection officer and the exposed workers. Non-exposed workers are trained in radiation protection principles.

4.14.2.7. Identification and marking of HASS

Documentation accompanying the HASS systematically includes source identification (on the source or container), information and photographs of source design type and information and photographs of the transport packaging. There are no HASS in Italy without identification number or without information on the nature of the source.

4.14.2.8. Transfers of HASS

The holder ascertains that the recipient holds the appropriate authorisation by asking a copy of it. The authority is informed of the transfer and the transport to the recipient in case of a national transfer.

As far as transboundary shipments of sealed sources and other relevant sources among Members States of the European Union are concerned, it must be mentioned that Council Regulation (Euratom) no. 1493/93, constitutes the legally binding act.

4.14.2.9. Long-term management of disused HASS

There is no requirement in any regulation to define a limited useful life for HASS. There is no encouraged national strategy regarding how to deal with HASS once the HASS becomes disused. In practice the source is sent back to the supplier or transferred to an authorized radioactive treatment/storage facility or stored at holder's premises.

An authorized storage facility for radioactive waste is available and disused HASS are in principle accepted, but its capacity is limited therefore sending back to supplier is the first implemented choice. Holders of HASS are forced to make adequate arrangements for the long-term management of the HASS after termination of the use because an authorisation is issued only if the long-term management route is already specified and planned.

Long term management is funded by “take back” provisions incorporated into supply contract, by fund set by the holder or by financial guarantee prepaid by the holder to the state or competent authority.

4.14.2.10. Security measures

The compulsory security measures should foresee fences, locked premises and fire detection systems (but not for places of use of mobile sources).

4.14.3. Detection

4.14.3.1. Detection of orphan sources

A threat assessment concerning orphan sources at national level has been performed by the competent authority. The strategic locations identified to detect orphan sources are metal scrap yards, metal scrap recycling facilities, metallurgic facilities, borders/customs and harbours. At all these sites detection equipment is compulsory. Portal monitors are requested at borders/customs and harbours. In addition also compulsory portal monitors are requested at conventional waste management facilities. The type of detection equipment is not imposed by the authority and it is not necessary to be authorized.

Legislative provisions are established into Italian legislation with a view to setting up detection apparatus measurement at the borders and at foundries or at facilities collecting metal scrap; in many instances apparatus and/or surveillance procedures are already in place. Ports and borders also have measuring equipment.

4.14.3.2. Campaign for orphan sources recovery

Recovery campaigns have already been organized in Italy through systematic analysis of the historical records available at the authority and investigations in the former holders’ records. There is a general lack of budget and a general lack of competent staff, so no frequency for these campaigns has been predefined.

Recovery campaigns have been based on type of sources, use of sources and particular industrial sources. The recovered sources have been returned to supplier/manufacturer, if identified or have been transferred to authorized storage/disposal facility. Italy is convinced that organizing of recovery campaigns is the best method to recover orphan sources.

4.14.3.3. International cooperation and information exchanges

Italy has communicated on international level cases of discovery to IAEA and EU and cases of illicit trafficking to IAEA. It contributes to the IAEA Incident and Trafficking Database.

4.14.4. Preparedness and Response

4.14.4.1. Emergency plans and procedures

There is no national radiological emergency response plan in place in relation with orphan source or HASS. According to Italian legislation, there are only local radiological emergency response plans issued by the Prefectures.

An emergency team is available to intervene 24/7 in case of emergency with an orphan source or HASS. Responsibility is on the Ministry of Interior (national fire brigade) in case of radioactive risk response, providing subsequent activation of various skill levels, activated by the National Operation Centre. Experts are available in ISPRA emergency centre shift. Available equipment is communication devices, measurement devices and individual protection equipment and decontamination material.

There are compulsory emergency preparedness and response requirements for HASS holders in place. The emergency response plans and/or procedures must be part of the documents submitted by the holder to obtain the authorization. There are no compulsory emergency preparedness and response requirements for the facility operators of institutions where orphan sources are more likely to be found.

According to emergency plans, the following responsibilities are set: emergency services deal with mobilization of responders, security of site and source and control of the contamination of the site after source removal. The authority is responsible for the first instructions to public. The qualified expert is responsible for radiological assessment and contamination control after source removal. Finally, another entity is in charge of transport of the source.

4.14.4.2. Training and information of persons potentially confronted with an orphan source

An extensive and adequate training and information plan is mandatory for all people who could potentially be confronted by orphan sources. For transport and facilities, the training includes all the relevant topics: potential confrontation with a source, visual detection of sources and containers, radiation protection principles and specific requirements for safe management of sources. The training courses are obligatory and documented and are regularly repeated. Comprehension tests are organized. The training sessions include practical exercises.

4.15. Latvia

4.15.1. Regulatory framework with respect to HASS

4.15.1.1. Regulatory authority

The primary Regulatory authority in the field of safety and security of ionising radiation sources in the country is the State Environment Service (VVD), within which a Radiation Safety Centre (RDC) is organised. Its main functions related to HASS include licensing, supervision and control. These functions are not limited to HASS, but cover all ionising radiation sources. Other functions of VVD and RDC include search, identification and evaluation of unknown or unregistered radiation sources on the territory and to organise the disposal of orphan sources when the legal person responsible for the source cannot be identified.

The regulating function is exercised by the Ministry of Environmental Protection and Regional Development. This ministry is also responsible for funding the disposal of orphan sources.

The State Company Latvian Environment, Geology and Metrology Centre is the manager of radioactive waste in the country. It is running the repository Radons. This repository accepts HASS only for temporary storage (near surface disposal). A final solution for disused HASS needs to be developed in the country.

Other main organisations involved with the regulatory management of HASS include the Security Police and the State Police (inspections of security aspects and orphan source detection), the Customs (transfer and record keeping) and the Fire & Rescue Service (orphan source detection and approval of emergency response plans of the licensees).

4.15.1.2. Legislative framework

The legislative framework in the country is based upon the *Law on Radiation Safety & Nuclear Safety* of 26th October 2000, as amended. Several regulations foresee in its implementation.

The Instruction 12 *Regarding Actions of Responsible Institutions in the Event of Finding a Substance or Object of Unknown Origin if it is Suspected that it Contains Explosive, Radioactive, Dangerous Chemical or Biological Substances, as well as if Indications of Terrorist Attack are Detected* (5th August 2008) complete the legislative framework with respect to HASS. This framework regulates the use of all types of radiation sources, including HASS. The same definition and related radiological criteria are being used for defining HASS as those used in the Directive, although in practice the sources are classified according to their actual activity. Therefore, the specific requirements for HASS do not apply anymore to sources of which the activity is decreased below the high activity levels.

The main differences between HASS and non HASS are to be found in records keeping and reporting. Requirements for users, authorisation regime, inspection, training, financial security are similar for HASS and non HASS.

4.15.2. Prevention and Deterrence

4.15.2.1. Authorization for practice with HASS

Before issuing an authorisation for the use of HASS, all relevant issues are considered by the Regulatory Authority, including external accidents (fire, flooding …), emergency procedures and the long term management of the disused source. Authorisation is only granted after all relevant information is received and has been judged as being adequate by the Regulatory Authority.

The license for use does not cover storage. The holders must notify the authority within 10 days after the end of the operations with the HASS. When the source is not used for 3 months, the holder must request a license modification authorising the storage of HASS.

All HASS are imported with a recommended working lifetime for the source, which depends on the type of source and the use of the source.

4.15.2.2. Records keeping and updating

All HASS holders are required to maintain records of the HASS under their responsibility. A written copy of these records is to be sent to the Regulatory authority at the time of acquisition of the source. From then on a yearly update of these records needs to be sent before January 31st through an annual report of the licensee. The Regulatory authority is furthermore informed of all important modifications related to HASS (modification of the use or storage, end of use, transfer, etc.).

4.15.2.3. National inventory

The information received through these records is used to maintain an electronic national inventory (RAIS – IAEA) which is covering all radiation sources. The Regulatory authority does not have indications that unrecorded HASS are present in the country. HASS decayed below the HASS levels are not accounted in the inventory. The national register is available to law enforcement authorities (police and customs) at their request.

4.15.2.4. Inspections and penalties

During inspections, a systematic verification between the records in possession of the regulatory authority and the actual situation at the licensee is performed for all HASS. Inspections are performed by the regulatory authority and by the Security Police (in relation with security issues). As a general rule, inspections are announced to the licensee and come with a frequency of 4 per year for HASS. In

addition, inspections are organised as part of follow-up actions after incidents or accidents. There are no unannounced inspections. Inspections cover all relevant items, except for the verification of security measures. The inspections are funded by the State. Inspectors receive training in all relevant fields, including practical experience in metrology and the necessary equipment for performing an inspection is available.

In case of non-respect of regulations, a system of administrative penalties is in place. These administrative penalties depend on the type of infraction and can range from €30 to €7000.

4.15.2.5. Control of HASS by the holder

Regular testing by the licensee of safety and security performances are required by the Regulatory Authority. Reports on the results are systematically transferred to the Regulatory Authority. Safety tests of HASS include visual verification, dose rate measurements and leak tests. These leak tests are limited to wipe tests on the source container once a year. The test performance is controlled during inspections.

4.15.2.6. Sources holders' training

HASS holder's staff requires training, which is defined by the Regulatory authority in combination with training organisation recognised by the authority for this purpose. A comprehension test is organised at the end of the training. Radiation workers have to repeat this training every 5 years.

4.15.2.7. Identification and marking of HASS

HASS need to be systematically accompanied by the necessary documentation. This documentation contains all relevant information, except the information and photographs of the transport packaging.

4.15.2.8. Transfers of HASS

All HASS are individually licensed and in case of transfer of HASS the Regulatory authority is informed of it by the fact that authorisations and permits have to be requested for transfer and transport. In case of a national transfer, a license needs to be requested by the recipient of the source and in case of an international transfer, the Competent Authority will be contacted by their counterparts of the country of the recipient. The holder transferring a HASS also needs to verify that the recipient holds a valid authorisation for the possession of the source. No cases where HASS got out of control during transfer are known to the Regulatory Authority.

4.15.2.9. Long-term management of disused HASS

The recommended working life, generally defined by the source manufacturer, is being made official by the Regulatory authority through the authorisation for use of the source. For most sources and types of applications, this recommended working life is 15 years. Currently an authorisation is only granted if the long-term management route of the sealed radioactive sources is already specified and planned. The country's policy on disused sources gives priority to returning the disused source to the supplier. If not possible, the disused sources should be considered as radioactive waste and be transferred to an authorised waste treatment or storage facility. The re-use of the source for another application is only considered as last possibility.

The country disposes of an interim storage facility for HASS, but no final disposal solution exists yet. The long-term management of HASS is funded through a tax or through take-back provisions incorporated in the supply contracts.

4.15.2.10. Security measures

Regulation n° 508 contains all requirements for physical protection as a function of the category of the sources (IAEA categorisation is used). For category 1 and 2 sources, a physical protection plan has to be elaborated by the user, which has to be accepted by RDC and the security police. In some category 3 and 4 installations not all requirements are implemented due to the financial situation of the users. In category 1 and 2 installations this is however not the case. Verification of the physical protection situation is part of the normal inspections carried out by RDC.

4.15.3. Detection

4.15.3.1. Detection of orphan sources

A threat assessment regarding orphan sources was performed by the Regulatory Authority, yielding as strategic location for finding orphan sources: metal scrap yards, metal scrap recycling facilities, conventional waste management facilities, border crossings, harbours and airports. The bigger scrap metal installations (> 100,000 ton/y) currently require the availability of portal monitors as well as portable radiation detectors. These devices are calibrated every 2 years. The personnel of these installations occupied in these radiation measurements require a specific training course every 5 years. They need to have emergency procedures related to the detection of orphan sources and some of these installations have a temporary storage place for these sources. For smaller installations, no radiation monitor is required. In conventional public waste dumps, portal monitors are available. The border crossing points are all equipped with portal monitors.

In the Riga Freeport the border crossing points in the harbours are only partly covered with well working monitoring equipment. At airports, this detection equipment is not mandatory. In addition to these, the Regulatory authority has available a mobile radiometric laboratory and the customs have a cargo inspection system.

4.15.3.2. Campaign for orphan sources recovery

Using the historic records available at the authorities, the suppliers and the licensees, and using the results of the site inspections, several sources at risk have been transferred to the waste storage facility during the 1990’s. No other specific campaigns have been organised since. Today recovery of orphan sources is dealt with on a case by case basis after notification of the existence of an orphan source through detection. These cases are financially taken care off by the State.

4.15.3.3. International cooperation and information exchanges

Latvia is actively participating in international cooperation and information exchange, mainly through the established IAEA channels. The country has been contributing to the IAEA Incident and Trafficking Database (ITDB) since 2004.

4.15.4. Preparedness and Response

4.15.4.1. Emergency plans and procedures

Latvia has a general emergency response plan in operation, also applicable in the case of radiological emergencies. HASS or orphan sources are not specifically addressed in the plan. HASS holders on the other hand do require an on-site emergency response plan, which needs to be approved by the local municipality and by the State Fire and Rescue Service.

In case of emergencies involving sealed radioactive sources or orphan sources, the Regulatory authority has an emergency team available to intervene 24/7 with full radiological intervention equipment available. Up to now the national emergency plan has not been initiated in Latvia in relation to situations involving HASS or orphan sources.

4.15.4.2. Training and information of persons potentially confronted with an orphan source

Since January 1st, 2011, an extensive and adequate training and information plan is mandatory for all people who could potentially be confronted to orphan sources at the level of the workers and at the level of the management. These training sessions are repeated every 5 years. There is a comprehension test organised and the Regulatory authority is organising a follow-up of the certificates. The emergency trainings include also practical exercises on identification of sources of ionising radiation.

4.16. Lithuania

4.16.1. Regulatory framework with respect to HASS

4.16.1.1. Regulatory authority

The Authorities designated in accordance with the HASS Directive are the Radiation Protection Centre (RPC) and the State Nuclear Power Safety Inspectorate (VATESI). Both these organizations are competent/ responsible for the implementation of the HASS Directive. The Radiation Protection Centre (RPC) is a competent authority under the Ministry of Health in field of radiation protection (except nuclear facilities). Its main responsibilities are connected with control of radioactive sources: keeping the registry of sources of ionizing radiation, investigation of cases of illicit trafficking of radioactive material, decision making, control and supervision of users of radioactive sources. The required license for any activities with sources is issued by the RPC. RPC has the right to suspend or withdraw the license, when the licensee does not follow the licensing conditions.

RPC maintains the State Register for Sources of Ionizing Radiation and Occupational Exposure (Register). All necessary data is present in the Registry (annual inventory of the sources, installation of new sources, decommissioning and disposal of the used sources) for all license holders. All licensees have possibility to review (no rights directly perform any changes) their own information stored in the Register: licenses, their annexes, possessed sources, workers, annual doses of workers, inspection results, non-compliances which were set during inspections, the terms of implementation. Also on behalf of a bilateral treaty; the Customs Department provides weekly information on all the sources that were imported to or exported from Lithuania and information about legal persons that carried out these procedures.

VATESI is the regulatory authority for nuclear safety and radiation safety concerning practices with sources in the nuclear energy sector. VATESI sets legal requirements for, authorises and exercises the state supervision of practices with sources in the nuclear energy sector.

4.16.1.2. Legislative framework

Lithuania has developed an effective control system for sources of ionizing radiation, having a great regard to high activity Cat. I-III sources (HASS). The established system is in line with IAEA recommendations, Code of Conduct on the Safety and Security of Radioactive Sources and requirements of the appropriate legislation of the European Community.

Main pieces of legislation and regulation related to usage, transportation and security of HASS are the following:

- *Law on Radiation Protection* - establishes general principles of radiation protection, responsibilities of state and other institutions and licensees as it regards safety and security of sources;
- *Regulations on the Import, Export, Transit and Transportation of Radioactive Materials and Radioactive Waste* - establishes the order of issuing permits for import, export and shipment of sources inside the country;

- *Regulations on the Control of High Activity Sealed Ionizing Radiation Sources and Orphan Ionizing Radiation Sources* - legitimated the requirements of The Council Directive 2003/122/Euratom of 22 December 2003 On The Control Of High-Activity Sealed Radioactive Sources And Orphan Sources;
- *Regulations On Physical Security of Sources of Ionization Radiation* - defines requirements of technical and administrative security measures;
- *Regulations on the Risk Categories of the Ionizing Radiation Sources and Methodology of Assigning to the Risk Category* - defines risk categorization methodology according to the IAEA categorization and Code of Conduct on the Safety and Security of Radioactive Sources recommendations.

The HASS Directive is fully transposed in the national regulatory framework and the date of enactment was the 23/12/2005. The act is named Control Regulations of High Activity Sealed Ionizing Radiation Sources and Orphan Ionizing Radiation Sources, approved by the Ministry of Health. The same definition and activity levels are used in the national regulatory framework as in the HASS Directive.

In accordance with Lithuanian regulations in the case when activity of the HASS falls below the defined high-activity level due to the radioactive decay the radioactive source is still covered by the HASS regulation. Only when its activity level is below the exemption level specified in the Directive 96/29/EURATOM the source is excluded from the regulatory control.

4.16.2. Prevention and Deterrence

4.16.2.1. Authorization for practice with HASS

All topics are being taken under consideration before giving an authorization for the use of a HASS: justification of use; responsibilities; staff competencies; adequacy of the source with respect to its utilisation; available documentation and procedures for work and maintenance; emergency procedures and communication links; adequate arrangement for long term management of disused sources; control measures to prevent inadequate use, unauthorized access, loss or theft of the HASS and control measures have been implemented to prevent damage of HASS by fire, flooding, etc. There have been no cases in Lithuania when regulatory authority refused an authorization for the use of a HASS.

4.16.2.2. Records keeping and updating

The HASS holder keeps records both electronically and in written copy under his responsibility, which is sent to the competent authority, respecting the time delay of 10 working days. The HASS holder provides the RPC with the recorded information in the case when the holder no longer holds or uses the source or/and when he no longer uses any other source. In addition annually (by the 31st January of the following year) the results of the physical inventory are notified by the holder to the RPC.

4.16.2.3. National inventory

The recorded information is used to establish a State Register of Sources of Ionising Radiation and Occupational Exposure, established in 1999 (electronic database). All the HASS on Lithuanian territory are recorded in the State Register. Information recorded in the State Register is in accordance with the Annex II of HASS Directive. The sources not covered by the HASS Directive are also kept in this Register. Holders' records are available for inspection by police organizations and customs under official request. During inspections, the Authority checks the match between the actual situation of the HASS and the information recorded by the Holder. The verification is made for each HASS.

4.16.2.4. Inspections and penalties

License holders are inspected on a routine and special basis, and are being prioritized according to the risk category of sources. Both announced and unannounced inspections are carried out. RPC has a programme for inspecting licensees, focusing these inspections on safety (Sf) and security (Sc) of sources (especially HASS).

The RPC inspectors are trained in Sf and Sc in the following fields: practical experience on nuclear metrology; information concerning potential confrontation with a source; visual detection of sources and containers; requirements for safe management of sources; possible consequences of loss, theft or inadequate use or damage of sources; procedures for prompt notification to the Authority and emergency responses in case of accident. The equipment of the inspectors consists of individual dosimeters and dose rate meters; contamination detectors; list of pictures of typical sources and containers. The inspections are funded directly by the State.

RPC examines cases of administrative violations foreseen in articles of The Code of Administrative Violations. Also there are measures of imprisonment to 10 years foreseen in Lithuanian Penal Code in case of illicit trafficking or breaches which has harmful consequences. Fines can also be applied.

4.16.2.5. Control of HASS by the holder

In accordance with the Lithuanian regulations the holder has to perform regularly the tests to control the good conditions of each HASS (integrity, place of use or storage, etc.). The holder’s testing usually includes the visual verification, leak tests and dose rate measurements. The RPC is regularly informed by the holder on the control measures implemented to prevent inadequate use, unauthorized access, loss or theft the sources or their damage by fire, flooding, etc. Such information is provided by the holder during the authorization process and in addition through regular reporting by the Holder, as required by the RPC. Additional control of the measures implemented is performed in the course of RPC inspections.

4.16.2.6. Sources holders’ training

The training programme of the HASS holder staff is defined by the Regulatory authority. The training material is prepared by an organization recognized by the Regulatory authority. After each training session the comprehension tests are organized by the training organization. The results of examination are recorded in the examination protocol. During their inspections the RPC inspectors verify that the holder's employees passed the training and they have the radiation protection certificate. The performance and efficiency of the training performed is also carried out during inspections checking the knowledge of holder's staff.

4.16.2.7. Identification and marking of HASS

The documentation accompanying a HASS includes all the documentation. The information on identification source containers and transportation packages is checked visually.

The manufacturer usually recommends a limited working life: depending on type of source, the recommended working time ranges from 5 to 15 or more years. After this, the working life period of source could be prolonged by RPC for one more year after evaluation of the state of HASS.

4.16.2.8. Transfers of HASS

In case of HASS transfer the holder has to ascertain that the recipient holds an appropriate authorization. This is done by request of a copy of such authorization. The Regulatory authority is informed of individual transfers of HASS from records, by issuing an authorization for the transfer, for the transport and to the recipient. Such approach is used for the national and international transfers.

The export/import transfers within the EU countries are performed following the provisions of the Council Regulation (Euratom) No 1493/93 of 8 June 1993 on shipments of radioactive substances between Member States.

For the shipments from non-EU countries the appropriate application should be submitted to the RPC in accordance with the provisions of the appropriate legal acts of Lithuania. Lithuania has never encountered a situation with source lost or out of control because of unrecorded transfers.

4.16.2.9. Long-term management of disused HASS

The national regulatory system does not define a limited useful life for HASS. The preferred strategy for the long-term management is the return to the supplier, then the transfer to authorized radioactive waste facility and transfer for reuse to another authorized holder.

There is a national authorized storage facility for radioactive waste that accepts disused HASS. Its capacity is adapted to the potential amount of disused sources. After termination of its use, the holder should dispose of the disused HASS in accordance with the legislation and is obliged, to transfer for conditioning the improper or disused sources of ionising radiation.

The Holder is forced to make adequate arrangements for the long-term management of the HASS due to the fact that the authorization is issued only if the long-term management route is already specified and planned. Alternatively, the import of a new source is conditioned on its re-export.

According to the Law on Radioactive Waste, sealed sources of ionizing radiation may be imported into the Republic of Lithuania if after their use it is intended to return them to the supplier of the sealed sources of ionizing radiation. The recipient of a sealed source of ionizing radiation enters into a contract with the radioactive waste manager on the management of the sealed source of ionizing radiation in case the sealed source of ionizing radiation cannot be returned to its supplier. The recipient of a sealed source of ionizing radiation obtains suretyship insurance in the amount specified in the contract with the radioactive waste manager for the services, except in the cases stipulated in the legal act.

Lithuania has never encountered a situation dealing with disused source without any long-term management solution. The long-term management of the disused HASS is funded by take-back provisions incorporated in the supply contract and in funds set by the holder. All used HASS must be returned to manufacturer or transferred to radioactive waste manager. So far Lithuania has not encountered any financial problems in the long-term management of disused HASS.

4.16.2.10. Security measures

Adequate security requirements are implemented, depending on risk category and the planned use of the source. Technical and administrative physical security measures are in place in the facilities using high activity sources of ionizing radiation. Amount of technical and administrative physical security measures depends on the source risk categories. Before being entrusted with the physical protection of the sealed sources of Cat. I-III or being accepted to work involving shipment of sealed sources of Cat. I-III the trustworthiness check of the person must be arranged.

4.16.3. Detection

4.16.3.1. Detection of orphan sources

The Authority has performed a threat assessment concerning the orphan sources. All locations identified in the questionnaire to detect orphan sources have been considered strategic with the exception of transit hubs. The controls are compulsory in all the strategic locations in accordance with the Lithuanian Regulations on the control of high-activity sealed radioactive sources and orphan sources (developed in accordance to the Euratom Directive 2003/122 of 22 December 2003).

State border control points with non EU countries (airport, port, rail and road) have stationary and portable detection equipment (fixed radiation portal monitors, personal radiation detectors, hand-held gamma/neutron search detectors, hand-held radionuclide identification devices). However the type of detection equipment is not imposed by the Authority. Detection equipment is not compulsory in the conventional waste management facilities but searching campaigns for orphan sources are performed by RPC there too.

RPC encourages the natural and legal persons who are engaged in activities with potential risk to encounter the orphan radioactive sources (the buyers, sellers of antique, etc.) to acquire the detection equipment on the voluntary basis. RPC pays great attention to education of the persons, who potentially might encounter an orphan source, prioritizing preparedness for radiological emergency situations.

4.16.3.2. Campaign for orphan sources recovery

The regulatory framework ensures that campaigns to recover orphan sources from past activities are organized. RPC continuously organizes and conducts orphan sources detection and recovery campaigns according to approved annual programmes. The recovery campaigns in Lithuania have been mostly focused on the types of the sources and the particular industrial sectors where probability to run into an orphan source is rather high.

The orphan sources searching campaigns focus on sites with the highest risk (e.g. buildings of former Institute of Oncology, aircraft repair plant, missile base, etc.). They include former Soviet military bases, factories, conventional waste management facilities and other facilities and places in the territory of the Republic of Lithuania.

About 20 persons are devoted to the organization of recovery campaigns. There is a specific budget dedicated to recover orphan sources. The recovery campaigns in Lithuania are organized approximately every 3 years and involve around 10 facilities, following the Regulations established by the State. Private sector is not involved in the recovery campaigns. Recovered sources are returned to the supplier if identified. Otherwise they are transferred to the authorized radwaste facility. There is a financial strategy covering intervention costs that is supported by the State.

The best method to recover the greatest number of orphan sources is organizing the campaigns and using or installing radiation detection equipment in strategic locations. According to RPC the most cost effective type of recovery campaigns is by means of public announcements. Public awareness rising on this topic has generated positive results: RSC annually receives calls from public about suspicious objects found. In many cases their information was correct and sources were found in the reported locations.

4.16.3.3. International cooperation and information exchanges

Lithuania contributes to the IAEA Incident and Trafficking Database since 1996. Information is transmitted through VATESI which is the national contact point.

4.16.4. Preparedness and Response

4.16.4.1. Emergency plans and procedures

Lithuania has a national radiological emergency response plan in place in relation to HASS and orphan sources. The emergency preparedness and response requirements are compulsory for HASS holders and the appropriate response plans and procedures are approved by the RPC. The same requirements are compulsory for those institutions where orphan sources are more likely to be found. During the inspections, the emergency response plans are evaluated by inspectors of RPC.

The first responders to the emergency situation are the Units of Fire and Rescue Department who are in charge 24/7. If expertise is needed, the experts or consultants are invited from RPC, whose availability is also ensured 24/7. The equipment available includes the dedicated vehicles (mobile laboratories), communication, measurement devices, individual protection equipment, shielded containers and necessary decontamination materials. The Radioactive Waste Management Agency is responsible for management of orphan sources and it owns shielded containers and decontamination materials.

4.16.4.2. Training and information of persons potentially confronted with an orphan source

The personnel confronted with an orphan source are trained and the training is addressed to managers and workers in all categories (emergency, transport, facilities). The content of the course covers all the relevant items. The training courses are obligatory according to regulations, documented, and regularly repeated at a frequency of 5 years. Once per year, briefings at the workplace are performed by the person responsible for radiation safety. Comprehension tests are organized and the training sessions include practical exercises. The specific facilities, devices and materials are used for these exercises. They include portal detectors, hand-held instruments, shielding, long arm pliers, etc.

4.17. Luxembourg

4.17.1. Regulatory framework with respect to HASS

4.17.1.1. Regulatory authority

The department of radiation protection (DRP) within the Ministry of Health is actually charged with the protection of the population against the hazards of ionizing and non-ionizing radiation. It is in charge with the preparation of laws, regulations and decrees in the field of radiation protection and nuclear safety. It is responsible for the formalities within the licensing procedure. DRP has been designated as the competent national authority charged with carrying out the missions provided for in the HASS Directive.

All activities and projects of the DRP are financed via state budget, allocating predefined credits on a yearly basis.

4.17.1.2. Legislative framework

In 1963, a framework law was enacted on the Protection of the Public against the Hazards of Ionizing Radiation. It is the legal basis for executive regulations which sets out the basic principles regarding radiation protection and nuclear safety. The executive regulations are regularly amended with the EU Directives on radiation protection and nuclear safety.

However being a non-nuclear country, Luxembourg does not dispose of very detailed regulations on nuclear matters which would cover all aspects related to nuclear activities. A list with relevant laws and regulations, including the ratification of laws for international conventions, is given hereafter:

Laws

- *Law of 25 March 1963 concerning the protection of the population against the dangers arising from ionizing radiation.*
- *Law of 21 November 1980 concerning the organization of the Directorate of Health.*
- *Law of 28 March 1984 concerning the approbation of the agreement between the government of the Grand Duchy of Luxembourg and the government of the French Republic concerning the information exchange in case of an incident or accident which might have radiological consequences, signed in Luxembourg on 11 April 1983.*

- *Law of 19 March 1997 concerning the approbation of the Convention on Nuclear Safety, adopted in Vienna on 20 September 1994.*
- *Law of 28 July 2000 concerning the approbation of the Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency, adopted in Vienna on 26 September 1986.*
- *Law of 28 July 2000 concerning the approbation of the Convention on Early Notification of a Nuclear Accident, adopted in Vienna on 26 September 1986.*
- *Law of 12 June 2006 concerning the creation of the rescue services agency*
- *Law of 27 April 2006 concerning the approbation of the agreement between the government of the Grand Duchy of Luxembourg and the government of the Kingdom of Belgium concerning the information exchange in case of an incident or accident which might have radiological consequences, signed in Eischen on 28 April 2004.*

Regulations and Decrees

- *Grand-ducal regulation of 27 November 1987 concerning the admissible levels of radioactivity in foodstuffs.*
- *Grand-ducal regulation of 11 August 1996 concerning the provision of information to the population on the applicable measures for the protection of public health and on the conduct to be adopted in the event of a radiological emergency.*
- *Grand-ducal regulation of 14 December 2000 concerning the protection of the population against the dangers arising from ionizing radiation.*
- *Grand-ducal regulation of 6 May 2010, defining the specific missions, the composition, organization and operation of the department of civil protection of the rescue services agency.*
- *National emergency response plan in case of an incident or accident in the nuclear power plant of Cattenom or in case of any other radiological or nuclear event (adopted by the Government on 2 December 1994).*

The Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources (HASS) was fully transposed into national law on 21 July 2006 by amending the Grand Ducal Regulation of 14 December 2000 on the protection of the population against the dangers of ionizing radiation.

4.17.2. Prevention and Deterrence

4.17.2.1. Authorization for practice with HASS

The DRP ensures that before issuing authorization for any practice involving a high activity source as defined in the Directive all relevant provisions of the Directive are in place, namely safe management of the source, security measures, emergency procedures, training, records keeping and transfers, etc. The Minister of Health may suspend or withdraw a license when the licensee contravenes the Regulation in force or the conditions of the license. The established practice is to limit licenses for holding, storing and using radioactive materials to 10 years.

4.17.2.2. Records keeping and updating

Facilities have to hold a register of all sources used or stored on their premises with indication of their exact respective location. Licensees have to notify the DRP of any modification of their inventory.

4.17.2.3. National inventory

The DRP have monitored and recorded in a national inventory in form of a database each individual sealed source active above the exemption level. The database contains information about the type,

activity and registration number of the source, its localization and a reference to the corresponding license.

4.17.2.4. Inspections and penalties

Licensed facilities are inspected at regular intervals by inspectors of the DRP. These periodic inspections focus on the radiological protection of the workers and the physical protection of the sources. The licensee has to demonstrate that internal procedures concerning the management of radioactive substances exist, are adequate and correctly applied. Inspectors of the DRP are further attributed with the legal power of police officers. Inspections are conducted at least once per year in all nuclear medicine and radiotherapy centres, and in around 50% of the other facilities licensed to use radioactive sources.

Penalties are defined by the Law of 25 March 1963 and comprise fines and imprisonment between 8 days to 1 year.

4.17.2.5. Control of HASS by the holder

A licence holder is fully responsible for the respect of all regulatory provisions concerning the safe management of their radioactive sources and if necessary interim storage of waste, as well as the organisation of the shipment to a foreign waste management storage in accordance with the applicable regulations. Leakage tests of the sealed sources are mandatory in case of an incident involving the sources and at the latest when the source is 10 years in use.

4.17.2.6. Sources holders’ training

The holder is responsible for taking the appropriate steps to optimize all exposure to ionizing radiation, to supervise the working conditions in the controlled and supervised areas, to implement the individual monitoring and the monitoring of the working place, to establish written procedures and instructions for the exposed workers, to appoint a qualified expert or assign persons responsible for the physical control, the safety and the security of the equipment and the radioactive source and to give appropriate training to the exposed workers on all relevant issues in radiation protection.

4.17.2.7. Identification and marking of HASS

HASS is systematically accompanied by the necessary relevant documentation provided by the producer.

4.17.2.8. Transfers of HASS

All radioactive sealed sources have to be imported from other countries, mainly from other European member States. In line with the regulation in force, each import and installation of a sealed source is submitted to a licensing procedure. This also applies to older sources not yet covered by these new regulatory provisions. Before the shipment is scheduled sources are stored at the users' premises. Only licensed carriers are allowed to transport radioactive materials in quantities above exemption level. For the transfer of radioactive sources, the EU Council Regulation of 8 June 1993 on shipments of radioactive substances between Member States is applicable.

4.17.2.9. Long-term management of disused HASS

As part of the licensing procedure, the applicant must have a written commitment from the foreign supplier, where the latter agrees to take back the source if disused. If it turns out that the supplier is unable to respect his commitment, e.g. in case of bankruptcy, the user or holder is obliged to take all necessary administrative steps to send his disused source to any other supplier of radioactive sources or foreign waste management facility.

Luxembourg has put in place a system under which the supplier is obliged to take back all sources, including when the user company becomes insolvent or goes out of business, while the company has to take out insurance to cover the risks of recycling the sources should it become insolvent. In order to anticipate any unforeseen situation in which the abovementioned guarantees were insufficient; Luxembourg has tasked the DRP with guaranteeing secure management and financing any necessary measure, as the case may be.

The practical implementation of certain parts of the Directive, involving high-activity sources situated on dredgers operating on the high seas, posed some difficulties and the way to solve them seems to be a strong point gained in implementing the Directive in the maritime field. Indeed the costs of taking a used source out of service can vary according to the dredger's location. For that reason it is more difficult to define what an adequate financial guarantee is. After examining various options, the DRP finally accepted a multi-stage system proposed by the companies concerned. First, the supplier guarantees, by a certificate, to take back all retired sources, while the company operating the dredger undertakes to cover the costs of transfer and recycling. Should the company become insolvent, the association of maritime dredging companies guarantees to take care of the radioactive sources and to cover the associated costs. A financial guarantee certificate from the association must be submitted with the application.

Another difficulty concern the controls, surveillance and monitoring of radioactive sources used on the territories of other Member States. The DRP's position is that sources on board of Luxembourg-registered dredgers are to be monitored, regardless of where the vessel may actually be operating. Permanent monitoring of these sources is guaranteed by the Luxembourg Maritime Affairs Agency, which can pinpoint the location of each dredger at any time. DRP monitoring ends when the source is returned to the supplier or the dredger is registered under another flag. In these cases the company concerned must apply to the DRP for authorization for the source to be exported or transferred to another Member State.

As a non-nuclear country Luxembourg is not operating a radioactive waste management facility. The small national interim storage facility (NSIF) only holds waste for which no license holder exists. This mainly concerns radioactive lightening conductors, radioactive smoke detectors, orphan sources, radium sources, small amounts of uranium or thorium salts, etc. An inventory of the disused sources stored either on the users' premises or on the authority's premises (NSIF) is managed by the DRP.

During the recent years, the amount of waste and disused sources stored in Luxembourg has been reduced. At the licensee's side this is due to the fact that some facilities have stopped using radioactive sources and returned all disused sources to the suppliers.

4.17.2.10. Security measures

The periodic inspections focus on the radiological protection of the workers and the physical protection of the sources.

4.17.3. Detection

4.17.3.1. Detection of orphan sources

All major metal recycling and industrial waste management facilities have installed detection portals at the site entrance. The equipment used is commercially available and specially designed for the detection of radioactivity in scrap. On the only existing harbour in Luxembourg a commercially available crane monitoring system is used for the unloading of scrap from ships. A systematic radiation monitoring at the international airport or at significant nodal transit points is not yet realized, but concrete plans exist for the future. Moreover, the DRP has provided tailored information for site staff on how to recognize and to deal with orphan sources. In general it can be said that the number of orphan source detections in Luxembourg is decreasing.

4.17.3.2. Campaign for orphan sources recovery

In the context of campaigns organization, the DRP collects radioactive waste and ensures the safe management of these products. This collection is billed to the firm concerned using an established procedure, and in certain cases is free of charge.

4.17.3.3. International cooperation and information exchanges

In the context of nuclear safety, the government of the Grand Duchy of Luxembourg and the government of Belgium and of France concluded an agreement concerning the information exchange in case of an incident or accident, which might have radiological consequences. The DRP reports also to the IAEA Incident and Trafficking Database.

4.17.4. Preparedness and Response

4.17.4.1. Emergency plans and procedures

As facilities are fully responsible for the safety of their radioactive sources, they have to take the necessary steps to cope with radiological emergencies. Depending on the quantities of radioactive substances, they have to draw up internal emergency response plans taking into account the most probable accidents. Periodic review of the plans and training of the staff by organizing regular exercises are part of the conditions set in the license. In case of an emergency, the license holder is obliged to notify immediately the DRP, the Rescue Services Agency (ASS) and the labour inspectorate (ITM), to evaluate the possible radiological consequences for the populations at risk, to take the necessary steps to avoid or to stop the release of radioactivity in the environment and limiting by that the exposure of individuals and to respect the legal provisions in case of emergency exposures.

The Government has set up a national emergency response plan to alert and to protect the population in case of a radiological emergency. The Minister of Health and the Minister of Interior are responsible for the off-site emergency planning. The plan is activated and regularly tested by the DRP and by the ASS, in national, bilateral and international exercises. Emergency teams have been formed to assist in the event of a nuclear disaster, and refresher courses are held periodically.

Bilateral agreements on mutual assistance have been concluded with Germany, France and Belgium. These general agreements also cover radiological and nuclear emergencies. A bilateral agreement on mutual early information has been concluded with France and Belgium.

4.17.4.2. Training and information of persons potentially confronted with an orphan source

Several drills, exercises and focused seminars have been organized over the last years in cooperation with specialized intervention teams from neighbouring countries. In particular with regard to contamination of radiological contaminated persons, a close cooperation has been set up with specialized intervention teams in Belgium and in France. Moreover the DRP has provided tailored information for site staff (metal recycling industry) on how to recognize and to deal with orphan sources.

4.18. Malta

4.18.1. Regulatory framework with respect to HASS

4.18.1.1. Regulatory authority

The Nuclear Safety and Radiation Protection Regulations which were published in January 2003 are primarily concerned with ensuring compliance with the EU directives in occupational exposure to ionizing radiation 96/29/EURATOM and 90/641/EURATOM. The NSRP regulation also establishes

the Radiation Protection Board (RPB) which acts as the regulatory authority in the field of nuclear safety and radiation protection.

The Radiation Protection Board is responsible for all the requirements of the Council Directive 2003/122/Euratom of 22 December 2003 on the control of high-activity sealed radioactive sources and orphan sources (HASS directive). In that frame, responsibilities are also assigned to the Civil Protection Department, member of the RPB, to deal with radiological emergencies due to orphan sources.

4.18.1.2. Legislative framework

The HASS directive was fully transposed into the national regulatory framework by the enactment on the 13th January 2006 of the Legal Notice 13 (regulations on the control and security of high-activity radioactive and orphan sources).

In the Legal Notice 13 (2006), the same definition is being used for defining HASS as the one specified in the HASS Directive. However, the related radiological criteria (activity levels) for several radionuclides are different. As the HASS directive was implemented together with the requirements of the IEAE Code of Conduct, the Maltese high-activity levels correspond to the Category 3 levels of the IAEA categorisation. Once a source is defined as a HASS, the requirements of the Legal Notice 13 apply during the whole lifecycle of the source on the territory of Malta.

All other radioactive sources (with activity levels lower than the “activity level 3”) are regulated by the provisions of the Legal Notice 44 of 2003 (NSRP regulation), which was already in force before the transposition of the HASS directive. The NSRP regulation also covers the sources whose activity had fallen down below the high-activity levels when the HASS directive was transposed.

The radioactive sources, including those defined as HASS, are released from the regulatory requirements once they fall below the exemption levels defined in the Directive 96/29/Euratom.

4.18.2. Prevention and Deterrence

4.18.2.1. Authorization for practice with HASS

The RPB requires the holder to obtain prior high activity source authorisation for any practice involving a source, including taking possession of a source. Before issuing an authorization for the use of HASS, the RPB ensures that all arrangements and provisions of the article 3 of the HASS directive are met. All these requirements to obtain prior authorisation are listed in the article 8 of the Legal Notice 13.

An authorization for the use of a HASS has never been refused in Malta.

4.18.2.2. Records keeping and updating

For the purpose of controlling radioactive sources, every holder has to keep up to date records of the quantity and location of radioactive substances under his responsibility. The records keeping is regulated by the article 10 of the Legal Notice 13, 2006 (control and security of high-activity radioactive and orphan sources regulations). The holder’s records shall be available for inspection by the Board.

The Board shall keep records of authorised holders and of the sources they hold. These records shall include the radionuclide involved, the activity at the time of manufacture, or if this activity is not known, the activity at the time of the first placing on the market or at the time the holder acquired the source, and the type of source. The Board shall keep the records up to date, taking transfers into account, among other factors.

The RPB receives on time every year the standard record form of HASS because yearly inspections are organised in January for the HASS holders. If not yet provided, the mandatory supply of the record form is reminded during that inspection.

4.18.2.3. National inventory

All radioactive sources (covered and non-covered by the HASS Directive) are recorded to establish the national inventory using the IAEA RAIS and an Excel sheet but without sub-inventory for HASS holders/sources. The register is not available to police organizations but a permanent mechanism for exchange information and cooperation is established by the RPB with the customs authorities in order to ensure adequate control over the sources entering and leaving the country.

Malta has a limited inventory of radioactive sources that fall under the scope of Council Directive 2003/122/EURATOM. The verification is made for each HASS, randomly and at least for all the HASS every 12 months during inspection to check the match between the actual situation of the HASS and the information recorded by the holder.

4.18.2.4. Inspections and penalties

The inspections of HASS holder are carried out once a year for the verification of compliance with regulatory requirements of the Legal Notice 13. The inspections are related to the fields of safety and security and are performed periodically (announced), randomly (unannounced) or as a follow-up action in case of incident.

Their scope concerns the documentation, the inventory, a visual inspection of HASS and their environment and the security measures. The match between the actual situation and the information recorded by the holder is also controlled.

The inspectors are not specifically trained but have a practical experience in nuclear metrology. They have standard equipment but it is generally not used during inspection of HASS holders. External dose rate equipment is measured when required and, if required, surface contamination can be detected (via wipe tests). All equipment is annually calibrated overseas.

Since the RPB is a governmental body, the inspections are funded by the State.

In case of breaches of regulations adopted pursuant to the HASS Directive, a system of penalties is in place but has never been applied up to now. Penalties are foreseen going up to 5 years imprisonment/ fine of 116 000 €.

4.18.2.5. Control of HASS by the holder

The requirements for holder are specified in the article 11 of the Legal Notice 13. In practice, except visual verification, no particular request is addressed to the holder for controlling the good conditions of its HASS. The regular performance of the tests is not verified during the annual inspections.

4.18.2.6. Sources holders' training

Before issuing high activity source authorisation, the RPB ensures that the potential holder of the source has provided minimum staff competencies, including information and training. The training and information is covered by the article 13 of the Legal Notice 13.

The training of the HASS holder's staff is defined and organized by the holder himself for its exposed staff. The frequency of the training is not specified in the regulation. After the training session, no comprehension test is organized and no verification of the efficiency is performed by the authority. The training sessions are however recorded because the trainee generally receives a certificate of attendance from the training organisation.

4.18.2.7. Identification and marking of HASS

The requirements for identification and marking are defined in the article 12 of the Legal Notice 13. The manufacturer shall identify or, in the case of sources imported from outside the European Community, the supplier shall ensure that each source is identified by a unique number. The manufacturer shall provide 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 indicating that the source is identified and marked. The information shall include photographs of the source, source container, transport packaging, device and equipment as appropriate.

The inspectors check on arrival the documentation accompanying the HASS which systematically includes the source identification. Once a year, the inspector performs a physical check of the source container.

4.18.2.8. Transfers of HASS

The regulation states that the holders shall notify and get approval in writing from the RPB prior to any transfer of any source. Actually both the holder and the consignee must notify the regulatory body and be authorised by the RPB before the transfer is carried out.

In case of international transfer, the RPB shall ensure that the foreign recipient effectively exists either by direct contact with the national competent authority or by other means. Moreover, in case of transfer between Malta and another Member State, the standard documents set in the 1493 Euratom Directive will be exchanged to obtain the prior written declaration by the consignee that he compiles, in the Member State of destination, with all applicable EU provisions.

The RPB keeps the records up to date, taking transfers into account, among other factor. The Regulatory authority does not grant authorization for importation or exportation or transit through the Maltese territory of nuclear material unless it receives assurance that such material will be protected at the levels of Physical Protection to be applied in International Transport of Nuclear Materials as categorized in Annex II – Schedule 6 of the NSRP regulations.

No cases where HASS got out of control during transfer are known to the RPB.

4.18.2.9. Long-term management of disused HASS

With respect to the long term management, the national regulatory framework does not define a limited useful life for HASS. Nevertheless, an authorization for using HASS is issued only if the long term management route is specified and planned in the request for authorization.

Adequate management of disused sources, including agreements regarding the transfer, if appropriate, of disused sources without undue delay after termination of the use to a supplier, another authorised holder or a recognised installation must be ensured before issuing the authorisation. The actual implemented strategy is therefore return to supplier or transfer to another authorised holder outside Malta. The authorisation is not issued to the HASS holder if such provisions are not foreseen: import of a new source is now conditioned on its re-export. The same rule also applies for non HASS: the authorization is granted only if the source is sent out of Malta once disused. To summarise, the long-term management of HASS and other sealed sources is today ensured through take-back provisions incorporated in the supply contracts.

A centralized storage facility still does not exist in Malta. The solution implemented is the storage at the holder’s premises awaiting the establishment of the centralised storage facility.

4.18.2.10. Security measures

The minimum compulsory security requirements for HASS are locked premises and security staff during use and storage at the holder's premises.

However, the RPB requires for issuing high activity source authorisation to be provided with measures to determine, as appropriate, the trustworthiness of individuals involved in the management of radioactive sources and the confidentiality of information relating to the security of sources and a security plan or assessment including measures to detect and delay the unauthorised access to, or the theft, loss or unauthorised use or removal of radioactive sources during all stages of management. The security plan or assessment shall be periodically reviewed and records of such reviews kept.

Moreover the holder must ensure that each fixed and mobile source is subject to adequate documented measures, aimed at preventing unauthorised access to or loss or theft of the source or its damage by fire and must promptly notify the Board of any loss, theft or unauthorised use of a source, arrange for a check on the integrity of each source after any event, and inform the Board thereof and of the measures taken

4.18.3. Detection

4.18.3.1. Detection of orphan sources

A general threat assessment for any radiological incident has been performed at national level by the authority but not specifically for HASS. The strategic locations identified to detect orphan sources are borders/customs, transit hubs and airports. These entities have been encouraged by the PRB to use detection equipment on a voluntary basis. Indeed, the RPB shall encourage the establishment of systems aimed at detecting orphan sources in places such as large metal scrap yards and major metal scrap recycling installations where orphan sources may generally be encountered, or at significant nodal transit points, wherever appropriate, such as customs posts.

The borders/customs, transit hubs and harbours are today equipped with both portal monitors and portable radiation detectors whilst airports are monitored only with portals. The Freeport of Malta where large number of containers arrives is equipped with a set of 7 portal monitors. There are procedures for that portal monitor system in place which involve Customs, RPB and the Port Operator.

The metal scrap yards are not equipped with detection means although the article 14.3 of the Legal Notice 13 mentions that scrap metal dealers shall have access to an appropriate radiation monitor in order to ascertain that no orphan sources are present within the scrap metal. There is no metal melting facility in Malta. The conventional waste management facilities or waste dump are not equipped with portal monitor.

4.18.3.2. Campaign for orphan sources recovery

Even if article 14.5 of the Legal Notice 13 specifies that the RPB shall organise, as appropriate, the recovery of orphan sources left behind from past activities, no recovery campaigns have taken place in Malta mainly because a centralised storage facility is not available. Other reasons are the lack of budget and of staff. In Malta, there is no financial strategy covering intervention costs related to the recovery of orphan sources. According to the RPB, the best method to recover orphan sources is the targeting of specific holders and former holders.

4.18.3.3. International cooperation and information exchanges

As member of the IAEA Incident and Trafficking Database (ITDB), Malta receives international information and notifications.

4.18.4. Preparedness and Response

4.18.4.1. Emergency plans and procedures

Malta has a national general radiological emergency plan based on a threat assessment, including possible incident with HASS and orphan sources. Operating procedures are established by the RPB.

The Civil Protection Department shall be responsible for preparing for and managing radiological emergencies which may occur in connection with practices or work activities on or outside Maltese territory and which may affect Malta. The response and management responsibilities of the Civil Protection Department shall not be limited to off-site emergencies but shall extend to any on-site emergencies which in the opinion of the Civil Protection Department, cannot be managed by the radiation user. The Civil Protection Department is the agency responsible to recover orphan sources and to deal with radiological emergencies due to orphan sources and the department shall draw up appropriate response plans and measures.

A compulsory emergency preparedness and response plan has also to be developed by the HASS holder. This one does need to be approved by the authority. The institutions where orphan sources are more likely to be found are not submitted to this obligation.

In case of emergency with an orphan source or HASS, the emergency services of the civil protection department are available to intervene 24/7 with adequate radiological intervention equipment (communication and measurement devices, individual protection equipment, shielded containers and decontamination material). The Civil Protection Department makes suitable provision for the appropriate training of personnel who may be involved in technical, medical and health intervention.

Up to now, the emergency plan has never been initiated because of incidents with HASS or orphan source detection.

4.18.4.2. Training and information of persons potentially confronted with an orphan source

The Legal Notice 13 of 2006 declares that the RPB will give specialised technical advice and assistance to persons, not normally involved in operations subject to radiation protection requirements, who suspect the presence of an orphan source. The primary aim of advice and assistance shall be the protection of workers and members of the public from radiation and the safety of the source.

A limited training which is not requested by the regulations is organized for people who could be confronted to orphan source. The training is addressed to emergency services (police, fire fighters, and medical staff), customs office, transit hub, harbour and airport personnel. The courses, never repeated, are documented but no comprehension tests are organized. The training session includes practical exercises with portal and hand-held instruments and a list of pictures of typical sources and containers is presented.

4.19. The Netherlands

4.19.1. Regulatory framework with respect to HASS

4.19.1.1. Regulatory authority

The Nuclear Installations and Safety Department of the Ministry of Economic Affairs is competent in all topics of the HASS directive except the record keeping and the inspections. The Radiation Protection Team of the Netherlands Enterprise Agency (a division of the Ministry of Economic Affairs) issues the authorisation, checks the availability of financial security for the long term management of the source, and maintains the records of the sources and the HASS holders.

The Human Environment and Transport Inspectorate, which is part of the Ministry of Infrastructure and Environment but working under the responsibility of the Ministry of Economic Affairs, is competent in the frame of inspections, orphan sources management, international cooperation and penalties. Both the Human Environment and Transport Inspectorate and the Labour Inspectorate monitor compliance with the requirements regarding HASS. The Labour Inspectorate's inspections focus on measures for the protection of workers, while the Human Environment and Transport Inspectorate focuses, in particular, on environmental protection, compliance with the additional requirements, such as financial security, and immediate transfer if the source is permanently withdrawn from use. The Human Environment and Transport Inspectorate is also in charge when orphan sources are found.

The responsibility for nuclear activities is thus not centralised, but is shared by several Ministers who consult each other and issue regulations jointly. There are some recent developments on this subject. The Dutch Council of Ministers decided on January 24, 2014 that the expertise in the area of nuclear safety and most of the expertise on radiation protection will be brought together in a single independent organisation in the Netherlands. The Authority for Nuclear Safety and Radiation Protection (Autoriteit Nucleaire Veiligheid en Stralingsbescherming, or ANVS) will be responsible for regulating the sector. The new organisation will optimally utilise of the expertise and experience available. As an Independent Administrative Authority (in Dutch a ZBO), the ANVS will fall under the responsibility of the Minister of Infrastructure and the Environment. Through the establishment of the ANVS, 150 staff members will be part of a single independent organisation that meets international standards, including those imposed by the International Atomic Energy Agency. The new authority will draft legislation, develop safety requirements, issue permits, carry out inspections, enforcement and provide information to the public. The ANVS will also be jointly responsible (with the local authorities and the ministry of Safety and Justice) for emergency preparedness in the event of incidents which could result in the release of radiation.

4.19.1.2. Legislative framework

In the Netherlands, the basic legislation concerning nuclear activities is set out in the 1963 Nuclear Energy Act ('Kernenergiewet'; Bulletin of Acts and Decrees, 1963, No. 82), as last amended in 2014.

The requirements of Directive 2003/122/Euratom have been implemented in Dutch regulatory regime by both the Radiation Protection Decree ('Besluit stralingsbescherming' Bulletin of Acts and Decrees No 260, 2006) and the Ministerial Order on HASS ('Regeling hoogactieve bronnen', Government Gazette No 114, 2006) which provides the HASS holders with technical instructions. Both regulations were last amended on January 1, 2014, the requirements from the Ministerial Order on HASS were transposed to the Regulation Implementing the Radiation Protection Decree ('Uitvoeringsregeling Stralingsbescherming EZ'; Government Gazette 32478, 2013).

Until January 1, 2014, the regulation used the same definition for a high-active source as the one from the HASS Directive. A HASS stayed covered by this regulation until decay below the national clearance levels. Sources that would have been considered as HASS but whose activity had fallen down below the high-activity levels before the transposition of the Directive were covered by provisions for non-HASS. On January 1, 2014 the definition of HASS was amended (Radiation Protection Decree), "high-activity sealed source" means a sealed source for which the activity of the contained radionuclide is equal to or exceeds the relevant activity value, thus anticipating the definition of HASS as stipulated in the 2013/59/EURATOM directive (but with the activity levels from the 2003/122/EURATOM directive).

Most of the requirements of the Directive were already applicable in the Netherlands because, when Directive 96/29/Euratom was implemented, the situation at the time was enforced by strict national rules on a number of points. The requirements of the HASS Directive with respect to orphan sources were already provided for in the 2002 Decree on the detection of radioactive contaminated scrap ('Besluit detective radioactief besmet schroot'; Bulletin of Acts and Decrees No. 661, 2002, as last amended in 2011) and the 2003 Order on the detection of radioactive contaminated scrap ('Regeling

detective radioactief besmet schroot'; Government Gazette No. 81, 2003, as last amended in 2009). Main differences between regulations before and after the HASS Directive transposition are found in the record keeping, the requirements for the holders, the identification and marking of the sources, the training of personnel, the financial security for orphan sources and the report on experience.

4.19.2. Prevention and Deterrence

4.19.2.1. Authorization for practice with HASS

For any activities involving a high-activity source, an operator must be authorised under the Nuclear Energy Act. The Radiation Protection Team of the Netherlands Enterprise Agency is otified as the competent authority for issuing, assessing and implementing the authorisation. Before issuing an authorisation for the use of a HASS, the authorities ensure that most of the arrangement and provisions of Article 3 "Authorisation" of the HASS directive are met. Furthermore, the operator must draw up written instructions aimed at preventing unauthorised access to a HASS, its loss or theft, or damage by fire. Before the acquisition of a new HASS, the holder must provide a financial security for the costs associated with safe disposal of the HASS. Within two weeks after acquiring the source, the operator must also notify the Netherlands Enterprise Agency by submitting the relevant data using the standard form available.

The license stipulates that within a maximum of 2 years after termination of use, the holder must get rid of the disused HASS. Once the HASS is removed, the holder must notify the authority within 2 weeks.

An authorisation has never been refused for use of a HASS in the Netherlands.

4.19.2.2. Records keeping and updating

HASS holders must keep records of the ionising radiation sources held by them and provide the recorded information to the Netherlands Enterprise Agency with the standard form available within two weeks after acquisition, annually and within two weeks when the holder no longer holds the source. Random checks are made during inspections. According to inspection's results, companies occasionally fail to submit the compulsory 'annual' declaration giving an overview of all HASS held. The information is considered as complete but the tolerated delay of two weeks is generally exceeded. In 2014 the annual declaration to the Netherlands Enterprise Agency has been complete (68 licensees with HASS sources).

4.19.2.3. National inventory

The national inventory is established from the information provided during the authorisation request and the annual declaration. A centralised inventory of all HASS within the Dutch territory will be established. This national inventory will depict the situation on January 1, 2014 and will be broadened in the future.

This inventory is available for inspection by competent Authorities, and would be communicated on request to Police and customs organization. The Authority checks the match of recorded information and actual situation during inspections.

4.19.2.4. Inspections and penalties

Both the Inspectorate of the Ministry of Social Affairs and Employment and the Human Environment and Transport Inspectorate perform inspections on radiological aspects using a systematic approach (risk based). In addition complementary unannounced inspections of HASS holders are organised two to three times per year. Inspections are also organized as follow-up action in case of incident or any other suspicious situation. Inspections are funded by the State.

Their scope covers safety aspects such as documentation, labelling, inventory, financial security, visual inspection of the HASS and their environment, contamination and dose rate measurements and security aspects. The inspectors verify the regular performance of suitable leak tests by the holder by asking the corresponding registration document.

The training of the inspectors contains practical experience in nuclear metrology, information concerning their potential confrontation with a source, the visual detection of sources and containers and the specific requirements for their safe management, possible consequences of loss, theft or inadequate use of sources and procedures/responses to be followed in case of emergency situation.

Penalties are foreseen in case of breach of the national provisions pursuant to the HASS Directive. Penalties depend on the kind of breaches and the seriousness of damage caused by them. This is determined by the public prosecutor's office.

4.19.2.5. Control of HASS by the holder

Visual verification, leak tests and dose rate measurements must be carried out by the holder once a year and also systematically in case of possible damage of the source. Leak tests must be understood as a contamination check of the device.

4.19.2.6. Sources holders' training

HASS are used by or under the responsibility of a radiation expert. HASS holder must prepare and organise the prescribed training of the radiation protection officer and the exposed workers once every two years. The scope of this training covers radiation protection principles, specific requirements for safe management of sources, possible consequences of loss, theft or inadequate use of sources, prompt notification to the competent authorities and emergency responses in case of an accident. Training sessions are recorded but there is no comprehension test organised. The competent authority checks the training records during inspection.

According to inspection's results, the level of compliance with the requirements for training is not respected in all industries. Holders must draw up the instructions themselves and conduct training that is specifically targeted to the company's own situation. In some industries, the expertise needed to do this is often insufficient.

4.19.2.7. Identification and marking of HASS

The documentation accompanying the HASS is generally complete including the source identification (on the source and on the container) and all relevant information and photographs concerning the source design, the source container, and the associated device or equipment. Transport packaging is less described.

In order to prevent the occurrence of high-activity orphan sources (including those of Dutch origin), a unique identification code on the source or the source holder has been required since the HASS Directive entered into force. The Netherlands Enterprise Agency has given ID-codes to ten licensees; one manufacturer, one supplier and eight holders of old sources (that didn't have a unique identification code). The correct identification marking of HASS is controlled during inspection.

4.19.2.8. Transfers of HASS

For national transfer of HASS, Netherlands Enterprise Agency must be notified by both the holder and the recipient. Moreover transfers are confirmed by the records of the holders. In case of transfer between The Netherlands and another Member State, the standard documents set in the 1493 Euratom Directive are also exchanged. In case of international transfer, Netherlands Enterprise Agency will be notified by the Dutch supplier or holder but will not request the prior consent of the authority of the importing State.

There is no case of source lost or out of control due to unrecorded transfer.

4.19.2.9. Long-term management of disused HASS

There is no recommended working life for HASS in the national regulatory framework. The long term management of the source is prepaid by the holder. Before receiving its license, the HASS holder must provide a financial security for the costs associated with safe disposal of the HASS. The financial security is required to each HASS holder even if the take-back of the disused HASS is contractually ensured by the supplier. All licensed holders that use HASS have provided a financial security in the form of a bank guarantee, insurance agreement or deposit.

In the past several cases of holders which did not provide financial security at the acquisition time have been encountered. These holders had to pay for the long term management of the source after the use.

The options for long-term management of the disused sources are return to supplier, re-use by another authorized holder and finally transfer to the waste management facility.

The authorisation of disused HASS storage at the user's premise is limited. Indeed, adequate arrangements should be made by the holder as soon as possible with a maximum of two years after termination of the use of the HASS. According to the Dutch regulation the take-back of the disused HASS by the supplier is mandatory. However, the existence of contractual take-back provisions is not formally verified by the authority.

The Central Organisation for Radioactive Waste (COVRA: Centrale Organisatie Voor Radioactief Afval) was created by the Netherlands Government in 1982 to assume responsibility for all aspects of the management of radioactive waste in the Netherlands, including collection and transport, treatment and conditioning, temporary and/or permanent storage and disposal, including the necessary research activities in line with government policy. This facility is authorised and has the capacity to accept disused HASS.

4.19.2.10. Security measures

In the Netherlands, the highest risk of loss of control exists with regard to the mobile use of HASS. Security requirements for HASS storage are general: the operator must draw up written instructions aimed at preventing unauthorised access to a high-activity source, its loss or theft, or damage of the source by fire. Locked premises are required for storage places; mobile sources must be equipped with a lock at the place of their use. New specific regulation on the security of radioactive material was enacted in the Regulation on the security of radioactive materials on April 1, 2013 'Regeling beveiliging radioactieve stoffen'; Government Gazette 25427, 2012, and were transposed to the Regulation Implementing the Radiation Protection Decree on January 1, 2014 ('Uitvoeringsregeling Stralingsbescherming EZ'; Government Gazette 32478, 2013).

Requirements include the measures to be taken by a licensee to reach a prescribed delay time after an attempt of theft of the source, to allow enough time for response. These measures can be organisational (e.g. screening of staff), constructional (e.g. locks and fences) and electronic (e.g. detection systems). The measures taken must be drawn up into the security plan, which has to be re-evaluated periodically.

4.19.3. Detection

4.19.3.1. Detection of orphan sources

A threat assessment concerning the orphan sources has been performed by the authority at the national level. It includes strategic locations for finding orphan sources such as metal scrap yards, metal scrap recycling facilities, metallurgical industries but not the conventional waste management facilities. As

required by the Decree on the detection of radioactive contaminated scrap (‘Besluit detectie radioactief besmet schroot’, as mentioned in section 1.19.1.2) and the Order on the detection of radioactive contaminated scrap (‘Regeling detectie radioactief besmet schroot’, also mentioned in section 1.19.1.2), the larger metal scrap yard sites are subjected to legal obligations to install their own detection gates and the use of detectors on grabs for bulk loads to avoid the entrance of contaminated scrap or orphan sources in the production chain. They are bound to handle their alarm detections with the Human Environment and Transport Inspectorate directly.

The customs authorities also carry out large scale screening of containers for the presence of radioactive materials.

With respect to goods submitted to the licensing requirements for import and export and related transport a risk oriented approach is used to define the goods that are effectively verified by the customs. This control is essentially based on document verification with respect to the licensing obligations. Furthermore the customs organization has realized completely integrated and centralized networks of radiation detection gates covering all ways of access/exit by road and rail to the port premises. Mobile detection systems on a car can be used to monitor internal transfers and access/exit by inland navigation as the latter terminals are only partially equipped with radiation detection gates.

Non acceptable and suspected loads are further handled under decision and surveillance of an inspector of the Human Environment and Transport Inspectorate on a case by case base, including for unloading of containers and isolation of radioactive objects, temporary storage at the terminal, transfer to COVRA and/or return to the country of origin.

4.19.3.2. Campaign for orphan sources recovery

There is no structural recovery campaign organized in the Netherlands. Orphan sources are detected fairly regularly by the detection systems installed at the scrap yards and at the national borders. Over the years, a limited number of high-activity orphan sources have been found, always in scrap of foreign origin. The recovery operations are normally paid by the scrap yard facility where the orphan source is found. The facility can afterwards turn against the importing scrap company. In addition each major metal company has set a financial security to ensure the funding of the costs of the source recovery and disposal in case the scrap facility is not capable of covering them (due to bankruptcy).

No high-activity orphan sources of Dutch origin have ever been found either in the Netherlands or, as far as known, abroad.

4.19.3.3. International cooperation and information exchanges

The Netherlands participates in international cooperation and exchange of information, mainly through the established IAEA-channels. The county contributes through notifications to the IAEA Incident and Trafficking Data Base (IDTB), the IAEA International Nuclear Events Scale (INES) and the ECURIE-system.

4.19.4. Preparedness and Response

4.19.4.1. Emergency plans and procedures

HASS holders and facility operators of institutions where orphan sources are more likely to be found must prepare an emergency response plan. These plans are neither to be approved nor to be reviewed by the Authority.

A national response plan in relation with orphan sources is in place. A team is available 24/7, equipped with dedicated vehicles, communication devices, measurement devices, shielded containers, individual protection equipment and decontamination material. In case of detection of orphan sources,

a single point of contact is accessible by dedicated emergency call number broadcasted to emergency services and institutions likely to be confronted with orphan sources.

4.19.4.2. Training and information of persons potentially confronted with an orphan source

Training of workers responsible for detection of radioactive material is mandatory for metal companies. The training addresses the complete information needed to detect and safely act in case of source detection. It includes practical exercises with portal detectors and hand-held instruments. The training is documented but there is no comprehensive test organised and it is not regularly repeated.

HASS holders must prepare and organise the prescribed training of the radiation protection officer and the exposed workers once every two years. The scope covers radiation protection principles, specific requirements for safe management of sources, possible consequences of loss, theft or inadequate use of sources, prompt notification to the competent authorities and emergency responses in case of an accident. Training sessions are recorded but there is no comprehension test organised. The competent authority checks the training records during inspection.

Training is not explicitly required for emergency services.

4.20. Poland

4.20.1. Regulatory framework with respect to HASS

4.20.1.1. Regulatory authority

The competent Authority in accordance with the HASS Directive is the National Atomic Energy Agency.

4.20.1.2. Legislative framework

The HASS Directive has been fully transposed in the national legislation by means of the Act of Parliament of 11 April 2008 amending the Act of Parliament of 29 November 2000, the Atomic Law. The Articles 5, 43 (4), 43a-c, 47, 77 of the Atomic Law contain the provisions for radiation safety. Furthermore, §19 of the Regulation of the Council of Ministers of 12 July 2006 include the detailed safety requirements for work involving ionising radiation sources.

The alternative HASS definition in the Polish legal framework is the following: "*high-activity source – sealed radioactive source containing a radioactive isotope whose activity at the moment of source manufacture or, if that value is unknown, at the moment when the source is introduced for sale, is equal to, or higher than, the threshold activity for a high activity source, as specified in Annex No. 2 to the Act, however the source ceases to be a "high-activity source" if its activity decreases below this threshold level."*

The regulation in force for the sources with activity levels below those defined in the regulatory framework for HASS is the same law and the above-mentioned regulation of 12 July 2006. There are minor differences between this regulation and the requirements of the transposed HASS Directive concerning the authorisation, transfers, records and identification and marking.

4.20.2. Prevention and Deterrence

4.20.2.1. Authorization for practice with HASS

All topics are being taken under consideration: justification of use; responsibilities; staff competencies; adequacy of the source with respect to its utilisation; available documentation and procedures for work and maintenance; emergency procedures and communication links; adequate arrangement for long-term management of the disused sources; control measures to prevent inadequate

use, unauthorised access, loss or theft of the HASS and control measures have been implemented to prevent damage of HASS by fire, flooding, etc…

The working life of HASS is not considered as a requirement when giving the authorisation.

4.20.2.2. Records keeping and updating

The HASS holder keeps records for HASS under his responsibility, which is sent to the competent authority, respecting a maximal time delay of 7 working days. The records have to be sent yearly and when the holder no longer uses the source. The information recorded by the HASS Holder is sent in written copy. This written copy is required as evidence that has to be kept. In Poland there does not seem to be a practical value for sending this data also in electronic form. This would require appropriate data protection measures.

4.20.2.3. National inventory

The recorded information received through the standard record sheet is used to establish a national inventory of the HASS and the authorised HASS holders. The data is processed in an electronic database. The data on the sources not covered by the HASS Directive are also kept in this register. Not all the information from the standard record sheet (in Annex II of the Directive) is transferred to the electronic database. The information that is not recorded concerns the type of equipment/container, the manufacturer details, if the source is mobile or fixed. Increasing the scope of data stored in the electronic database is considered unnecessary.

Data in the national inventory are available to police organisations and to customs after official request.

4.20.2.4. Inspections and penalties

During inspections directly funded by the State, the Authority checks the match between the actual situation of the HASS and the information recorded by the holder. The National Atomic Energy Agency is in charge of the inspection of HASS holders for Safety (Sf), Security (Sc) and Non Proliferation (NP). The planning is organised periodically (announced) and randomly (unannounced) for the three fields. The frequency of periodic inspections of authorised holders in the medical sector is yearly, in other sectors 2 yearly.

The inspectors are trained in the following fields: practical experience on nuclear metrology; information concerning potential confrontation with a source; visual detection of sources and containers; requirements for safe management of sources; possible consequences of loss, theft or inadequate use or damage of sources; procedures for prompt notification to the Authority and emergency responses in case of accident.

Penalties to infringement are described in the Art. 123 of the Atomic Law. An administrative penalty is imposed in an amount not exceeding the fivefold average monthly pay in the national economy in the calendar year prior to the commitment of the offence. The penalties have already been applied.

4.20.2.5. Control of HASS by the holder

HASS are tested by the holders every 2 years. These tests are limited to a visual inspection and a verification of the dose rate. Leak tests are not performed. During the inspections, the Regulatory authority verifies the performance of these tests.

4.20.2.6. Sources holders' training

The definition of the training program of the HASS holders' staff is done by the holder and the training material is prepared by an organisation recognised by the Authority. According to the

legislation, the head of the organisation shall be obliged to ensure, at least every 5 years, the preliminary and periodic training of workers on nuclear safety and radiological protection issues, according to the defined training program. Appropriate training shall be also given to workers participating in the transport of nuclear materials, radioactive sources, radioactive waste and spent nuclear fuel. All categories of workers are subjected to training. The training sessions are recorded and comprehension tests are organised. The performance and efficiency of the training sessions is carried out by checking training records during inspections

4.20.2.7. Identification and marking of HASS

Verification of the correct marking of the source is performed by the producer (one in Poland). Documentation accompanying the HASS includes the source identification, information and photographs of the source design type and information and photographs of the typical source container. Information on the transport package and photographs of the device and equipment are generally not present.

4.20.2.8. Transfers of HASS

The Authority is informed of individual transfers by issuing an authorisation/permit to the holder for the transfer and to the recipient in case of a national transfer. The holder ascertains that the Recipient holds an appropriate authorisation by asking a copy of it.

Third country recipient should fill out the declaration required by the Regulation on the terms for import into, export from and transit through the territory of the Republic of Poland, of nuclear materials, radioactive sources and equipment containing such sources, and send it to the Holder after obtaining confirmation from competent authority of the country of destination. According to the Council Regulation No.1493/93/EURATOM, the standard declaration form is required within the EU.

4.20.2.9. Long-term management of disused HASS

The national regulatory system does not define a limited useful life for HASS. The preferred strategy for the long-term management is the transfer for re-use to another authorised holder and in second place, return to the supplier. Transfer to storage facility would be the third option.

The solutions actually implemented are the return to the supplier, then the transfer for re-use, and finally the transfer to storage facility. There is a national authorised storage facility for radioactive waste that accepts disused HASS. Its capacity is adapted to the potential amount of disused sources.

After termination of its use, the holder is not authorised to store the disused HASS at its premises. The holder is forced to make adequate arrangements for the long-term management of the HASS due to the fact that the authorisation is issued only if the long-term management route is already specified and planned.

The long-term management of disused HASS is funded by take-back provisions incorporated in the supply contract and by funds set by the holder of the source and managed by the Radioactive Waste Management Plant - State owned company (RWMP-SC).

4.20.2.10. Security measures

Adequate security measures are implemented in all sites where HASS are used and/or stored.

4.20.3. Detection

4.20.3.1. Detection of orphan sources

The Authority has performed a threat assessment concerning the orphan sources. All locations considered strategic were considered with the exception of transit hubs. The controls on radioactivity in all these strategic locations are compulsory. The detection equipment consists of portals and portable systems.

4.20.3.2. Campaign for orphan sources recovery

The regulatory framework does not ensure that searching campaigns to recover orphan sources are organised. No systematic recovery campaigns have been organised in the country. However, a systematic training was conducted at the scrap recovery points with regard to the identification of orphan radioactive sources. Those responsible for the management of such businesses recognise that this is for the benefit of their workers and cooperate fully. There is also appropriate equipment available to identify radioactive material and sources.

There is a financial strategy covering intervention costs supported by the State. The best method to recover the greatest number of orphan sources is using or installing radiation detection equipment in strategic locations.

4.20.3.3. International cooperation and information exchanges

Poland contributes to the IAEA Incident and Trafficking Database since 1996.

4.20.4. Preparedness and Response

4.20.4.1. Emergency plans and procedures

Poland has a national radiological emergency response plan in place with relation to HASS and orphan sources. The national emergency plan is activated when the impact of radiation emergency event extends, or may extend, over a large territory. Each province has got its own crisis management centre (operated 24/7) collecting information about any emergency situation, including radiation emergency events. In the case of an orphan source discovery in a public place, the regional emergency plan is activated. If needed, the regional services can be supported by the survey team of the National Atomic Energy Agency (PAA), available 24/7 with all necessary devices.

There are compulsory emergency preparedness and response requirements for HASS holders and for the operators of facilities and institutions where orphan sources are more likely to be found. The Border Guard and Customs Service are obliged to develop and maintain a response procedure in case of discovery of illicit trafficking.

There is a unique contact point in case of discovery of an orphan source: the National Warning Point placed in the Radiation Emergency Centre.

4.20.4.2. Training and information of persons potentially confronted with an orphan source

The head of an entity, whose workers may come into contact with orphan sources during their work, in particular the head of an organisation that stores, sells or processes scrap metal, shall provide such workers with the training that includes information on the possibility of contact with such source, visual detection of orphan sources and their containers, basic information on ionising radiation and its consequences, and information on actions which should be undertaken in the event of detection or suspected presence of an orphan source.

The training is addressed to workers and customs managers are trained as well. Training is provided in accordance with the emergency preparedness plan to be submitted as part of the application for the license given to the source holder. This plan is required to predict potential accident scenarios that are then covered in the training, including practical drills. The courses are documented, regularly repeated at a frequency of 1-5 years. There are comprehension tests organised and the training sessions include practical exercises.

4.21. Portugal

4.21.1. Regulatory framework with respect to HASS

4.21.1.1. Regulatory authority

Portugal has a complex regulatory framework characterized by the existence of various entities with competences in the areas of radiation protection and nuclear safety being allocated to several institutions under different Ministries. According to Decree-Law 165/2002, the licensing authorities in the different areas of health, energy production and mining, industry and research are generally part of or assigned to the respective Ministries, as follows:

- The Lisbon Tech (Instituto Superior Técnico, IST), of the Ministry of Education and Science, is responsible for authorizing all operations associated to the use of sealed sources by issuing ownership, transfer, transport, selling and renting licenses;
- The Directorate-General of Health (DGS), of the Ministry of Health, is responsible for licensing all equipment and activities which produce ionising radiation, excluding all activities related with nuclear fuel cycle;
- The General-Directorate for Energy and Geology (DGEG) authorizes the transfer, transport and return of fresh nuclear fuel;
- The Regional Directorates of Economy (DRE) are responsible for licensing the extraction and processing of radioactive ores.

Thus according to Decree-Law 165/2002, Directorate-General of Health (DGS), of the Ministry of Health is responsible for authorizing each practice (equipment and activities) which produces ionising radiation, excluding all activities related with nuclear fuel cycle. To implement Directive 2003/122/Euratom, the Instituto Tecnológico e Nuclear, I.T.N., I.P. (Technological and Nuclear Institute) was designated as the competent authority under Decree Law No 38/2007.

However, recently, pursuant to Article 1 of Decree Law No 29/2012 of 9 February 2012, the Instituto Superior Técnico (IST) merged with the ITN, I.P., and therefore now IST has the responsibility for ensuring the mission, functions and powers which the Law conferred on the former Institute. Accordingly, IST of the Ministry of Education and Science is responsible for authorizing all operations associated to the use of sealed sources by issuing ownership, transfer, transport, selling and renting licenses.

The Decree-Law No 30/2012 of 9 February created the Regulatory authority for the Safety of Nuclear Installations (COMRSIN) responsible for licensing nuclear fuel cycle facilities.

4.21.1.2. Legislative framework

There is no nuclear power programme, neither source manufacturer in Portugal. The IST (Instituto Superior Técnico) owns and operates, for research purpose, a light-water research reactor (1 MWe).

The regulatory framework governing the nuclear sector is complex including several laws, regulations and decrees, frequently derogating each other.

The Council Directive in occupational exposure to ionizing radiation 96/29/EURATOM (Basic safety Standards) is transposed in the following:

- Decree-Law 165/2002: amended by Decree-Law 215/2008, setting out the competencies of the bodies intervening in the field of protection against ionising radiation, as well as general principles of such protection;
- Decree-Law 167/2002: amended by Decree-Law 215/2008, setting out the legal framework for the licensing and functioning of entities protection against ionising radiation, as well as general principles of such protection;
- Decree-Law 174/2002: set out the rules applicable to interventions in case of a radiological emergency;
- Decree-Law 139/2005: creation of the CIPRSN Commission for Radiological Protection and Nuclear Safety
- Decree-Law 140/2005: set out the exemption levels
- Decree-Law 222/2008: set out basic security rules concerning the sanitary protection of the population and of workers against dangers arising from ionising radiation
- Decree-Law 227/2008 establishes the requirements for training in radiation protection

The Decree-Law 38/2007 of 19 February 2007 is setting out the legal framework for the control of sealed radioactive sources, including orphan sources. It fully transposes the HASS Directive and used the same definition for a high-active source as the one from the HASS Directive. The Decree-Law is applicable for HASS, non-HASS and for existing sources which would have been declared as HASS before the transposition of the HASS Directive. A HASS falling below the defined high-activity levels is still covered by this law until its activity falls below exemption levels. No clearance levels are set.

4.21.2. Prevention and Deterrence

4.21.2.1. Authorization for practice with HASS

DGS authorizes the use of sources in the context of a specific practice. IST authorizes ownership, transfer, transport, selling and renting of the sources.

Before issuing an authorisation for the use of a HASS, the justification of use, responsibilities, staff competencies, adequacy of the source and its associated device with respect to its use, availability of documentation and procedures for work and maintenance, emergency procedures and communication links, adequate arrangements for long term management of disused sources, control measures implemented to prevent inadequate use, unauthorized access, loss or theft or fire flooding etc. are considered.

In addition, an emergency plan is requested whenever the source exceeds 1 TBq and the design of parts of the equipment is requested if the end-use of the source justifies this.

Like Article 3(3) of Directive 2003/122/Euratom, Article 4(9) of Decree Law No 38/2007 lays down that the licence must include the following references:

a) legal responsibilities of the holder of the authorisation;

b) minimum skills required of those responsible for the source, including information and training;

c) minimum source, source container and additional equipment performance criteria;

d) requirements for emergency procedures and communication links;

e) work procedures to be followed;

f) maintenance of equipment, sources and containers;

g) instructions on the proper handling of disused sources, including agreements regarding the transfer, if appropriate, of disused sources to a supplier, another authorized holder or a recognized installation.

Regarding the system of authorization of a HASS, the IST is the competent authority to issue the licence for the use and the possession of a HASS. The DGS is the national competent authority to grant a licence to all activities that involves ionizing radiation. Therefore, all HASS holders shall own two different licences, which are the following: i) the licence to develop activities which involves ionizing radiation, ii) the authorization for the use and possession of a HASS. The licence to develop activities which involves ionizing radiation is granted by DGS in accordance with the Decree-Law 165/2002, which partially transposes the Directive 96/29/Euratom.

The IST has already refused an authorisation for use and possession of a HASS because the holder had no license of activity issued by DGS.

4.21.2.2. Records keeping and updating

In accordance with the legislation, the HASS holder keeps records of the sources under its responsibility and their location. He provides the recorded information to IST, at the acquisition time, annually, when requested and when the holder no longer holds the source. The Holder must record all the sources. These records are subject to inspection by the competent authority. The tolerated delay to provide the information is 30 days, 15 days after acquisition of the source. The information is transferred electronically or through written copy.

4.21.2.3. National inventory

The information for sealed sources is recorded in the national inventory which is processed by electronic database since 2009. HASS and non HASS are gathered in the same database, the recorded information are mainly holder's details, radiological characterization of the source (radionuclide, activity at the time of manufacture or, if this activity is not known, the activity at the time of the first placing on the market or at the time the holder acquired the source), type of source and equipment (mobile or not), location of the source, the manufacturer's details are not recorded.

The Directorate-General for Health must be informed on a quarterly basis of the record made by the competent authority (IST). IST shall send to DGS a quarterly report covering the record of HASS.

The national inventory is not considered complete as some HASS were not recorded in the past.This inventory is available to customs and police organizations.

4.21.2.4. Inspections and penalties

There is neither periodic inspection nor unannounced inspection on HASS. Inspections for safety and security aspects are realized by IST only as follow-up action in case of incident or in any other suspicious situation. No information is available about the training of the inspectors and their standard equipment, about the scope of the inspections and how these inspections are funded.

Decree Law 38/2007 (Article 17) foresees penalties ranged from 250 to 44 890 € depending on the importance of the breaches.

These penalties have never been applied.

4.21.2.5. Control of HASS by the holder

As well as it is established in the Annex II of the Directive 2003/122/Euratom - Standard Record Sheet for High Activity Sealed Sources (HASS) -, the Decree-Law nr. 38/2007 foresees in its Annex IV some data information to provide by the HASS holder. The paragraph 6 of the Annex IV of the Portuguese Decree-Law corresponds to the operational control HASS. The fulfilment of the paragraph 6 by the HASS holders allows the competent authority to verify the regular performance of suitable tests to control good conditions of the HASS.

Tests carried out by the holder are only dose rate measurements. The competent authority is informed on the control measures to prevent any incident involving the HASS during the authorization process. No further control is organized.

4.21.2.6. Sources holders' training

The training program of the HASS holder's staff is defined by the DGS (Directorate-General of Health). IST (recognized organization) is giving the training sessions. Frequency is not set: training is given at request of the HASS holders.

Training covers all the relevant items and is given to all the categories of workers. Participation to the training session is recorded and comprehension tests are organized, the authority does not check the performance and the efficiency of the training session.

4.21.2.7. Identification and marking of HASS

There is no more HASS manufacturer in Portugal. The documentation accompanying a HASS is generally limited to the source identification on the source or on the container. It is the duty of the source holder to have documented information with photographs of the source, the source container, transport packaging, and the device or equipment as appropriate.

The correct identification and marking of the HASS is not currently verified.

4.21.2.8. Transfers of HASS

National competent authority authorizes transfer of HASS by issuing licenses to the holder, to the recipient (if national) and to the transport company. Before transferring a HASS, the holder asks a copy of the recipient's authorization.

4.21.2.9. Long-term management of disused HASS

There is no recommended working life in the national regulatory framework. The holder is forced to make adequate arrangements for long-term management after termination of use by the following manner. The licensee must pay a deposit for each sealed source. Once the licensee considers that the source is no longer used for the practice for which the authorization has been granted, it should be either returned to the manufacturer or collected by the IST. Article 10 (4) of the Decree-Law No. 38/2007 establishes that the IST will then refund the deposit made by the licensee after proof that the spent and/or disused source was returned to the manufacturer or collected by the IST. Licensees also have to deliver the annual declaration of the sources in use. However, this deposit does not cover the cost of long term management of disused sealed source. Whenever the disused sealed source is collected by IST, it is considered as radioactive waste. In this case, the cost of the long term management is supported by the state budget.

There is no information about the maximum storage time at user's premises after termination of use. The options for long-term management of the disused sources are, by order of preference, return to supplier, re-use by another authorized holder and finally collection by IST for long-term management. In facts, re-use is the least implemented option.

The national interim storage facility (PAIRR) is also authorized for HASS interim storage but its capacity is limited. It is only an interim storage and it is not adapted for disposal of HASS. The Portuguese government must find a solution for the long-term management of the sources.

There is no plan for final disposal facility in Portugal.

4.21.2.10. Security measures

Security measures at the holder's premises during use of HASS are locked premises and fire detection system. No measures are defined for other places.

4.21.3. Detection

4.21.3.1. Detection of orphan sources

A threat assessment concerning the orphan sources has been performed by the authority at national level. It includes strategic locations for finding orphan sources such as metal scrap yards, metal scrap recycling facilities, metallurgical industries, conventional waste management facilities, borders, harbours, airports and transit hubs. All these strategic locations are currently equipped with portable and/or portal detection means. However, as these kind of equipment's is subject to a voluntary basis, therefore some metal scrap yards, metal scrap recycling facilities, conventional waste management facilities, or borders are not equipped with portable and/or portal detection. The equipment are not authorized by the authority.

There is no other strategy implemented to detect orphan sources.

4.21.3.2. Campaign for orphan sources recovery

There has been no recovery campaign organized in Portugal. There is no dedicated budget for this. Recovery campaigns are considered, with the use of detection equipment in the strategic locations, like the best methods for orphan sources recovery. It is the responsibility of the competent authority (IST) to organise annual campaigns for the collection of orphan sources. However, it has been difficult in practice to implement these campaigns.

Intervention cost related to intervention in case of source detection is supported by source holder or by the state in case of orphan source. The collected source(s) would be returned to the supplier if possible or transferred to the storage facility.

4.21.3.3. International cooperation and information exchanges

Portugal doesn't contribute to the IAEA Incident and Trafficking Database, but provides information when requested by other Members States or third countries.

4.21.4. Preparedness and Response

4.21.4.1. Emergency plans and procedures

A national radiological emergency plan is in force. It covers HASS incidents and orphan source detection. The emergency services give the first instructions to the public, ensure the security of the site and mobilize the responders. The unique contact point is IST.

There is no structure for 24/7 service, but it is the responsibility of the competent authority (IST) to give advice and technical assistance whenever an orphan source is detected. Available equipment is measurement devices, shielded containers, decontamination material and individual protection equipment. A team of 4 persons is responsible of the radiological assessment, the transport of the source, the contamination control of the site after the source removal and the treatment of the source.

Holders of HASS which activity is higher than 1TBq are required to organize a local emergency preparedness and response plan, but it has not to be approved by the authority. No such requirement applies to institutions where orphan sources are more likely to be found.

The emergency plan has never been activated neither for orphan source detection nor for incident involving a HASS.

4.21.4.2. Training and information of persons potentially confronted with an orphan source

According to the legislation, the training sessions are obligatory and address the complete information needed to detect sources and safely act in such case. Training and information are addressed to persons potentially confronted with an orphan source such as first responder services, scrap yards and metal recycling plants, waste management facilities and metallurgical industries. Customs officers are trained but the staffs from transit hubs, harbours and airports are not trained.

The training includes practical exercises with portable measurement device and material. It is documented and comprehension test is organized, but there is no periodic review. They are repeated at the request of the holder.

4.22. Romania

4.22.1. Regulatory framework with respect to HASS

4.22.1.1. Regulatory authority

The national authority in relation with HASS management is the National Commission for Nuclear Control Activities (CNCAN) having responsibilities of regulation, authorization and control in nuclear field in Romania. Other organisations are the Nuclear Agency and for Radioactive Waste, the National Emergency Situations Inspectorate and the National Customs Authority.

4.22.1.2. Legislative framework

The law 111/1996 is in force and gives CNCAN competence in the areas of nuclear activities. The HASS Directive has been fully transposed in the national regulatory framework in 2008. The reference is the High Activities and Orphan Sources Norm. In Romania, a new regulation on the radiological monitoring of scrap metal is in force (regulation NIN-03).

4.22.2. Prevention and Deterrence

4.22.2.1. Authorization for practice with HASS

All topics are being taken under consideration for giving the authorisation: justification of use; responsibilities; staff competencies; adequacy of the source with respect to its utilisation; available documentation and procedures for work and maintenance; emergency procedures and communication links; adequate arrangement for long term management of the disused sources; control measures to prevent inadequate use, unauthorised access, loss or theft of the HASS and control measures that have been implemented to prevent damage of HASS by fire, flooding, etc.

4.22.2.2. Records keeping and updating

HASS holders are required to keep records of all HASS under their responsibility. This fact is indicated in an annex to the license and it is mandatory to keep records and inventories. The HASS holder provides the Authority with the recorded information periodically (each 6 months). Inspections are performed with the same frequency. The maximum tolerated delay to provide the information is 15 days.

4.22.2.3. National inventory

The recorded information is used to establish a national inventory of authorised HASS holders and the HASS they hold. For security reasons the information is provided to the authority only in written copy.

The data (all information requested in the standard record sheet given in Annex II of the HASS Directive) are processed into a national electronic database (national register). Sources not covered by HASS directive are also included in the national register. There are no HASS in Romania which are not covered by the database.

The register of authorized source holders is available to customs on request; the register of HASS is available to police organizations on request.

4.22.2.4. Inspections and penalties

Inspectors of CNCAN are in charge of the inspections of HASS holders. Controls concern Safety (Sf), Security (Sc) and Non-proliferation (NP). The planning is organised periodically (announced) each 6 months for Sf and Sc and once a year for NP. Random (unannounced) inspections are foreseen for the three fields.

Follow-up training in case of an incident or any other suspicious situation is given only for Sf and Sc.

The inspectors are trained in all Sc, Sf and NP fields. Their equipment consists of individual dosimeters; contamination detectors; pictures of typical sources and containers. The scope of an inspection related to HASS includes for all fields (Sf, Sc and Np) documentation, inventory, visual inspection of HASS and their environment, contamination measurements, dose rate measurements of leakage radiation and security measures.

The inspections are directly funded by the State. Penalties in case of infringement are foreseen. More details on penalties can be found in Chapter VI of the Law No.111/1996.

4.22.2.5. Control of HASS by the holder

The competent authority verifies the regular performance of suitable tests by the holder of each HASS and associated device during inspections. They concern visual verification, leak test and dose rate measurement.

4.22.2.6. Sources holders' training

The definition of the training program of the HASS holder staff is done both by the holder itself and by an external organisation – recognised by the authority. The preparation of the training material is developed by both of them. The frequency of the training sessions varies between 3 to 5 years.

The training sessions are recorded and a comprehension test is organized. The performance and efficiency of the training sessions are carried out by checking training records during inspection and through regular reporting by the holder.

The categories subjected to training are the management staff, the radiation protection officer and the exposed workers. The prompt notification of the authorities in case of accidents is part of the training and also included as a condition in any license issued by CNCAN. Non-exposed workers are not included in any kind of training.

4.22.2.7. Identification and marking of HASS

There is no HASS manufacturer in Romania. The documentation accompanying an imported HASS systematically includes the source identification, information and photographs of source design, source container and transport packaging, information and photographs of the device and equipment.

The verification of the correct identification and marking of the HASS is performed during inspection on site and recorded.

4.22.2.8. Transfers of HASS

The holder ascertains that the recipient holds the appropriate authorisation by asking a copy of it. The authority is informed by issuing an authorisation/permit for the transfer, for the transport and to the recipient in case of a national transfer. The international transfer is covered by the norms on authorisation procedures (NSR-03); the transfer, import and export of sources, as well as the transport of sources has to be licensed by CNCAN. According to NSR-03, the import and export of a source (not only HASS, but all the sources exceeding the exclusion levels defined in the Romanian BSS) is not allowed if the recipient of the source does not have a valid license to receive or possess that source.

4.22.2.9. Long-term management of disused HASS

According to the producer prescriptions, the national regulatory framework defines a limited useful life for HASS. Once this period is expired, the source must be sent back to the supplier, must be considered either as disused and stored/disposed or retested for a new working period.

Periodic testing of the sources is asked by the regulations and performed by each user, the results of the verification tests being used for revalidation of the license and controlled during inspections. Disused sources can be stored on site, provided that safe and secure conditions are ensured by the holder and that a holding license is issued. In order to force the holders of disused sources to return them or to send them to a RW storage/disposal, this holding license is issued for maximum two years.

The preferred strategy for the long-term management is the return to the supplier of the disused sources. This is the solution actually implemented.

There is a national authorized storage facility for radioactive waste located in Baita Bihor accepting disused HASS. The capacity is adapted to the potential amount of disused sources. The long-term management of disused HASS is funded by a fund pre-paid by the holder to the State or competent authority.

4.22.2.10. Security measures

The security measures that are compulsory should foresee video-surveillance at the place of use of mobile sources; sources should be locked (not only at the authorised radwaste storage facility); recorded control access should be done also at the holder’s premises during storage. Fire detection systems and security staff should be ensured everywhere.

4.22.3. Detection

4.22.3.1. Detection of orphan sources

Threat assessment concerning orphan sources at national level has been performed by the competent authority. The strategic locations have been identified to detect orphan sources with exception of conventional waste management facilities. Conventional waste management facilities are not considered to be a strategic location, since all metal scrap usually goes to metal scrap collecting points.

The detection equipment available is of portable type and/or portals. The equipment is imposed and authorised by the competent Authority. The controls are mandatory in all locations considered strategic.

4.22.3.2. Campaign for orphan sources recovery

Orphan sources recovery campaigns have not been organized up to now in Romania. But in the past, several actions have been performed in order to prevent events involving orphan sources. These actions have been performed by CNCAN resident inspectors, as part of their annual inspection plan.

4.22.3.3. International cooperation and information exchanges

Romania contributes to the IAEA Incident and Trafficking Database.

4.22.4. Preparedness and Response

4.22.4.1. Emergency plans and procedures

A radiological emergency response plan is in place in Romania in relation with orphan sources or HASS. Emergency team is available to intervene 24/7 in case of emergency with an orphan source or HASS; permanent services are provided by the National Emergency Situations Inspectorate (IGSU). A unique contact point is designated in case of detection of an orphan source, with a general emergency call number. Its coordinates are broadcasted to potentially involved people by information campaign to general public.

The equipment available in case of emergency is dedicated vehicles (mobile laboratories), communication devices, measurement devices and individual protection equipment.

Romanian emergency response plan has been initiated in 2011 due to orphan source recovery.

There are compulsory emergency preparedness and response requirements for HASS holders in place; these emergency response plans and/or procedures have to be approved by the authority.

There are also compulsory emergency preparedness and response requirements for the facility operators of institutions where orphan sources are more likely to be found, they generally have the obligation to notify an incident. These emergency response plans and/or procedures have to be approved by the authority.

4.22.4.2. Training and information of persons potentially confronted with an orphan source

A quite extensive and adequate training and information plan is mandatory for all people who could potentially be confronted by orphan sources. The training includes information concerning the potential confrontation with a source, radiation protection principles, specific requirements for safe management of sources, possible consequences of loss, theft or inadequate use or damage of sources, procedures for prompt notification to the competent authority(ies) and emergency responses in case of (potential) detection/accident, actions to be taken on site in the event of the detection or suspected detection of a source. The training courses are obligatory, the training courses have to be approved by CNCAN, together with the training program and the lecturers and are documented. They are regularly repeated. Comprehension tests are organized at the end of the training session. The training sessions do not include practical exercises. Practical exercises are extensively performed under the responsibility of the employers.

4.23. Slovakia

4.23.1. Regulatory framework with respect to HASS

4.23.1.1. Regulatory authority

The Ministry of Health is responsible for radiation protection and for the related legislation. The Public Health Authority of the Slovak Republic (PHASR) is the central authority responsible for all nuclear matters. Besides the central authority, there are also local authorities. These authorities are issuing licences and controlling medical sources, industrial sources, workplaces with unsealed sources and workplaces with high activity sealed sources.

The responsibility for nuclear safety is by the Nuclear Regulatory Authority of the Slovak Republic.

4.23.1.2. Legislative framework

Slovakia has fully implemented the HASS Directive into the national legal framework with reference Gov. Dec. No. 348/2006.Coll, issued 1st June 2006. The activity levels in the Slovakian legislation for HASS follow Annex 1 of the HASS Directive. All sources with activity levels below the high-activity levels are regulated by Law no. 355/2007 Coll; Gov. Dec. No. 345/2006 Coll. & Decree No. 545/2007 Coll. Before the transposition of the HASS-Directive, sources were covered by an older legislation.

The main differences in the requirements regarding the HASS between old legislation and HASS directive are identification and marking, financial security for orphan sources and the report on experience.

A HASS stays covered by the HASS regulation until the activity level falls below the exemption levels. This is valid also for existing sources at time before the transposition of the HASS Directive came into force. These provisions are resulting directly from definition of HASS, which is exactly transposed in national legislation. Sources are excluded from regulatory control when their activity is below exemption levels.

4.23.2. Prevention and Deterrence

4.23.2.1. Authorization for practice with HASS

Before issuing an authorisation for the use of HASS, all relevant issues are considered by the regulatory authority, including external accidents, emergency procedures and the long-term management of the disused source. Authorisation is only granted after all relevant information is received and has been judged by the regulatory authority as being adequate. An authorisation for HASS has never been refused in Slovakia.

4.23.2.2. Records keeping and updating

All HASS holders are required to maintain records of the HASS under their responsibility. A written or electronic copy of these records is sent to the regulatory authority. Regulations do not foresee an allowable delay for providing the records to the regulatory authority.

4.23.2.3. National inventory

There is no national inventory of sources available in Slovakia. At a regional level, inventories of HASS are established and maintained by the regional authorities, based on the licenses granted by them. It is to be noted that only one regional authority has a complete inventory. In the regions, not all holders have sent the required records. The holders' records sent to the regional authorities are in general not used to compose or complete an inventory of sources. At present the register of doses is under construction and afterwards the national register of sources will also be established.

4.23.2.4. Inspections and penalties

Inspections are performed by the local regulatory authorities taking care of only safety measures. Systematic verification between the records in possession of the Regulatory authority and the actual situation at the licensee can be performed for all HASS. Both announced and unannounced inspections exist. In addition there are inspections as a follow-up in case of an incident or any other suspicious situation. Inspections cover all relevant items related to safety only. Regular testing by the licensee on safety performances is part of the inspection. Inspections are funded directly by the State. Inspectors receive no special training. The necessary equipment is limited to individual dosimeters and contamination monitors.

In case of non-respect of regulations, a system of administrative penalties is in place. These administrative penalties depend on the type of infraction and can range up to €100.000. The system of penalties has not been used up to now.

4.23.2.5. Control of HASS by the holder

The regulatory authority verifies regular performance of suitable tests by the holder during inspection. The legislation prescribes acceptance tests, constancy tests (every three years) and routine tests (every year) for all sources. These are performed by a national testing company. The intervals and content of tests are fixed by the testing company (usually according to the recommendations of the manufacturer) at the acceptance test. The testing company provides once a year complete information on acceptance, constancy and routine tests with copies of protocols and copies of certificates to the public health authorities and to PHASR.

4.23.2.6. Sources holders' training

The content of the training program of HASS holder's staff is defined by the holder. This training is given at the start of the engagement and repeated yearly. The training sessions are recorded and there is no comprehensive test organised. Non-exposed workers and management staff are not trained.

Radiation protection officer and exposed workers are trained in radiation protection principles, specific requirements of safe management of sources, possible consequences of loss, theft or inadequate use or damage of sources, and notification to the competent authorities and emergency responses in case of accident.

4.23.2.7. Identification and marking of HASS

There is no HASS manufacturer in Slovakia. There is no HASS in Slovakia without ID. Most of the HASS is come with all necessary signs and with a complete documentation exceeding the requirements of HASS directive. Identification number can be seen from documentation that accompanies each HASS. Recommended limited working life is stated in the certificate accompanying the source.

4.23.2.8. Transfers of HASS

Before the transfer of a HASS, the holder has to ascertain that the recipient holds appropriate authorization by requesting a copy of the authorization. The competent authority would be informed of individual transfers of HASS from the holder's records.

Before use of HASS, the holder must obtain the license (authorization) for use of HASS. Only a licensed user can obtain, store and use a HASS. The license is issued for certain number of sources. Individual transfers of HASS between users are allowed. Usually if any user will purchase a HASS, he will use it and finally will return it to the supplier or producer. Initial control is done also by the supplier, who has a duty to control, if the receiver has a license (at least for the storage until he will receive a license for use).

There is no evidence of loss or out of control because of unrecorded transfer.

4.23.2.9. Long-term management of disused HASS

The working life of a HASS is recommended by the supplier and defined in the source documentation. The national legal framework does not define a limited useful life for HASS. An authorisation is only granted if the long-term management route is already specified and planned. The country's policy on disused sources gives priority to returning the disused source to the supplier. Another possibility is the transfer to another authorised user. If this would not be possible, the disused sources should be considered as radioactive waste and be transferred to the national authorised waste treatment and

storage facility. The actual situation of disused HASS corresponds to this policy, but it has to be taken into account that radioactive source storage is not functional at this time. A storage facility is foreseen. As the national storage facility is not functional, usually all sources are returned to the manufacturer or supplier. Storage of disused sources at the holder's premises is possible for maximum 12 month.

The long-term management of disused HASS is solved by "take back" provisions usually incorporated into the supply contract, by a fund set by nuclear industry for orphan sources and by a fund prepaid by the holders to the competent authority.

4.23.2.10. Security measures

The competent authority is informed on the control measures implemented to prevent inadequate use etc. only during the authorisation process. There is no further information available regarding security measures.

4.23.3. Detection

4.23.3.1. Detection of orphan sources

A threat assessment regarding orphan sources was performed by the Regulatory Authority, yielding as strategic location for finding orphan sources metal scrap yards, metal scrap recycling facilities and the metallurgic industry. At these strategic locations portal and portable detection equipment is available on a compulsory basis. At borders this detection equipment is also available. Detection equipment at borders is under responsibility of the Customs Authority and the Border Police. For detection of orphan sources a portal monitor is installed at the border to Ukraine to screen railway wagons, as scrap metal is transported mainly by railway. An additional portal monitor is installed at the road border checkpoint at the border with Ukraine.

4.23.3.2. Campaign for orphan sources recovery

The regulatory framework does not ensure that campaigns are organised to recover orphan sources left behind from past activities. No such campaigns have taken place and there is a lack of budget, of competent staff and of equipment to do so. However, it is evident that organising recovery campaigns and using radiation detection equipment in strategic locations are the best methods to recover the greatest number of orphan sources. Nevertheless orphan sources have been recovered and transferred to the authorised interim storage/disposal facility. There is also a financial strategy for funding the storage of recovered sources e.g. sources in scrap metal. This is supported by the State.

Additionally an information campaign was carried out by the Regulatory Bodies at the scrap metal yards. In this campaign, information about sources, shielding containers that can be found in scrap, information about risks, methods of protection, actions how the found orphan sources are recovered and financed were provided to the employees of the scrap yards.

4.23.3.3. International cooperation and information exchanges

Slovakia is contributing to the IAEA Incident and Trafficking Database (ITDB).

4.23.4. Preparedness and Response

4.23.4.1. Emergency plans and procedures

Slovakia has no general emergency response plan in operation and there is no emergency team available as a result of missing human resources and budget. There are compulsory preparedness and response requirements for HASS holders and these have to be approved by the authority. There are no compulsory emergency preparedness and response requirements for institutions where orphan sources

are more likely to be found. There is no unique contact point designed in case of detection of an orphan source.

4.23.4.2. Training and information of persons potentially confronted with an orphan source

There is no training and no information available for personnel potentially confronted with an orphan source.

4.24. Slovenia

4.24.1. Regulatory framework with respect to HASS

4.24.1.1. Regulatory authority

There are two regulatory bodies responsible for HASS in Slovenia: the Slovenian Nuclear Safety Administration (SNSA) and the Slovenian Radiation Protection Administration (SRPA). SRPA is responsible for sources and practices in medicine and veterinary care while SNSA is responsible for sources and radiation practices other than medicine and veterinary. SNSA also carries out actions and protection measures related to orphan sources.

4.24.1.2. Legislative framework

Slovenia has fully implemented the HASS Directive into the national legal framework in beginning of 2006. The legal and regulatory regime in the country is based on the Ionising Radiation Protection and Nuclear Safety Act, as amended (Official Gazette RS, No. 102/2004, and 60/2011). Based on the Act the following decrees and rules were adopted and transpose the provisions of the HASS Directive:

- *Decree UV1 on activities involving radiation, (Official Gazette RS, No. 48/2004 and 9/2006)*
- *Rules JV2/SV2 on the use of radiation sources and on activities involving radiation, (Official Gazette RS, No.27/2006),*
- *Decree UV11 on checking the radioactivity of shipments of metal scrap (Official Gazette RS, No. 84/2007)*

The high-activity levels defined in the Slovenian regulations for HASS are those of the Annex 1 of the HASS Directive. A HASS stays covered by the HASS provisions until the activity level falls below the exemption levels. However, existing sources which would have been declared as HASS before the transposition of the HASS Directive are covered by the provisions for non-HASS.

All sources with activity levels below the high-activity levels but above the exemption levels are also regulated by the above mentioned documents. Due to relatively strict Slovenian regulatory requirements related to the use of radioactive sources, only minor amendments of existing legislation were needed for the implementation of the HASS Directive. The main differences in the requirements regarding the HASS are records, requirements for the holder and financial security for sources.

4.24.2. Prevention and Deterrence

4.24.2.1. Authorization for practice with HASS

All HASS are subject to authorisation. The compliance with transposed provisions of the HASS Directive is verified through review of prescribed documentation in the licensing process for the radiation practice and use of sources by the competent authorities. Before issuing an authorization for the use of HASS, all relevant issues are considered by the regulatory authority, including external accidents (fire, flooding, etc.), emergency procedures, long term management and financial security of the disused source. Authorization is only granted after all relevant information is received and has been judged as being adequate by the regulatory authority.

An authorization of a HASS has never been refused in Slovenia.

4.24.2.2. Records keeping and updating

All HASS holders are required to maintain records of the HASS under their responsibility. A written copy of these records is to be sent to the regulatory authority at the time of acquisition of the source through the licensing process. From then on a yearly update of these records needs to be sent through an annual report of the licensee. The regulatory authority is furthermore informed of all important modifications related to HASS (modification of the use or storage, end of use, transfer, etc.). In practice the periodical records are provided by technical support organisations, which also perform annual technical checks. Regulations do not foresee an allowable delay for providing the records to the regulatory authority. The recorded information supplied by the HASS holder is complete and is used to establish a national inventory of authorized HASS holders and the HASS they hold.

4.24.2.3. National inventory

The information received through these records is used to maintain an electronic national inventory which is covering all radiation sources. There are no HASS in the country which are not recorded in the national database or identified in the holder's records.

The register of authorized source holders is available to customs and police organizations on request.

During inspections, a systematic verification between the records in possession of the regulatory authorities and the actual situation at the licensee is performed for all HASS.

The original documentation is kept by the holder of HASS and is presented during inspection.

4.24.2.4. Inspections and penalties

Inspections are funded directly by the State and are performed by inspectors of the SNSA and SRPA at the HASS holders in respective area of their competence. The inspections deal with both safety and security aspects. There are inspections as a follow-up action in case of an incident or any other suspicious situation such as the report by TSO of incompliance. Inspectors receive training in all relevant fields, including practical experience in metrology and the necessary equipment for performing an inspection is available.

As a legal requirement, the HASS and their containers/equipment are controlled by two authorised technical support organisations (TSO) every year at the cost of holder in addition to inspection. The scope of inspections carried out by the inspectors or the TSO covers documentation, inventory, visual inspection and measurements.

In case of non-respect of regulations, a system of administrative penalties is in place. These administrative penalties depend on the type of infraction and can range up to € 250.000. The system of penalties has been used once up to now.

4.24.2.5. Control of HASS by the holder

Regular tests of HASS carried out by the holder include visual verification and dose rate measurements. The measurements are necessary for the evaluation of the radiation protection of exposed workers. The performance of the control is checked during inspection. Moreover, supervision and leak tests (contamination measurements) are performed once a year by the recognized TSO which systematically informed the regulatory authorities by sending a report.

The competent authority is informed on the control measures to prevent inadequate use, loss or theft or damage of the sources during authorization process, by regular reporting by both the holder and the recognized TSOs as well as during inspections.

4.24.2.6. Sources holder's training

The content of the training program for exposed workers and RPO is defined by the rules on the obligations of the person carrying out a radiation practice and person possessing an ionizing radiation source (SV8 - Official Gazette RS, No. 13/2004). The training is carried out by organizations recognized by the regulatory authority. Only radiation protection officers and the exposed workers are trained, not the managerial staff nor the non-exposed workers.

The training material is prepared by a recognized organization and the lecturers and the training sessions are recorded. The training is repeated every 2 or 5 years and trainees have to pass a written test. Radiation protection officer and exposed workers are trained in radiation protection principles, specific requirements of safe management of sources, possible consequences of loss, theft or inadequate use or damage of sources, and notification to the competent authorities and emergency responses in case of accident.

4.24.2.7. Identification and marking of HASS

Usually the documentation accompanying the HASS is complete and includes source identification, information and photographs of source design type, of typical source container, of transport packing and of device and equipment. To the knowledge of the regulatory authorities, there is no HASS without identification number in Slovenia. The identification number of the HASS is found in the documentation that accompanies each HASS and of which a copy is transferred to the regulatory authorities during the licensing process. The original documentation is kept by the holder of HASS but must be shown during inspection.

4.24.2.8. Transfers of HASS

The HASS can be transferred to another licensed Slovenian radiation practitioner. All transfers are notified to the competent authority. In case of transfer of HASS to the country outside of the EU, the competent authority of country of destination is notified in advance about such transfer. Before the transfer of a HASS, the holder ascertains that the recipient holds appropriate authorization by direct contact with the national authority of the recipient’s country.

No situation with a HASS lost or out of control due to unrecorded transfer has been encountered in Slovenia. The only exception is the loss of two old lightning rods (in 2010; the SNSA reported into IAEA ITDB).

4.24.2.9. Long-term management of disused HASS

The Slovenian regulatory framework defines a limited use for HASS which depends on the application and license. The holder is forced to make long term management arrangements after termination of HASS use because authorization is issued only if the long-term management route is already specified and planned and also because routine re-authorizations for the re-use of HASS are obligatory. The country’s policy on disused sources gives first priority to returning the disused source to the supplier. In the case of the disused source cannot be returned to the supplier, it shall be transferred to the Central Storage Facility for Radioactive Waste. A HASS can be also transferred to another licensed user.

Short-term storage of disused sources at the holder’s premises is authorised but for a limited period of three months.

The national centralised waste storage facility accepts disused sources and its capacity is adapted to the potential amount of disused sources.

The long term management of disused HASS is funded by the holder, via a bank guarantee or insurance policy issued during the licensing process. The state shall assure financial resources for the management of orphan sources.

Up to now no situation dealing with disused sources without any long-term management solution has occurred.

4.24.2.10. Security measures

For the HASS it is explicitly requested to provide evidence in the licensing process that security measures are assured. However, security measures are not specified in detail in the Slovenian regulations or in the licenses.

4.24.3. Detection

4.24.3.1. Detection of orphan sources

Slovenia has a good overview of all radioactive sources on its territory. In recent years efforts were made to bring sources at museums, universities and institutes under regulatory control. An overview regarding orphan sources was performed by the SNSA and its stakeholders, yielding at the identification of the strategic locations for finding orphan sources: metal scrap yards, metal recycling facilities, metallurgic industry, conventional waste management facilities, borders/customs, harbours, transit hubs, military sites and museums.

Most of these locations are equipped with portal or portable detectors. The main concern being the orphan sources in imported scrap metal shipments, all imported scrap metal shipments are subject to radiometric survey. All main smelters and scrap dealers are equipped with portal monitors and hand-held detectors. The requirements for compulsory detection equipment are laid down in the legislation. In case of discovery, orphan sources are returned to the country of origin. If the evidence about the origin is insufficient it is stored in the Central Storage Facility for Radioactive Waste.

At the other strategic locations identified, the installation of detection equipment is made on a voluntary basis.

4.24.3.2. Campaign for orphan sources recovery

The regulatory framework ensures that campaigns are organized. Such campaigns have taken place in Slovenia even if no special budget or staff is dedicated for this purpose. Organizing specific and focused actions was the most effective type of recovery campaign.

The following actions have been realized or are planned: systematic analysis of the historical records at the regulatory authority, investigation in the manufacturer's records, investigation in the former holder's records, systematic inspection of facilities, specific campaigns in universities, research centres, material testing facilities, scrap yards, metal recycling facilities, metallurgic industries and former military sites.

The state shall assure financial resources to cover the costs related to further management of source and for mitigation of eventual radiological impact caused with such source if the owner is not known.

4.24.3.3. International cooperation and information exchanges

Slovenia is actively participating in international cooperation and information exchange, mainly through the established IAEA channels. The country is contributing to the IAEA Incident and Trafficking Database (ITDB) since 1999.

4.24.4. Preparedness and Response

4.24.4.1. Emergency plans and procedures

Slovenia has a general emergency response plan in operation, also applicable to orphan sources and HASS. Procedures aimed at taking measures in case of discovery of an orphan source (elevated radiation) or mitigation of eventual emergency, are in place. The responsibilities of participating parties are clearly assigned.

An emergency team of Civil Defence with adequate equipment is available 24/7. There is a unique contact point designed in case of detection of an orphan source with a dedicated emergency call number. Its coordinates are broadcasted through SNSA website to emergency services and people of organisations likely to be confronted with orphan sources. The Slovenian emergency plan has not been initiated so far due to orphan sources or an incident with HASS.

HASS holders have to implement on-site emergency procedures which need to be approved through licensing process. On the holder's level, emergency requirements are obligatory for its own employees. However, there are no compulsory requirements for the facility operators of institutions where orphans sources are more likely to be found.

4.24.4.2. Training and information of persons potentially confronted with an orphan source

A quite extensive and adequate training is mandatory for all workers who could potentially be confronted by orphan sources. However, there is no obligatory training for the management. The training is also not mandatory for police and customs although the training is provided to them on a voluntary basis. The training sessions are documented and repeated periodically. A comprehension test is organised for the obligatory training courses, but not for stakeholders being involved voluntarily. The emergency trainings include also practical exercises using pictures of typical sources and containers, hand-held instruments and portal detectors if available at the place where the session is organised.

4.25. Spain

4.25.1. Regulatory framework with respect to HASS

4.25.1.1. Regulatory authority

The primary regulatory authority in the field of safety and security of ionising radiation sources in the country is the Consejo de Seguridad Nuclear (CSN). Its main functions related to HASS include safety assessment in the licensing process, supervision and control. These functions are not limited to HASS, but cover all ionising radiation sources. Other functions of CSN include training and information, recording, reporting and international cooperation.

Enforcement and financial aspects of orphan sources are however covered by the two other organizations involved with HASS safety and security, i.e. the Ministry of Industry, Energy & Tourism (MIET) and the regional Authorities in charge of industry. These regional authorities have activities in the fields of transferring of HASS, records keeping and enforcement (penalties). The MIET however is also involved in all regulatory activities, especially in the field of non-proliferation. The management of radioactive waste is the responsibility of ENRESA.

4.25.1.2. Legislative framework

The legislative framework in the country is based upon the Law on Nuclear Energy (Law 25/1964 of 29th April 1964) with its subsequent modifications. The legislative framework is further completed by two other laws:

- *Law creating the Nuclear Safety Council (Law 18/1980 of 22nd April, amended by Law 33/2007 of 7th November 2007) and the corresponding Royal Decree approving the Statute of the Nuclear Safety Council (Royal Decree 1440/2010 of 5th November 2010);*
- *Law governing Public Prices and Fees for Services Rendered by the Nuclear Safety Council (Law 14/1999, of 4th May 1999).*

The HASS Directive is fully implemented into the Spanish regulations. The same definition and related radiological criteria are being used for defining HASS. However, it seems that for practical implementation, the actual activity of the source is used instead of the activity at the moment of production of the source.

The main differences between HASS and non-HASS at the level of the records are the periodic testing by the holder, the identification and the labelling and at the level of the financial guarantees.

As the main difficulties encountered during the implementation of the HASS Directive, Spain reports the discrepancy that exists between the EC and IAEA source classification and the construction of the HASS inventory. However a web-based system for filling out the information is available, allowing users to upload the information into the database.

4.25.2. Prevention and Deterrence

4.25.2.1. Authorization for practice with HASS

Before issuing an authorization for the use of HASS, all relevant issues are considered by the regulatory authority, including external accidents (fire, flooding, etc.), emergency procedures and the long term management of the disused source. Authorizations for HASS have already been refused due to failure to comply with regulatory requirements.

4.25.2.2. Records keeping and updating

All HASS holders are required to maintain records of the HASS under their responsibility. A written and an electronic copy of these records are to be sent to the regulatory authority at the time of acquisition of the source. Further-on a yearly transfer of these records to the regulatory authority is required. Finally, once the holder transfers in any way the HASS, the regulatory authority is again sent a copy of the corresponding records. In general the information transferred to the authority in this way is considered to be complete. There is however no maximal delay defined in the regulations for sending the updated records.

4.25.2.3. National inventory

The information received through these records is used to maintain an electronic national inventory which is covering only HASS. Information on the other radiation sources can be found in the separate non-electronic database on licensed facilities. The national register is currently not available to law enforcement authorities (police and customs).

4.25.2.4. Inspections and penalties

During inspections, a systematic verification between the records in possession of the regulatory authority and the actual situation at the licensee is performed for all HASS. These verifications are carried out annually for all HASS. Inspections are performed by the regulatory authority (CSN) in the fields of safety and security of radiation sources, whereas the MIET is responsible for the inspections in the field of non-proliferation. As a general rule, inspections are announced to the licensee and are performed yearly. In general there are no unannounced inspections or inspections organized as part of follow-up actions after incidents or accidents. Inspections cover all relevant items for safety and security of the HASS. The inspections are funded through an annual tax linked to the authorization.

Inspectors receive training in all relevant fields, including practical experience in metrology. The necessary equipment for performing an inspection is available.

In case of non-respect of regulations, a system of administrative penalties is in place. These administrative penalties depend on a very detailed system of different types of infractions and can range from €1200 to €600,000. The system of penalties has reportedly already been used.

4.25.2.5. Control of HASS by the holder

Regular testing by the licensee of safety and security performances are required by the regulatory authority: monthly visual verification and yearly leak testing. The correct performance of these tests is verified during the inspections. The precise content of these tests for different types of sources is described in a technical guidance published by CSN.

4.25.2.6. Sources holders' training

HASS holder's staff requires a comprehensive training, of which the detailed content is defined by the holder himself. These trainings, without comprehension test, are given yearly to the radiation workers. The training records are checked by the regulatory authority during the inspections.

4.25.2.7. Identification and marking of HASS

HASS need to be systematically accompanied by the necessary documentation. This documentation contains all relevant information. As there are no HASS manufacturers in Spain, all HASS are imported. HASS arrive without a recommended working lifetime for the source.

4.25.2.8. Transfers of HASS

In case of transfer of HASS, the regulatory authority is informed of the transfer either through the request of an authorisation by the recipient of the source, either through the records of the sender and the recipient that have to be sent to CSN immediately after the transfer. If this system would fail, the transfer of the source will be discovered during the yearly inspections. In case of an international transfer, the holder transferring a HASS needs to verify that the recipient holds a valid authorization for the possession of the source. This can be done either by requesting the license from the recipient, either through direct contact with the national competent authority of the country of the recipient (compliance with EURATOM Regulation 1493/1993 and/or Guidance for the import and export of radioactive sources attached to IAEA Code of Conduct is required).

No cases where HASS got out of control during transfer are known to the regulatory authority.

4.25.2.9. Long-term management of disused HASS

With respect to the long-term management of HASS, the national regulatory framework in Spain does not define a recommended working life. The authorization process for HASS takes also into account the adequacy of the long term management of the disused sources. An authorization will only be issued if the long term management route is already specified and planned. This long term management option also needs to be covered by a financial guarantee. A list of financial instruments that can be used for setting this financial guarantee was published by CSN on its website. However, the precise amount of this financial guarantee is not precisely fixed and the physical availability of the amount is not absolutely required. The country's policy on disused sources gives priority to returning the disused source to the supplier. If this would not be possible, the disused sources should be considered for re-use in another application. Transfer to an authorized waste treatment or storage facility is only considered as last possibility. The actual situation of disused HASS shows however that a more important number of sources are transferred to the waste facility than are being reused in other applications.

Today, the long-term management of HASS is organised through take-back provisions incorporated in the supply contracts and funded through the above-mentioned financial guarantees to be foreseen by the holders of sources. Additionally, ENRESA manages a fund for waste management which can be used in very specific situations for the management of licensed sources or for orphan sources.

4.25.2.10. Security measures

A technical regulation on minimal compulsory security requirements for radioactive sources has been drafted and published in June 2013.

4.25.3. Detection

4.25.3.1. Detection of orphan sources

A threat assessment regarding orphan sources is currently being organized. Strategic locations for finding orphan sources currently considered are: metal scrap yards, metal scrap recycling facilities, metallurgical industries and harbours and airports. All of these, and additionally the conventional waste management facilities, currently have available, on a voluntary basis, portal monitors for detecting radioactive sources. Portable radiation detectors are not considered. Also at border crossings no portal monitors are available to the customs (no land borders outside of EU). The regulatory authority is not authorizing this equipment, but a national co-operation protocol between de authorities and the metal sector companies has been implemented.

4.25.3.2. Campaign for orphan sources recovery

The regulatory framework foresees the organization of recovery campaigns for orphan sources as appropriate and such campaigns have been organized. Financial resources are considered appropriate for this type of campaigns. Recovery actions so far have been based on the historic records available at the authorities, the former source manufacturers, the suppliers and the (former) licensees, and using the results of the site inspections. Specific campaigns have been organized in hospitals, medical practitioners' offices, schools and universities, research centres, material testing facilities, mines and at former military sites. Recovery campaigns are considered to be an efficient method for recovering important numbers of orphan sources. The most recent recovery campaign was organised from 2008 and lasted for 3 years.

4.25.3.3. International cooperation and information exchanges

Spain is contributing to the IAEA Incident and Trafficking Database (ITDB) since its creation.

4.25.4. Preparedness and Response

4.25.4.1. Emergency plans and procedures

Spain has an emergency response plan applicable to HASS in place. It has not been necessary to activate this plan as a result of problems with HASS or orphan sources. HASS holders also require an on-site emergency response plan, which needs to be approved by the authority. Installations in which orphan sources are more likely to be found do not require an internal emergency plan.

In case of emergencies involving HASS or orphan sources, the regulatory authority has an emergency team available to intervene 24/7. This team has full radiological intervention equipment available, except for decontamination material. This team is reached through the general emergency phone number. Emergency services and institutions likely to be confronted with orphan sources have the emergency phone number of the regulatory authority available. Up to now the national emergency plan has not been initiated in Spain in relation to situations involving HASS or orphan sources.

4.25.4.2. Training and information of persons potentially confronted with an orphan source

A quite extensive and adequate training and information plan, including practical exercises, exists for all people who could potentially be confronted to orphan sources and this for most of the cases both at the level of the workers as at the level of the management. These training sessions however do not seem to exist at the level of customs and transport personnel. These training sessions are not mandatory and are not regularly repeated. There is no comprehension test organized.

4.26. Sweden

4.26.1. Regulatory framework with respect to HASS

4.26.1.1. Regulatory authority

Regulatory control of radioactive sources is stipulated by the Radiation Protection Act (1988:220). According to this Act, the competent nuclear authority is the Swedish Radiation Safety Authority (SSM). The SSM is responsible for all the requirements of the HASS Directive except for the juridical and transposition matters which are made through SSM: the State is responsible and SSM as the competent authority has the right to issue regulations based on the Swedish Radiation Protection Act (1988:220) and ordinance (1988:293). Penalties are given in the law that is issued by the parliament. The government issues the ordinance.

4.26.1.2. Legislative framework

The HASS Directive has been transposed into the Swedish regulatory framework primarily through SSMFS 2008:9 as well as SSMFS 2008:10 and SFS 2007:193 and also through minor legislative adjustments of the Radiation Protection Act (SFS 1988:220). Additional security regulation is in progress but is closer to IAEA CoC security and safety of radioactive sources.

The definition for a high-active source (and activity levels) used in the Swedish regulatory framework is the same as the one from the HASS Directive. A HASS falling below the defined high-activity levels is still covered by the law for HASS in accordance with the Directive, until exemption. A source is released from regulatory control when its activity level is below the national clearance levels.

The fundamental regulations for any radioactive sources are in the Radiation Protection Act (1988:220) and Ordinance (1988:293) and in addition in SSMFS regulations (and sometimes also in licence specific requirements). For non-HASS, licences are issued for holding an activity above the exemption level of EU-BSS.

Before the transposition of the HASS Directive, all sources were regulated but with lower/other requirements. The main differences between the old version and amended one are to be found in records keeping, requirements for holders, identification and marking, training and information, orphan sources, financial security for orphan sources and international cooperation and information exchange.

A source whose activity would have defined it as a HASS but whose activity had fallen down below the high-activity levels when the HASS Directive was transposed is covered by the law for non-HASS.

4.26.2. Prevention and Deterrence

4.26.2.1. Authorization for practice with HASS

Before issuing an authorisation for the use of a HASS, all relevant items are considered by the Regulatory Authority. Until now, the SSM has never refused an authorisation for use of a HASS.

4.26.2.2. Records keeping and updating

Each HASS Holder has the obligation to keep records of all HASS (and all radioactive material) under its responsibility. According to the legislation, the holder has to provide the SSM with the recorded information at the acquisition time, annually, when the holder no longer holds or uses the source and when conditions specified in a record sheet have changed, within one week. However the practical handling routine delay is about 1 month.

The information is transferred both electronically and through hard copy.

SSM keeps an electronic database of all authorized HASS holders and sources including all information requested in the standard record sheet given in Annex II of the HASS Directive. The non-HASS are recorded in the same database. Thus the information of all sources is gathered in one database.

4.26.2.3. National inventory

According to SSM all HASS are required to be registered in the national database. Due to other reasons however some HASS may unintentionally escape registration.

The register of authorized sources holders and of HASS is available to customs organisations and to police only on request.

4.26.2.4. Inspections and penalties

During inspections, the authority (SSM) has access to the holder's records. The match between these records and the actual situation of the HASS is checked. During an inspection, the HASS records vs. actual situation are thus either comprehensively (for each HASS) or partially (on a certain number of sources) verified according to the inspection planning of the authority.

Inspection looks at safety (and security) fields. Non-proliferation is restricted to fissile material/nuclide in accordance with regulations for non-proliferation. Inspections are announced to the licensee and realized according to annual inspections planning but due to limited resources without a regular frequency. Inspections are also held as follow-up action in case of incident or any other suspicious situation. Inspection scope covers documentation, inventory, organization, competence check and visual inspection of HASS and their environment. No measurements are realized and the security measures are not considered. There is an annual fee for all licensees that should cover all the costs for the competent authority.

Safety inspectors are trained for visual detection of sources and containers, safe management of sources and procedures for prompt notification and emergency response. Actual training is on-the-job led by experienced inspectors, but formal training should be available soon. The focus of inspections is to check the conformance with applicable regulations. No measurements are made by the inspectors.

Penalties are foreseen in case of violation of the regulations. It is up to a court to decide about the type and range of penalties based on the interpretation of the law.

4.26.2.5. Control of HASS by the holder

Tests carried out by the holder to ensure the good conditions of each HASS are visual verification and leak tests (no dose rate measurement) carried out annually. Leak tests may be carried out by competent contractors. The results of the tests are communicated to the competent authority. The licensee must report to the authority in accordance with regulations (i.e. through the standard record sheet).

The security measures required in regulations are examined during inspections and through regular reporting by the holder.

4.26.2.6. Sources holders' training

The legislation stipulates that the holder shall conduct regular training of the personnel involved in the practice using the source. Such training shall in particular encompass locally established rules for safe handling of the source and potential consequences should the source be lost or damaged. Completed training shall be documented.

The content of training is the responsibility of and defined by the holder. The authority sets the regulations but no detailed instructions are given within. It is up to the holder to follow the regulations and ask for guidance if needed. The holder may engage a third party to prepare and give the training. Only exposed workers are trained on radiation protection principles, specific requirement for safe management of sources, prompt notification to competent authorities and emergency procedures and rules for potential consequences in case of loss or damage.

The frequency is decided by the holder and usually depends on personnel turnover and holder's judgment. The trainings are not recorded and no requirement is made for a comprehension test.

4.26.2.7. Identification and marking of HASS

According to the legislation, HASS should be systematically accompanied by the relevant documentation. When new sources are taken into the country by a licensed trading company all the documentation are actually present. A significant number of HASS holders have sources manufactured before the HASS regulations that may be less complete in documentation.

There is no more HASS manufacturer in the country. For imported HASS some producers recommended a working life (usually about 10 years with possible repeated extensions).

There are cases of HASS without identification or information on its nature in the country. These are older sources which may not have ID numbers.

4.26.2.8. Transfers of HASS

In accordance with regulations and Euratom 1493/93, the regulatory authority is informed of the transfer because a license needs to be requested by the recipient of the source and because the holder needs to have a permit for the transfer and transport. The records of the holder also show indication of the transfer.

The holder transferring a HASS has to check that the recipient holds a valid authorization for the possession of the source.

No cases where HASS go out of control during transfer are known to the regulatory authority.

4.26.2.9. Long-term management of disused HASS

Concerning the long-term management of HASS, no limited working life is defined in the national regulatory framework. If the producer sets a working limit, it can be used as an indirect limit during the licensing process. An authorization is only granted if the long-term management route is already specified and planned.

The country's policy on disused sources gives priority to returning the disused source to the supplier. The next preferred option is the transfer of the source for re-use. If this would not be possible, the source should be considered as radioactive waste and be transferred to an authorized waste treatment or storage facility. Disused sources can also be stored at the holder's premises for a period of maximum 6 months. Individual prolongation set by the authority is also an option (e.g. for universities that cannot find any receiver for their sources).

Cases of disused sources (not only HASS) without long-term management solution are known to the authority. Also cases without any financial solution have been solved by transfer to another user.

A national authorized storage facility for radioactive waste is available in the country and is managed by a private company. It doesn't accept all type of sources/HASS. Its capacity is considered adapted to the potential amount of disused sources on a commercial national basis.

Currently the long-term management of disused HASS is funded through a fund set by the holder (bank guarantee or equivalent).

4.26.2.10. Security measures

Currently, the security requirement for installations where HASS are present is locked premises and lock on the source (also at the working site temporary storage in case of mobile use such as industrial radiography). Security regulations are in progress.

4.26.3. Detection

4.26.3.1. Detection of orphan sources

No comprehensive risk/threat assessment regarding orphan sources has been performed by the regulatory authority but this issue is currently in discussion. Strategic locations identified on indication or information are: metal scrap yards, metal scrap recycling facilities, conventional waste management facilities, borders/customs, harbours, transit hubs and airports.

Detection equipment at some strategic location for finding sources is present on voluntary basis encouraged through information to scrap dealers, smelter industry, customs and first responders on the possibility of such sources and through promoting the importance of detection and actions to take if detected. The producer's responsibility for orphan sources is described in Ordinance SFS 2007:193. The used equipment has not to be authorized by the competent authority. In that context, portals are present in metal scrap yards and metal recycling plants, the last place being also equipped with portable equipment. Portable equipment is also present in conventional waste management facilities and harbours. There is no monitoring equipment at the borders.

4.26.3.2. Campaign for orphan sources recovery

No recovery campaign has been organized in the country but discussions are ongoing. The private sector will probably become involved through technical contribution. No specific budget is dedicated for this topic but there is some money available to pay for discovered sources handled by the authority.

4.26.3.3. International cooperation and information exchanges

Sweden is participating in international cooperation and information exchange mainly through the established IAEA channels. The country is contributing to the IAEA Incident and Trafficking Database (ITDB).

4.26.4. Preparedness and Response

4.26.4.1. Emergency plans and procedures

Sweden has a national radiological emergency response plan dedicated to orphan sources or HASS. The emergency organisation for nuclear accident also handles other radiological events that falls outside the ordinary authority organisation. The nuclear emergency team has all adequate material except shielded containers and decontamination material. The team can be reached through the general emergency call number (112) or directly by phoning to SSM.

The HASS holders are required to report events with HASS but are not required to have emergency preparedness and response plans in any more explicit meaning. Similarly there is no requirement for institutions where orphan sources are likely to be found.

4.26.4.2. Training and information of persons potentially confronted with an orphan source

Training of personnel at the licensee is required but not for other persons potentially confronted with an orphan source. Rescue services and similar personnel may have training through other channels but not based on Radiation Safety Authority regulations.

4.27. United Kingdom

4.27.1. Regulatory framework with respect to HASS

4.27.1.1. Regulatory authority

The controls over HASS are principally the concern of the environmental regulators in the UK, who also maintain the UK's national inventory of HASS. Permits are issued and enforced by the relevant environmental regulator within the UK:

- Environment Agency (EA) for undertakings in England and Wales;
- Scottish Environment Protection Agency (SEPA) in Scotland;
- Northern Ireland Environment Agency (NIEA) in Northern Ireland.

The HASS Directive requirements were transposed through environmental legislation in the UK. The Health and Safety Executive (HSE), which is responsible for safety in the workplace throughout UK, also has an interest in the control of HASS, as undertakings using HASS also need to comply with requirements set out in the Ionising Radiations Regulations 1999 (mainly relating to worker safety and the prevention of accidents). On nuclear sites, the holding of sealed sources/waste sealed sources is regulated under the Nuclear Installations Act 1965, and enforced by the Office for Nuclear Regulation (ONR). The ONR is the nuclear safety regulator for the civil nuclear industry in the UK, and is an agency of the HSE.

4.27.1.2. Legislative framework

In the UK, legislation has been in place to regulate the use of radioactive substances and the disposal of radioactive waste since 1948, with major revisions in 1960, 1993 and 2011. The principal piece of legislation dealing with nuclear installations (licensing, controlling the nuclear plants, liability for nuclear damage) is the Nuclear Installations Act 1965, and amendment.

Council Directive 2003/122/Euratom was fully transposed into UK legislation through the High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005 (Statutory Instrument 2005 N°2686), which came into force on the 20th October 2005. These regulations remain in force in Scotland and Northern Ireland. England and Wales incorporated the control of HASS provisions in the Environmental Permitting Regulations (EPR) 2010, which were subsequently amended by the Environmental Permitting Regulations 2011, which came into force on 1st October 2011. The authorisations issued for HASS in the UK include conditions to cover the requirements of the HASS Directive, in addition to those of the Basic Safety Standards Directive (BSSD).

The main Laws and Regulations related to the protection of people and the environment in relation to radioactive sources are:

- Radioactive Substances Act 1993 in Scotland and Northern Ireland,
- High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005, now included in (1) and (3),
- Environmental Permitting Regulations 2010, and

- Ionising Radiations Regulations 1999.

The regulatory framework uses the definition of the HASS Directive for High Activity Sealed Source. A HASS stays covered by this law until decay to the European BSSD exemption values (Directive 96/29/Euratom). Sources purchased with activity levels below the HASS threshold are controlled by the general requirements of the Environmental Permitting Regulations 2010 in England and Wales and the Radioactive Substance Act 1993 in Scotland and Northern Ireland. The main additional controls applied to HASS are the requirements related to authorisation (article 3§2 adequate arrangements and financial provision for management of disused source), transfers (article 4), orphan sources (article 9), financial security of orphan sources (article 10), international cooperation and information exchanges (article 11) and report on experience (article 14).

4.27.2. Prevention and Deterrence

4.27.2.1. Authorization for a practice involving HASS

Before issuing an authorisation (permit) for the use of a HASS, the authorities ensure that all arrangement and provisions of Article 3 “Authorisation” of the Directive are met. In broad terms the conditions are based on suitable arrangements in the management system for: resources (including sufficient competent and trained persons); sources which become disused or are transferred; the maintenance of the security and integrity of sealed sources (checked by suitable tests) and finally record-keeping.

Permits have been refused for use of a HASS because the holder had no ability to provide financial provision for the disused source.

4.27.2.2. Records keeping and updating

The authorisation/permit requires HASS holders to keep records of the sources, and provide the recorded information to the authority, at the time of acquisition, annually (by the end of January), when the holder transfers the source and at the disposal of the source.

The regulator must be informed within 14 days, and this is generally respected. The information is transferred through written copy. Checks are made during annual inspections.

4.27.2.3. National inventory

The complete information of the standard record sheet is recorded in a secure electronic database. This national inventory is considered as complete. The database was established specifically to meet the HASS Directive requirement, and tracks the transfers of all HASS from acquisition to disposal, but it was not designed to produce a total inventory or summary reports by sector. The total number of HASS changes daily and the total number of HASS at any given time is not calculated or reported.

This inventory is available, by country, for inspection by competent authorities, and would be communicated on request to Police and customs organization. Authorities check the match of recorded information and actual situation during inspection for each HASS site at least every 12 months.

4.27.2.4. Inspections and penalties

Environment Agency SEPA and NIEA inspectors carry out annual inspections on each HASS site, and as follow-up action in case of incident or in any other suspicious situation. Inspections are funded by annual charges linked to the authorisation.

The scope of these inspections includes safety and security aspects such as documentation, inventory, visual inspection of the HASS and their environment and security measures. Inspectors verify the regular performance of suitable leak tests by the holder. They do not control the potential contamination or dose rate of the equipment.

The training of the inspectors carrying out such inspections includes practical experience in radiation protection, safety precautions, the visual recognition of sources and containers and the specific requirements for their safe management, possible consequences of loss, theft or inappropriate use of sources and procedures/responses to be followed in case of emergency situation.

Enforcement and prosecution policies are published by the environmental regulators, and national legislation identifies offences and maximum penalties ranging from fines to two to five year imprisonment).

There have so far not been any prosecutions in the UK in relation to HASS offences.

4.27.2.5. Control of HASS by the holder

Leak tests are carried out by, or on behalf of, the holder at a frequency no longer than two years. Frequency of visual inspection is not defined. It depends on the use and the location of the source, but some verification of whereabouts will be expected during the annual inspection. The competent authority is informed on the control measures to prevent any incident involving the HASS during the authorisation process, and these measures are checked during inspections.

4.27.2.6. Sources holders' training

The training of the HASS holder's staff is defined by the holder (programme, categories of trained workers, material, frequency, organization, records and tests) in consultation with qualified expert approved by the authority. The competent authority checks the training records during inspection.

The UK has established a system of recognised "Radioactive Waste Advisers" (RWAs) who are approved against a set level of experience and training. RWAs are appointed by the holders.

4.27.2.7. Identification and marking of HASS

The documentation accompanying the HASS is generally complete including the source identification (on the source and on the container) and all relevant information concerning the source design, the container, the transport packaging and the associated device or equipment.

The correct identification and marking of the HASS is not currently directly verified by the regulators, reliance is placed on the manufacturer's QA system and the documentation provided. However, the Environment Agency has published guidance entitled "How to comply with your EPR RSR environmental permit – sealed sources", which states: "No HASS manufactured after 31 December 2005 shall be brought onto the premises unless all the information concerning identification and marking of the source and container are provided".

4.27.2.8. Transfers of HASS

Before the transfer of any HASS the holder shall prepare and provide to the recipient written information indicating identification number, how it is marked, details of its radioactive content, and, where appropriate, the identification number of the source container. The holder transferring a HASS must ask for a copy of the recipient's authorisation before transfer, this is to ensure that the recipient is entitled to receive HASS sources. The recipient must have an authorisation from the competent authority. It is an offence to receive HASS without the appropriate permit.

The regulator is informed of individual transfers of HASS from the records of the holder. Where a source is transferred to a nuclear site licensee for long-term storage or final disposal, a receipt shall be obtained from the recipient and a copy provided to the authority as soon as reasonably practicable.

There has been no case of a source lost or out of control due to unrecorded transfer; however, there has recently been a case of theft of a HASS from an authorised courier's vehicle.

4.27.2.9. Long-term management of disused HASS

Some suppliers provide Recommended Working Live (RWL) but this information is not an element of the national regulatory framework.

Where suppliers specify Recommended Working Life, a review of continued use of the source is carried out at the end of the RWL. The holder should take appropriate steps to confirm the integrity of the source capsule and plan for the replacement and disposal of the source. This RWL information is used by regulators as part of the “leverage” to get sources disposed of promptly. It is for the user to justify the continued use of a source beyond its RWL.

The disposal arrangements for each category of HASS must be specified and planned before the authorization or delivery of a HASS. The HASS holder must have either a “take-back” agreement incorporated into the supply contract, or make financial provision for the long-term management/disposal of the source. The UK has accepted take-back agreements in source supply contracts as a suitable mechanism for end of life management of certain categories of sources.

For HASS, the UK has established a panel of experts so called the HASS Financial Provision Panel to approve proposed mechanisms for financial provision for HASS disposal. This HASS Financial Provision Panel checks that arrangements are robust to insolvency of the applicant. If the financial provision is needed due to insolvency, the funds are managed by the regulator.

The options for long-term management of a disused source are, by order of preference: re-use by another authorized holder; return to supplier; and finally collection as waste. In practise, re-use is not always attainable.

HASS of significant half-life that are not re-used or returned to the supplier are eventually transferred after packaging/conditioning/intermediate-storage to the UK's principal store for intermediate level waste at Sellafield. Waste HASS are a very minor addition to the waste from the nuclear sector, no special adaption is required. Though storage capacity is not an issue, access to shielded facilities to unload sources can be a restriction at time. Eventually waste HASS in long-term storage at Sellafield will be disposed of in the proposed national repository.

4.27.2.10. Security measures

Security requirements are based on IAEA source categories. Additional security measures are also required including a security plan, ability to upgrade security for increased threat, information security plan and personnel background checks.

4.27.3. Detection

4.27.3.1. Detection of orphan sources

In the UK the threat is principally related to national security and counter-terrorism, and the strategic locations for this are ports, airports and other access points. This is a Government funded program. Detection equipment at UK borders is managed by an agency of government.

A secondary threat relates to orphan sources in the metals recycling industry, here the threat is managed by the companies involved and is a matter of commercial risk management rather than national strategy. Metal industries are equipped with detection equipment on a voluntary basis.

4.27.3.2. Campaign for orphan sources recovery

There is no regulatory framework for orphan source collection campaigns. Nevertheless, a Government funded programme of subsidized disposal "Surplus Source Disposal Programme" dealt with most of the UK's legacy of disused sources, including a small number of orphan sources. The first

campaign largely targeted public sector organizations more than 11,000 surplus sources were collected and disposed of at a cost of £7.14 million. The main difficulty during the campaign was the availability of shielded facilities for sorting, conditioning and packaging sources for long-term storage. Recycling/re-use would be the preferred option, but it is seldom applicable to genuine orphan sources.

Collection, packaging, transport, recycling/disposal was achieved through specialist private sector companies paid for by government funded subsidies and holder contributions.

As sources held in universities, hospitals and industries are considered under management and regulatory control, a second recovery campaign is planned which will target scrap yards. The objective is to retrieve orphan sources in use before the transposition of the HASS Directive.

4.27.3.3. International cooperation and information exchanges

UK participates in the Incident and Trafficking Database of IAEA.

4.27.4. Preparedness and Response

4.27.4.1. Emergency plans and procedures

HASS holders must prepare an emergency response plan which is reviewed at periodic inspections, improvements may be required but there is no formal approval process. Such emergency plan is not required for the facility where orphan sources are more likely to be found.

For more than 30 years, the "National Arrangements for Incidents involving Radioactivity" (NAIR) is invoked in relation to genuine orphan sources found in public places or unauthorized premises. NAIR relies on nuclear site and hospital radiation specialists to respond at the scene of an orphan source. The NAIR has been triggered many times over the last 30 years for orphan sources but there is no record of recent NAIR response to an incident involving HASS. The NAIR scheme does not apply to Northern Ireland, but equivalent arrangements are in place there.

The emergency services often contact the relevant environment agency's duty specialist for advice which operates a 24/7 on call roster for such cases.

4.27.4.2. Training and information of persons potentially confronted with an orphan source

Training and information of personnel potentially confronted with an orphan source is not required under UK environmental law, but may be considered necessary under the Health & Safety at Work Act 1974, if a risk assessment identifies this to be a foreseeable occupational risk. Scope of training, periodical review, categories of personnel trained and organization of the training is specified by the employer. Requirements vary.

5. LOSS OF HASS CONTROL INCIDENTS IN EUROPE

Despite the control measures implemented under the Directive there have been a few incidents in the European Union where control of a registered HASS has been lost or an unregistered HASS has been found. Very few of these (perhaps 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.

From the data provided by the Member States, it can be concluded that the discovery of radioactive sources or contaminated items in scrap metal is by far the most frequent incident encountered, occurring at scrap metal facilities and also at national borders. The second most frequent event reported by the responding EU States is the discovery of orphan sources. Orphan sources have been discovered at public places, municipal dumps and during the take-over of facilities or on the premises of bankrupt companies.

6. DEVELOPMENT OF HASS REGULATIONS IN THE EU

6.1. Directive 2003/122/EURATOM requirements as a part of the new EU Basic Safety Standards Directive 2013/59/EURATOM

The new EU Basic Safety Standards Directive (BSS) [6] was adopted at the end of 2013. In addition to updating the current BSS Directive [1] the new Directive incorporates and updates requirements of five other existing Directives, including the HASS Directive. It also takes into account the latest ICRP[2] guidance and the new International Basic Safety Standards drafted by the IAEA. The old Directives have been repealed and the EU Member States have four years to enact the new Directive in their national legislations, i.e. until 6 February 2018.

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

6.2. Regulatory harmonisation with the IAEA

When the HASS Directive was written the activity values defined for the IAEA regulations for the safe transport of radioactive materials (A-values/100) [7] were selected as the basis for the HASS definition. Later on the IAEA developed the D-values (dangerous quantity of radioactive material) [4] 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) [8]. The new EU BSS removes this discrepancy by adopting the IAEA D-values as a basis for the HASS definition. This means that 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 definitions at international level is a problematic situation. The HASS Directive and the IAEA CoC on sources 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 are 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 D-values is sound and to a certain degree supported by actual doses in real source accidents.

The 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).

Table I presents a comparison of the old and new HASS activity limits. For most nuclides the new definition is indeed a relaxation of requirements, since the D-values are higher than the HASS Directive values (ratio (A_1/100)/D < 1). However, in practice, most of the registered HASS sources have activities much higher than the D-value so the group of sources falling between the old and new definition (i.e. the sources which can be removed from the HASS registers after transposition of the new BSS) is actually quite small.

For a few nuclides the D-value is lower that the HASS Directive value (Am-241, Cm-244, Pu-238 and Po-201). For these nuclides the activity level harmonisation means stricter control requirements, although the differences between the old and new values are hardly significant in practical operation of the HASS registers.

[2] International Commission on Radiological Protection

Nuclide	HASS-Directive (A_1-value/100) TBq	New BSS (D-value) TBq	Ratio (A_1/100)/D
Am-241	1.0E-01	6.0E-02	**1.667**
Cf-252	5.0E-04[3]	2.0E-02	0.025
Cm-244	2.0E-01	5.0E-02	**4.000**
Co-60	4.0E-03	3.0E-02	0.133
Cs-137	2.0E-02	1.0E-01	0.200
Gd-153	1.0E-01	1.0E+00	0.100
I-125	2.0E-01	2.0E-01	1.000
Ir-192	1.0E-02	8.0E-02	0.125
Kr-85	1.0E-01	3.0E+01	0.003
Pm-147	4.0E-01	4.0E+01	0.010
Pu-238	1.0E-01	6.0E-02	**1.667**
Ra-226	2.0E-03	4.0E-02	0.050
Se-75	3.0E-02	2.0E-01	0.150
Sr-90 (Y-90)	3.0E-03	1.0E+00	0.003
Tm-170	3.0E-02	2.0E+01	0.002
Yb-169	4.0E-02	3.0E-01	0.133
Au-198	1.0E-02	2.0E-01	0.050
Cd-109	3.0E-01	2.0E+01	0.015
Co-57	1.0E-01	7.0E-01	0.143
Fe-55	4.0E-01	8.0E+02	0.001
Ge-68	5.0E-03	7.0E-01	0.007
Ni-63	4.0E-01	6.0E+01	0.007
Pd-103	4.0E-01	9.0E+01	0.004
Po-210	4.0E-01	6.0E-02	**6.667**
Ru-106	2.0E-03	3.0E-01	0.007
Tl-204	1.0E-01	2.0E+01	0.005

Table I. Numerical comparison of the activity limits of the HASS Directive and the proposed new EU Basic Safety Standards

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.

[3] According to the 2009 revision of the Regulations for the Safe Transport of Radioactive Material, No.TS-R-1, the A_1- value of Cf-252 is 1.0E-01 TBq, so the HASS Directive value should be 1.0E-03 TBq.

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

6.3. 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 the following:

- Definitions for sealed sources and source containers have been slightly modified.
- 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 included in the Directive Annex XIV has been improved by updating layout and terminology[4,5]. This sheet provides the information required for each HASS in the national register. Optional information is marked with Italics.
- 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 the extent possible, 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.

7. CONCLUSIONS

HASS Directive principles have been implemented well in the EU, although there are significant differences in implementation practices among the EU Member States. The low number of HASS-related inquiries to the Commission over the years indicates that the Directive requirements are well understood and accepted.

The authorities of the EU Member States recommend the following in order to keep radioactive sources under control and to safely manage incidents:

- systems for ensuring traceability of radioactive sources throughout their life cycle,

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[4] In accordance with Article 5 of the HASS Directive, the Commission has made the standard record sheet available in electronic format (Excel and Pdf) at http://ec.europa.eu/energy/nuclear/radiation_protection/radioactive_sources_en.htm.

[5] Section *'Special form certificate*' has been replaced with '*IAEA source category*' and a new section on neutron sources has been added.

- regular inspections,
- requirements of physical protection in high-risk facilities,
- compulsory training of the personnel,
- controls to detect radioactive materials in strategic locations,
- exchange of information among the national and international competent authorities,
- public information,
- testing of pre-established plans for prevention of and response to incidents involving HASS.

Directive 2003/122/Euratom is repealed, with effect from 6 February 2018, 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. The new EU BSS 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 EU Member States have until 6 February 2018 to transpose the new BSS Directive into their national legislation. The Commission encourages each Member State to take into account the content of this review when redrafting the national regulations and guidance on safety and security of radioactive sources.

References

[1] 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].

[2] 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].

[3] 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].

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

[5] Communication from the Commission to the European Parliament and the Council of 24 June 2009 on Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union – an EU CBRN Action Plan, 2009.

[6] 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 L13/1 of 17.1.2014].

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

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