Study on the current status of radioactive sources in the EU, on the origin and consequences of loss of control over radioactive sources and on successful strategies concerning the detection and recovery of orphan sources
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Directive 2003/122/EURATOM (HASS Directive) requires European Union Member States to establish a system for ensuring the safety and security of high-activity sealed radioactive sources. These sources need to be subject to a strict supervision from the moment they are manufactured to the moment they are placed in a recognised installation for long-term storage or final disposal. In addition, the Directive requires Member States to make arrangements for recovering orphan radioactive sources and for dealing with situations in which orphan sources are unexpectedly encountered. These requirements are in line with the international guidance provided by the IAEA.

According to Article 14 of the HASS Directive, Member States were required to report before the end of 2010 on the experience gained during the implementation of the Directive. This study was initiated within the framework of the EU CBRN Action Plan implementation. Based on an all-hazard approach, the Action Plan’s overall goal is to reduce the threat of, and damage from CBRN incidents of accidental, natural and intentional origin, including terrorist acts. The purpose of the study was to review the HASS Directive implementation feedback and to complement the Member States’ reports by independent assessments of the current status of radioactive sources in each EU Member State. The study also provides an overview of the corresponding regulations in Canada and the United States and reviews cases in Europe in which control over sources has been lost. In addition the study outlines current best practises in the EU Member States and presents the positions of the source manufacturing industry.

In 2018 the HASS Directive will be repealed and replaced by the corresponding provisions in the new EU Basic Safety Standards Directive 2013/59/EURATOM. Despite this change the basic HASS safety and security control requirements in the EU will remain and their importance will grow as the number of high-activity radioactive sources used in industry, medicine and research increases. The Commission has published this study in order to facilitate a constant improvement in source control measures in Europe and to outline those areas where improvements are needed, not only within the EU but also in a wider international context.

Ivo Alehno
Head of Radiation Protection Unit
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<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>CBRN</td>
<td>Chemical Biological Radiological Nuclear</td>
</tr>
<tr>
<td>CEDO</td>
<td>Certified Exposure Device Operator</td>
</tr>
<tr>
<td>CNSC</td>
<td>Canadian Nuclear Safety Commission</td>
</tr>
<tr>
<td>DG ENER</td>
<td>Directorate-General Energy of the European Commission</td>
</tr>
<tr>
<td>DG HOME</td>
<td>Directorate-General Home Affairs of the European Commission</td>
</tr>
<tr>
<td>HASS</td>
<td>High-Activity Sealed Source</td>
</tr>
<tr>
<td>HRS</td>
<td>High Risk Source</td>
</tr>
<tr>
<td>IAEA</td>
<td>International Atomic Energy Agency</td>
</tr>
<tr>
<td>ISSPA</td>
<td>International Source Suppliers and Producers Association</td>
</tr>
<tr>
<td>MS</td>
<td>European Union Member State</td>
</tr>
<tr>
<td>NNSA</td>
<td>National Nuclear Security Administration (USA)</td>
</tr>
<tr>
<td>NRC</td>
<td>Nuclear Regulatory Authority (USA)</td>
</tr>
<tr>
<td>NSSR</td>
<td>National Sealed Source Registry (CAN)</td>
</tr>
<tr>
<td>NSTS</td>
<td>National Sources Tracking System (USA)</td>
</tr>
<tr>
<td>RPO</td>
<td>Radiation Protection Officer</td>
</tr>
<tr>
<td>SSTS</td>
<td>Sealed Source Tracking System (CAN)</td>
</tr>
<tr>
<td>TSO</td>
<td>Technical Support Organisation</td>
</tr>
</tbody>
</table>
The study project, "Study on the current status of radioactive sources in the EU, on the origin and the consequences of the loss of control over radioactive sources and on successful strategies concerning the detection and recovery of orphan sources", was launched by the European Commission in order to provide an overview of the situation in the EU Member States (MS) on (1) the control over high-activity sources in use, (2) the management of disused sources and (3) strategies for handling orphan sources. The project was part of the EU CBRN Action Plan implementation. Based on an all-hazard approach, the Action Plan's overall goal is to reduce the threat of and damage from CBRN incidents of accidental, natural and intentional origin, including terrorist acts. The project reviews the current status of the implementation of the EU Council Directive 2003/122/Euratom (HASS Directive) in the 27 MS. According to the data reported by 25 EU Member States, it concerns the management of about 31,000 HASS, of which 50% is represented by only Germany and France.

To assess the implementation status, compliance of the current situation prevailing in each MS 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 major weak area in implementation is the organization of orphan source recovery campaigns, which have been implemented in only about 50% of the MS.

The analysis of the level of implementation of the HASS requirements in the 27 MS 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 financed by the holders or suppliers, the identification of strategic location 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.

The position of the industry regarding the HASS Directive requirements is also reported. With regard to the analysis of incidents in Europe resulting from a loss of control over radioactive sources, very few incidents have involved harmful 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.

From a comparison with the legal framework regulating the management of HASS and disused sources in Canada and USA, it appears that the European legislation is at least as well developed as the US/Canadian ones. Several good practices in force in Canada and the USA could advantageously be transposed at the European level although the opposite is also true.
1 INTRODUCTION

The general objective of this particular study was to evaluate the risk of the use of high-risk radioactive sources by criminals and terrorists and/or their loss of control with potential damage for population and environment. The study focused on the current status of the High-Activity Sealed Sources (HASS) Directive (2003/122/Euratom) implementation in the 27 Member States (MS). It aimed on the one hand at identifying the difficulties encountered by MS as well as the best practices and on the other hand at proposing solutions to improve the implementation of the HASS Directive.

The approach focussed on the situation and trends prevailing in each MS concerning legal aspects, best practices and existing gaps in managing sources in use, disused sources and in recovering orphan sources with regard to the requirements of the HASS Directive.

In addition to the regulatory framework, the study and the results have been structured and reported according to the three following basic security functions:

- Prevention and deterrence
- Detection to prevent incidents
- Preparedness and response to incidents

For each security function, the compliance with and the level of implementation of the HASS Directive was analysed in each MS. Moreover, a comparison at the European level was performed to provide a general overview of the status of the HASS Directive implementation.

The study addressed the following sources:

- **HASS in use and disused** as defined by the High-Activity Sealed Sources (HASS) Directive (almost corresponding to IAEA Category 1, 2 and 3 as described in the IAEA Code of Conduct on Safety and Security of Radioactive Sources) and used in industry, medicine and R&D

- **Orphan sources** as defined by the HASS Directive regardless of their activity level.
2 PROJECT METHODOLOGY

2.1 Situation of EU Member States regarding the HASS Directive implementation

The first essential task was the collection of information from the 27 MS. This was realized through the elaboration and distribution to the national contact points of a quite extensive questionnaire. Phone calls and reminder emails were used to keep the motivation of stakeholders high and to ensure a high level of return of filled questionnaires.

The selection of the MS to be visited was mainly based on the evaluation of the management systems and strategies. Countries that are facing some difficulties or have interesting solutions and well established procedures resulting from the implementation of the HASS Directive, or that differ from other MS in a positive or negative way, or that have specific relevant experience (e.g. due to the previous occurrence of incident(s)) were selected to be first and foremost visited. The list of countries to be visited was proposed for approval by the EC. The selection included larger Member States, small countries and also new Member States. In total, eighteen MS were selected. Upon EC approval of the list, the fact-finding missions have been organized in selected MS to meet the relevant stakeholders and to deepen the preliminary analysis and complete likely missing information.

The following table presents the countries which have been visited.

<table>
<thead>
<tr>
<th>#</th>
<th>Country</th>
<th>Date of visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Austria</td>
<td>10.01.2013</td>
</tr>
<tr>
<td>2</td>
<td>Belgium</td>
<td>09.04.2013</td>
</tr>
<tr>
<td>3</td>
<td>Bulgaria</td>
<td>17.01.2013</td>
</tr>
<tr>
<td>4</td>
<td>Cyprus</td>
<td>no mission</td>
</tr>
<tr>
<td>5</td>
<td>Czech Republic</td>
<td>06.02.2013</td>
</tr>
<tr>
<td>6</td>
<td>Denmark</td>
<td>no mission</td>
</tr>
<tr>
<td>7</td>
<td>Estonia</td>
<td>no mission</td>
</tr>
<tr>
<td>8</td>
<td>Finland</td>
<td>29.01.2013</td>
</tr>
<tr>
<td>10</td>
<td>Germany</td>
<td>24.01.2013</td>
</tr>
<tr>
<td>11</td>
<td>Greece</td>
<td>no mission</td>
</tr>
<tr>
<td>13</td>
<td>Ireland</td>
<td>no mission</td>
</tr>
<tr>
<td>14</td>
<td>Italia</td>
<td>31.01.2013</td>
</tr>
<tr>
<td>15</td>
<td>Latvia</td>
<td>21-23.11.2012</td>
</tr>
<tr>
<td>16</td>
<td>Lithuania</td>
<td>21.01.2013</td>
</tr>
<tr>
<td>18</td>
<td>Malta</td>
<td>14-16.01.2013</td>
</tr>
<tr>
<td>19</td>
<td>Poland</td>
<td>12.03.2013</td>
</tr>
<tr>
<td>20</td>
<td>Portugal</td>
<td>no mission</td>
</tr>
<tr>
<td>21</td>
<td>Romania</td>
<td>28.01.2013</td>
</tr>
<tr>
<td>22</td>
<td>Slovakia</td>
<td>no mission</td>
</tr>
<tr>
<td>23</td>
<td>Slovenia</td>
<td>10.12.2013</td>
</tr>
<tr>
<td>24</td>
<td>Spain</td>
<td>9-10.01.2013</td>
</tr>
<tr>
<td>25</td>
<td>Sweden</td>
<td>no mission</td>
</tr>
<tr>
<td>26</td>
<td>The Netherlands</td>
<td>28-29.01.2013</td>
</tr>
<tr>
<td>27</td>
<td>United Kingdom</td>
<td>no mission</td>
</tr>
</tbody>
</table>
The collected information (through the questionnaires, emails, phone calls and missions) was compiled into 27 country reports, presenting the situation in each country.

Each country report describes the:

- Status of HASS Directive implementation
- Inventory of HASS
- Management system once radioactive sources are disused (long-term storage, take-back provisions, financial security)
- Security requirements
- Overview of existing recovery program and detection means
- Emergency preparedness and response
- List of incidents, causes and consequences, countermeasures

The main steps performed to draft the final country reports for each MS are presented in the following flowchart.
## 2.2 Compliance and comparison

The critical analysis of the situation in the 27 MS regarding their compliance with the requirements of the HASS Directive and the evaluation of practices was performed according to the steps described in the following flowchart. Similarly the situation in Canada and USA was assessed and compared.

The results of the analysis are presented in sections 4 and 5. Comparison with USA and Canada is discussed in section 6 (see also Appendix 2).

### Compliance of MS with HASS Directive
- Check in each MS of compliance with each article of the HASS Directive
- Cross comparison analysis between all MS
- Overview table 1 per MS
- Global compliance analysis table

### Comparison and Evaluation of practices
- Evaluation of implementation in each MS
- Identification of weak and strong points in each MS
- Cross comparison analysis between MS
- Identification of best practices
- Overview table 1 per MS
- Global comparison analysis table

### Situation in USA & Canada and Comparison with EU
- Overview of situation in USA & Canada
- Evaluation of situation
- Identification of similarities and discrepancies vs EU
- Country Report USA & Canada
- Overview table USA & Canada
3 INVENTORY OF HASS IN THE EUROPEAN UNION

According to the data reported by 25 MS, the EU inventory of HASS counts about 30 700 HASS of which 50% is represented by only 2 MS (Germany and France) and 70% by 4 MS (Germany, France, Poland and Hungary). Nine MS have a HASS inventory with less than 100 HASS. About 3 200 HASS holders are recorded in 24 MS of which 63% is represented by only 4 MS (Germany, France, Poland and UK).

On average per MS, a holder would typically hold between 1 and 40 HASS. This important difference in the average number of HASS held per user between MS is a result of the fact that the way HASS are counted is not harmonised between MS. For instance a MS will record one HASS for an industrial high-activity irradiator while another MS will register each pencil as a separate HASS, resulting in several hundreds of HASS for such a facility. The question about the need for a uniform accountancy system therefore rises.
4 IMPLEMENTATION OF HASS DIRECTIVE

4.1 Introduction

The first objective of the project is to analyse the compliance of the transposition of the HASS Directive requirements in the national legal and regulatory framework of the MS. The compliance analysis was performed by checking the implementation status of the different Articles of the HASS Directive on the basis of the answers to the questionnaires fulfilled by the MS and the additional information collected during visits with the regulatory authority. 17 different subjects divided in 4 areas (regulatory framework and the three main security functions) were checked for the compliance analysis:

- Regulatory framework
  - Regulatory authority
  - Legislative framework
- Prevention and deterrence
  - Authorization for practice with HASS
  - Records keeping and updating
  - National inventory
  - Inspections and penalties
  - Control of HASS by the holder
  - Source holders’ training
  - Identification and marking of HASS
  - Transfers of HASS
  - Long-term management of disused HASS
  - Security measures
- Detection
  - Detection of orphan sources
  - Campaigns for orphan sources recovery
  - International cooperation & information exchange
- Preparedness and response
  - Emergency plans & procedures
  - Training and information related to orphan sources

Compliance with the HASS Directive requirements was objectively evaluated according to 3 different types of results:

- **OK**  Implemented in compliance with the HASS Directive requirements;
- **Point of attention** Implementation is in general compliant but some particular point(s) of attention exist(s);
- **NOK** Provision of the HASS Directive is not implemented as required.

In a first step, the compliance analysis was carried out for each of the 27 MS from the available information compiled in the country report describing the national situation. In a second step, the results obtained for each MS were gathered to give a general overview of the situation regarding the compliance of the HASS Directive transposition at the European level.
4.2 Overview of the compliance status

The overall results of the compliance analysis with the transposition of the HASS Directive for the 27 MS are represented in the graph below.

As it can be deduced from the graph analysis where the green colour is dominant, there is in general a good compliance of the implementation of the HASS Directive requirements.

4.3 Case of possible lack of implementation

Only one requirement is poorly implemented in about half of the MS: the organisation of orphan sources recovery campaign. Indeed, the Article 9.4 of the HASS Directive requests that MS shall ensure that campaigns are organised, as appropriate, to recover orphan sources left behind from past activities. The interpretation of the project team with respect to this requirement is that MS are obliged to organise such recovery campaigns. Therefore, the evaluation was determined as non-compliant for the 14 MS where no orphan sources recovery campaign has been organised. However several arguments were forwarded by the MS to justify why such recovery campaigns are not organised. These main arguments are:

- HASS are under control and cannot become orphan sources;
- 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 to store any recovered orphan sources;
- Recovery campaigns were organised before HASS Directive transposition.
In 3 MS the requirements about the records keeping (Article 5) are also not properly implemented as the direct notification of modifications of the status of HASS to the authority is not ensured.

4.4 Points of attention on implementation

Although in general compliant with the requirements of the HASS Directive, 5 subjects frequently show points of attention.

The points of attention related to the legislative framework that are observed in 12 MS 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 MS which use the same HASS definition than the one 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.

The main points of 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;
- Test programme carried out by the source holders is limited (only visual verification or no dose rate measurements or no leak tests).

In 10 MS the documentation accompanying the HASS is not fully compliant with the requirements of the Article 7 of the Directive which requests that \textit{the manufacturer shall provide a photograph of each manufactured source design type and of the typical source container. Moreover, 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.} Historical sources without an ID number are also present in some MS.

The main point of attention regarding 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 termination of the use. However, several MS 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 MS the financial guarantee for the safe long-term management of the disused sources is uncertain. Finally it seems that the HASS holders are not obliged to make adequate arrangements for the long-term management of disused HASS during the licensing process in one MS although it is required by the Article 3.2 (b) of the HASS Directive.

The last subject requiring attention is the training and the information of workers potentially confronted to orphan sources. In 4 MS such trainings are not organised while in 8 other MS these trainings are either not required by regulation, or not given to all types of workers or not in all facilities at risk, or not documented nor repeated.
5 COMPARISON BETWEEN EU MEMBER STATES

5.1 Introduction

Besides the compliance analysis with the transposition of the HASS Directive, the level of implementation of the Directive was also evaluated for each MS. The main objective of this second analysis is to identify the strong and weak points in the implementation of the different subjects of the HASS Directive. In total 43 items over the 17 subjects of the HASS Directive were identified for comparison between MS. Several more items were identified but as the information was not always available for all MS or was very specific to one MS, they were discarded when the information was available for less than half of the MS. Again, all the results from the individual evaluation per MS were compiled for the purpose of comparison.

The level of implementation of the HASS Directive requirements was evaluated according to 4 different types of results:

- **Strong point**: Noteworthy practice;
- **Normal**: “On-average” way of implementing;
- **Point of attention**: Implementation on-average but some particular point(s) of attention exist(s);
- **Weak point**: Insufficient way of implementing or unimplemented.

To ensure to the extent of possible the objectivity of the evaluation, the assessment was made by 4 experts independently on the basis of an evaluation grid. The evaluation grid aims at defining a specific criterion for every item allowing a selection between strong point, normal, point of attention, and weak point. Following this methodology, the same evaluation was given for a similar situation in different MS. The evaluation grid is given in Appendix 1.
5.2 Overview of the level of implementation

The overall results for the evaluation of the implementation level of the 43 items of the HASS Directive are given in the graph below.

For the purpose of this report, the discussion is structured according to 4 categories: the regulatory framework and the three basic security functions (prevention and deterrence, detection to prevent incidents, and preparedness and response to incidents).

5.3 Regulatory framework

The results of the comparison regarding the regulatory framework with respect to HASS are given below.
Regarding the regulatory authority, there is more than one single federal authority dealing with all radiation protection and nuclear matters in 11 MS so that the responsibilities are spread over several institutions.

Unsurprisingly, the HASS Directive is reportedly well implemented in the most of the MS, although some requirements are not yet fully implemented in 2 MS. One MS will fully cover the provisions of the Articles 5 and 7 with a ministerial decree in 2013 while the requirement for the financial security of orphan sources is not yet transposed because of lack of economic resources in another MS.

As previously discussed in the part on the compliance analysis, 10 MS either use different high-activity levels as those of the HASS Directive or implement the national requirements not in compliance with the HASS definition (actual activity levels are considered).

5.4 Prevention and deterrence

The items covered by the prevention and deterrence deal with authorisation for practice with a HASS, records keeping and updating, national inventory, inspection and penalties, controls of HASS by the holder, source holder’s training, identification and marking of HASS, transfer of HASS, long-term management of disused HASS and security measures. Comparison between MS of the level of implementation of the items dealing with prevention and deterrence is shown in the figure below.

In most of MS, all relevant issues as listed in Article 3 of the HASS Directive are considered during the licensing process. Moreover, several MS have practical experience with refusing an authorisation.
The maintenance of records regarding HASS is required in all MS even if one MS reported a defective practical implementation. The notification of records to the authority is an item requiring attention. Indeed, several MS have not defined in regulation the tolerated delay for notifying the authority on modifications of the status of HASS so that the direct notification is not ensured. In most of the MS, the data recorded are those required in Annex II of the HASS Directive although a few MS only record partial data. Usually a central registry of all sealed sources above exemption levels or a central registry of HASS exist at the national level but these registries are often only available on request to enforcement authorities.

Inspections and penalties are strong areas in regard to the HASS Directive implementation. Inspections are regularly performed during which records for all HASS are generally checked. The scope of inspection deals with both safety and security aspects. The inspectors seem adequately trained in most of the MS. A system of penalties is in place in all MS but only 8 MS have practical experience with enforcement.

As previously mentioned, the performance of tests by HASS holders is a point of attention. Indeed, the leak tests are not systematically performed in 5 MS while no test or limited tests are carried out in 4 MS. Limited tests mean that only visual inspection or only leak tests or only dose rate measurements are performed. However, the verification of the tests performance is made by the authority during inspection in most of the MS.

According to Article 8.1 of HASS Directive, exposed workers must be trained on the safe management of sources. Training and information must be both repeated at regular intervals and documented. In 9 MS the training programme is defined by the holder only while in 12 MS the training programme is either defined or approved by the regulatory body. In 6 MS the training programme is defined by the holder but with the involvement of recognised organisation(s). Except in 2 MS, the training sessions are documented but comprehension tests for the trainees are not organised in about half of MS. The repetition of HASS holder’s training at regular interval is a poorly implemented requirement. In 2 MS the frequency of repetition is defined by the holder himself and not by the authority while in 13 MS the frequency is not defined or is set at once every 5 years which is considered too long by the project team. In 10 MS, the HASS holders trained staff includes both exposed workers and the management. In 6 MS the records related to the training of the HASS holder’s staff are not checked during inspections.

8 MS have reported that the documentation accompanying the HASS is not in compliance with the requirements of the HASS Directive. Still the available documentation is checked during inspections by the authority or by the TSO in 15 MS. In 6 MS, this documentation is not verified. Five MS have recognised that some historical sources are not properly identified and 1 MS has old Russian sources on the territory without a readable identification number.

The transfer of HASS is a strong item in the implementation of the HASS Directive. The holder ascertains that the recipient is authorised and a system of control allows the supervision of the transfer.

Adequate arrangements for the long-term management of HASS are a prerequisite to authorisation in the vast majority of MS. However, the time frame during which storage at holder’s premises is authorised before transfer is not regulatory defined in 9 MS. In other words, the disused sources can be stored for an undetermined period of time at the holder’s facility, potentially increasing the risk of loss of control. In 7 MS, the tolerated storage time at holder’s premises before mandatory transfer is regulatory set but it is equal to or longer than 5 years. In 20 MS the adequate provision made for the safe management of sources when they become disused is take-back provisions included in the supply contract together with financial arrangements paid by the HASS holders, HASS suppliers or the nuclear industry. In 5 MS, take-back provisions are included in supply contracts but without financial arrangements which does not guarantee the effective removal of the disused HASS. Besides the recovery of disused HASS by the suppliers, a second option implemented in the MS for the long-term management of such disused sources is their placement in a recognised
installation. 13 MS have access to a centralised storage facility with a sufficient capacity adapted to the potential amount of disused sources. The capacity of the centralised storage facility is limited in 8 MS while a centralised storage facility is lacking in 2 MS. As for the remaining 4 MS, the capacity of the centralised storage facility was not known.

The security (physical protection) of the HASS is more and more considered as a main issue with respect to malevolent actions. Therefore, regulations specifically dedicated to the security are implemented in 11 MS and under preparation in 5 MS.

5.5 Detection

The items gathered under the detection security function are the detection of orphan sources, campaigns for recovery orphan sources and the international cooperation and information exchange. The results of the comparison for those items at the European level are presented in the figure below.

In 24 MS the strategic locations where orphan sources could be detected are identified or the identification is in progress. In 12 MS, the installation of detection means at the identified strategic locations is regulatory imposed, while monitoring equipment is installed on a voluntary basis in 11 MS. As already pointed out, the organisation of orphan sources recovery campaign has been implemented in only about 50% of the MS.

Another item to which attention should be paid is the establishment of a system of financial security to cover the costs relating to the recovery and management of orphan sources. In only 8 MS financial arrangements paid by the HASS holders, nuclear industry or scrap yard facilities are in place. In 12 MS, the costs associated to the recovery and management of orphans sources are covered by the State while no clear financial strategy is implemented in 7 MS.

Almost all MS have contributed to the IAEA Illicit Trafficking Database for several years and all MS provide information when requested by other MS or third countries.
5.6 Preparedness and response

The items included in the preparedness and response security function encompass the emergency plans and procedure as well as the training and information of persons potentially confronted with an orphan sources. The overall comparison of the level of implementation for these items is illustrated in the graph below.

A national off-site emergency plan is established in all MS even if no general emergency response plan specifically applicable to HASS and orphan sources is in place in 2 MS. In the vast majority of MS an emergency team is available 24/7.

As requested in the Article 3 of the HASS Directive, the authorisation for any practice involving a source must cover requirements for emergency procedures and communication links. On-site emergency procedures for HASS holders are required in 26 MS and these procedures must be approved by the authority in 21 MS. However, the establishment of response and alarming procedures in facilities where orphan sources are likely to be found is much less implemented in the MS. These procedures are required in only 11 MS and they are approved by the competent authority in only 6 MS. In 3 MS such response and alarming procedures may exist but they are not required by regulation. Finally, there are no response and alarming procedures in facilities at risk in 6 MS.

Article 8.2 of the HASS Directive requires information and training for the management and workers in installations where orphan sources are likely to be found and in significant nodal transit points. Even if such training and information sessions are organised in 24 MS, they are obligatory according to regulation in only 14 MS. A weak point in the organisation of the training for people potentially confronted with orphan sources is the frequency at which the training is given. In 11 MS the training is not repeated at regular intervals and a yearly repetition is organised in only 4 MS. Moreover the training is not documented in 8 MS. On the other hand, 9 MS record the training course and organise comprehension tests.
5.7 Identification of best practices

Based on the analysis of the level of implementation of the HASS requirements in the 27 MS, several best practices were identified. They are described hereafter for the main HASS provisions.

The licensing process is a key step in the management of HASS. Prior authorisation for any practice with a HASS could include as prerequisite a.o. that adequate arrangements, including financial guarantees, have been made for the long-term management of the HASS, including the case where the holder or supplier becomes insolvent or goes out of business. The long-term arrangement could exclude as option the long-term storage of the disused HASS at the holder’s premises. The authorisation could also describe 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 workers and the interval of repetition.

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 should be defined in national regulation transposing the HASS Directive.

Announced and unannounced inspections are regularly carried out to check both safety and security issues. The inspections aim at verifying all HASS records kept by the holder in order to check on-field the correctness of the information notified to the authority. The documentation accompanying the source should also be verified. During inspections the regular performance of tests on the HASS and of the training of HASS holder’s staff is controlled based on the related records. In addition to the documentary control, visual inspection of the HASS and measurements performed by the inspectors allow to assess the integrity of the source and its proper use.

The HASS holder’s staff training programme is defined or approved by the authority and the frequency of repetition is regulatory set at a reasonable time interval (for instance yearly). The training courses are recorded and comprehension tests are organised. The training records are checked during inspections.

The HASS Directive requests that each holder of sources shall return each disused source to the supplier or place it in a recognised installation or transfer it to another authorised holder unless otherwise agreed by the competent authority, without undue delay after termination of the use. As “undue delay” is not precisely defined in the Directive, the period before mandatory transfer greatly varies among MS, from less than one year over several years to no defined time frame. The best practice consists in defining in 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 sector could also be available for the long-term management of disused HASS transferred to a recognised storage facility. Where transfer of disused HASS to a recognised storage facility is one of the long-term management options, MS should provide for the access to a facility of sufficient capacity.

The establishment and enactment of specific provisions regulating the security and physical protection of HASS is another good practice observed in several MS. The security requirements should be defined based on a graded approach taking into account the risk posed by the sources.

To avoid incidents with orphan sources, the strategic locations where they are more likely to be found or from where they can enter the country should be identified at the national level. Moreover, the installation of detection and monitoring equipment at these places could be regulatory imposed by the authority. Orphan sources recovery campaigns should be organised, especially in old or former installations where radioactive substances were or are
still used. The financial burden for recovering and managing orphan sources should not be supported by the community through State budget but should be borne by the concerned sectors. The response and alarming procedures for installations where orphan sources are more likely to be found could be approved by the authority and exercises would be organised to test them. Managers and workers potentially confronted with an orphan source in all types of installations at risk could be regularly trained in compliance with the requirements of the national regulation. The content of the training would be either defined or approved by the authority which ensures that the sessions are documented and effectively given. The good understanding of the trainees should be evaluated. To increase the awareness of the persons potentially confronted with orphan sources the authority may organise information sessions and develop guides, documentation, movies, posters, etc.
6 COMPARISON WITH CANADA AND USA

6.1 Introduction

The following analysis is based on a comparison of the legislations and strategies in force in Canada and in the United States of America (USA) with respect to the requirements of the HASS Directive.

As a result of this analysis, good practices existing in both countries were evidenced and could be implemented at the European level for improving the control of HASS. The criteria used to assess the different topics of the American and Canadian legislations are those defined previously in the analysis on the good practices identified in the different EU MS.

All the information gathered in this analysis is from the annexed country reports established for Canada and for the USA. This assessment needs to take into consideration the following data which allow quantifying the real impact of good practices on the safety and security of the use of HASS:

- **CANADA**: Canada’s inventory contains approximately 60,000 sealed sources (Cat. 1 to 5) for more than 2,500 licensees. In 2011, there were 2,777 Cat. 1 sources and 22,778 Cat. 2 sources (HRS, high-risk sources) for 500 licensees.

- **USA**: It is assessed that more than 75,000 high-risk radioactive sources are possessed by approximately 1,300 licensees.

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### Legend for general evaluation:

This appreciation gives an overview of the situation in the country for the different topics and points out the strong and weak points, with corresponding explanations on the compliance or non-compliance with the Directive requirements.

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<td>Strong point and good practice</td>
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<td>Normal requirement/suitable</td>
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<td>To be improved/attention point</td>
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<td>铒 Erie</td>
<td>Weak point</td>
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6.2 Comparison of the legislations in force in Canada and USA related to the requirements of the HASS Directive

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<th>CANADA</th>
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<td><strong>COMMENTS</strong></td>
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**Part 1: Regulatory framework with respect to HASS**

<p>| ☑ | The Canadian Nuclear Safety Commission (CNSC) is the sole authority for regulating the use of all nuclear energy and materials in Canada under the Nuclear Safety and Control Act. | ☑ | The Nuclear Regulatory Commission is an independent agency which regulates the possession and use of radioactive sources, under the U.S. Atomic Energy Act 1954, as amended. |
| ☑/☻/☺/☺ | Under the Nuclear Safety and Control Act, CNSC has implemented regulations and by-laws. The Canadian regulatory control of sealed sources fully conforms to the requirements of the IAEA Code of Conduct. High-risk sources (HRS) are category 1 and 2 sources defined by the IAEA Code of Conduct. | ☑/☻/☺/☺ | This Act also provides that the Commission may delegate portions of its regulatory authority to the governments of the 50 States provided that these governments have standards and guidelines that are compatible to the NRC’s regulatory program. |
| ☑/☻/☺/☺ | The NRC’s regulations most relevant to sealed sources and HASS are found in Chapter I of Title 10 (&quot;Energy&quot;) Sections 30-39 and 110 of the Code of Federal Regulations. High-risk sources are radioactive materials identified by the IAEA as being at or above (or aggregating to) category 2 sources thresholds defined the IAEA Code of Conduct. |</p>
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<th>Part 2: Prevention &amp; Deterrence</th>
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<td>Authorization for practice with HRS</td>
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<td>Records keeping and updating</td>
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The National Sealed Source Registry (NSSR) is a CNSC-managed national database that maintains inventory information on all categories of sealed sources in Canada. It contains detailed information on high risk (Categories 1 and 2) and some information on (Categories 3, 4 and 5) radioactive sealed sources. The Sealed Source Tracking System (SSTS) is an electronic system that provides licensees with a more convenient and efficient way to report any movement of sealed sources. Only CNSC licensees who are authorized to possess high-risk sealed sources can use the system. These licensees must obtain an authorization code from their CNSC licensing officer.

In general inspections are announced however inspectors do have the right to enter a premise at any reasonable time to inspect. The inspection program concerns radiation protection (dose control), training & qualifications, operational procedure (leak test), organization and management.

Inspection frequency is based on a risk assessment and is defined in the regulations.

Different options in case of non compliance (written notices, requests for information, prosecution) but no monetary penalty. An administrative penalty system will be established in the future.

Thanks to the NSTS (National Sources Tracking System) the NRC implements a national source registry, as described in the Code of Conduct. NSTS is a secure, user–friendly, web-based database designed to track high-risk radioactive sources (Category 1 and 2 radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until they decay below the Category 2 threshold). NSTS enhances the ability of the NRC and Agreement States to conduct inspections and investigations, communicate information to other government agencies, and verify legitimate ownership and use of nationally tracked sources.

NRC’s Regional offices and Agreement States conduct typically unannounced and periodic inspections of licensed activities. These inspections cover areas such as training of personnel, radiation protection programs, radiation dose records, and security of nuclear materials.

An inspection priority code is assigned to each radioactive material license. The priority code (i.e. 1, 2, 3, 4 or 5) is the interval between routine inspections, expressed in years.

For licensees who violate the regulations, sanctions may include notices of violation, monetary fines, or orders to modify, suspend, or revoke a license or require specific actions because of a public health issue.
## Comparison with Canada and USA

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<tr>
<th>Requirement</th>
<th>Comparison</th>
<th>USA Requirement</th>
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<tr>
<td>Leak test, frequency, limits and requirements upon discovery of a leak are detailed in the regulations.</td>
<td>NRC makes the Inspection Reports available for public review through its electronic document retrieval system (ADAMS).</td>
<td>Typically, products are required to be leak tested at intervals not to exceed 6 months.</td>
</tr>
<tr>
<td>Training requirements for all users of sealed sources are assessed at the time of the license application.</td>
<td>In order to receive the special license dedicated to a defined application, the applicant submits an adequate program for training the workers.</td>
<td></td>
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<tr>
<td>Specific regulatory requirements for Certified Exposure Device Operator (CEDO) and Radiation Safety Officer who must apply directly to CNSC.</td>
<td>The applicant identifies and lists the qualifications of the individual(s) designated as the RPO and potential designees responsible for ensuring that the licensee’s radiation safety program is implemented in accordance with approved procedures.</td>
<td>A NNSA-funded training is designed to teach on voluntary basis facility personnel and local law enforcement officials on how to protect themselves and their communities when responding to alarms indicating the possible theft or sabotage of nuclear or radioactive materials.</td>
</tr>
<tr>
<td>No CNSC regulatory requirements for labelling the source. Labelling requirements for containers and devices.</td>
<td>Identification and marking of HRS</td>
<td>The documentation accompanying the source is computerized in the NSTC (engraved serial number, isotope, activity and date of assay, the last known user of the source, distributor’s name or logo, labelling requirements for containers).</td>
</tr>
<tr>
<td>Transfers and exports must be reported at least 7 days before the actual shipment takes place. Receipts and imports must be reported within 48 hours of reception.</td>
<td>Transfers of HRS</td>
<td>Imports, transfers and exports must be recorded in NSTS by close of next business day.</td>
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<td></td>
<td></td>
<td>When transferring sources within the United States, licensees are required to verify that the recipient is authorized to possess the source. Proof is normally provided in the form of a copy of the recipient’s license.</td>
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<tr>
<td>😊 For controlling the export and import of Category 1 and 2 radioactive sources, the CNSC ensures that only authorized persons are recipients of Category 1 and 2 radioactive sources. Canadian exporters are required to apply for and obtain an Export License from the CNSC prior to exporting Category 1 and 2 sealed sources.</td>
<td>😊 A licensee who transfers a sealed source shall provide the transferee with a record of the most recent leak test conducted to ensure he is not transferring a leaking source which could potentially lead to contamination.</td>
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<tr>
<td>😊 Responsibility of the licensee includes making appropriate plans for the termination of licensed activities, including the termination of operations, the short- and long-term management of radioactive waste.</td>
<td>👎 Long-term management of disused HASS</td>
<td></td>
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<tr>
<td>😊 Disused sources can be stored on site, transferred to another licensee, returned to the supplier/manufacturer or stored/disposed of to a licensed waste facility. In the case of storage on site, there is no time limit for storage. The expectation is that the sources will be securely stored at all times under a valid license that authorizes storage.</td>
<td>😊 There are no time limits for storage at user’s premises established in the regulations. Under present practices, the secondary market for disused sources is vulnerable to theft. Take-back options by supplier are encouraged.</td>
<td></td>
</tr>
<tr>
<td>😊 Licensing documents of the NRC and the Agreement States are not uniform. Consequently, verifying authenticity of licenses is a challenge and presents a potential security concern.</td>
<td>😊 The long-term management options for the disused sources must not be specifically defined in the license application.</td>
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Currently the requirement for financial guarantees has been limited to Class I nuclear facilities but CNSC’s plan outlines to broaden the financial guarantee program over the next 2 years to require all sites and activities licensed to have financial guarantees, including sealed source users.

Greater than class C waste (class with T1/2 > 5 years) may not be disposed at the commercially operated near-surface disposal facilities. DOE has been storing this waste at an interim storage site at Los Alamos Laboratory (Off-Site Recovery project - OSR) awaiting a permanent repository. Funds for developing a permanent disposal plan have yet to be provided. Licensees are usually uninformed of the costs and are unprepared to pay them.

A draft CNCS regulatory document “Security Measures for Sealed Sources” has been published in 2013. This document sets out the minimum security measures required to prevent the loss, sabotage, illegal use, illegal possession, or illegal removal of sealed sources while they are in storage at the site of a licensed activity, in transport or being stored during transportation.

The regulations on security are generic with broad requirements. NRC is in the process to improve its regulation by implementing increased security measures (access controls, monitor and response).

On a voluntary basis, facilities may request a security assessment by the DoE to evaluate the security level. DoE can also financially contribute to the costs for the security improvements.

The CNSC has not performed a national threat assessment to determine strategic locations of portal monitors but it is currently being completed.

The performance of a national threat assessment to determine the strategic location where detectors have to be installed is not under NRC’s jurisdiction. The Domestic Nuclear Detection Office (DNDO) of Department of Homeland Security (DHS) has worked on it but without real efficiency.

The CNSC does not regulate portal monitor users and as such it is not compulsory to have portal monitors at any location.

The Environment Protection Agency (EPA) has developed voluntary programs and training to help reduce the incidences of orphan sources in scrap metal.
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<td>😊😊</td>
<td>Continuous outreach to steel producers is done by professional associations (brochure/pamphlet-technical posters).</td>
<td>😊😊</td>
<td>Coordination of different partners in this field is a priority of DHS for the near future.</td>
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<tr>
<td>😞</td>
<td>No specific recovery campaigns organized in Canada and no specific budget set aside for them.</td>
<td>😊😊</td>
<td>Source recovery is an ongoing effort: a series of initiatives has been taken in that field since the 9/11 event (OSRP/GTRI- 28 000 disused sources, SCATR project, etc.).</td>
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<tr>
<td>😐</td>
<td>If the owner of an orphan source can be found, the owner is responsible for the cost of recovery and/or disposal of the source. If the owner cannot be found, currently it is the responsibility of the “finder” to pay for the recovery and/or disposal of the source. It is important to note that this determination is examined on a case by case basis and the CNSC will step in to manage the situation if deemed necessary.</td>
<td>😊😊</td>
<td>Budget of DOE/NNSA allocated year to year.</td>
</tr>
<tr>
<td>😊😊</td>
<td>“CNSC Report on Lost or Stolen Sources and Radiation Devices” published on CNSC website</td>
<td>😊😊</td>
<td>The NRC contributes to the IAEA Illicit Trafficking Database.</td>
</tr>
<tr>
<td>😞</td>
<td>Cooperation with the IAEA illicit database</td>
<td>😊😊</td>
<td>Continuous exchange of information with the CNSC</td>
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<tr>
<td>😊😊</td>
<td>Continuous exchange of information USNRC, FPTRPC, CSPA, CARI, Canutec.</td>
<td>😊😊</td>
<td>Continuous exchange of information with the CNSC</td>
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### Part 4: Preparedness and response

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<th>Emergency plans &amp; procedures</th>
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<td>😊</td>
<td>Each licensee emergency procedures are assessed at the time of license application to ensure they meet CNSC expectations.</td>
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<td>😍</td>
<td>The NRC and Agreement States have 24/7 emergency ‘hotlines’ that can be called when orphan sources are found and present a safety or security concern.</td>
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<tr>
<td>😍</td>
<td>In the event of an emergency involving a high risk source, there is a CNSC Duty Officer emergency telephone line. This person is on call 24/7.</td>
<td></td>
<td>😊</td>
<td>In the event of an emergency due to an orphan source that threatens public health and safety, the DOE, on request of the NRC, can recover and secure the source. This has happened 20 times involving over 500 sources since 1990.</td>
</tr>
<tr>
<td>😍</td>
<td>The CNSC provides extensive training to law enforcement and emergency services organizations.</td>
<td>Training and information of persons potentially confronted with an orphan source</td>
<td>😍</td>
<td>A National Nuclear Security Administration (NNSA)-funded training is designed to teach facility personnel and local law enforcement officials how to protect themselves and their communities when responding to alarms indicating the possible theft or sabotage of nuclear or radioactive materials.</td>
</tr>
<tr>
<td>😊</td>
<td>As the CNSC does not regulate portal monitor users, training requirements would be determined by the facility/agency using the systems.</td>
<td></td>
<td>😍</td>
<td>The Environment Protection Agency worked with state, federal, and industry organizations to develop CD-ROM-based training programs that help workers at scrap metal yards and at demolition sites to identify and properly handle radioactive materials found on site.</td>
</tr>
</tbody>
</table>
6.3 Conclusions

The status of the regulations concerning the management of the high-activity sealed sources/high-risk sources and orphan sources is relatively similar in Canada, in the United States and in the different MS of the European Union. The European legislation is at least as well developed as the US/Canadian ones.

However, in comparison with the requirements of the HASS Directive some points of attention appear for both American countries:

- A system of financial security to guarantee that the costs relating to the long-term management of disused HASS and recovered orphan sources are covered could be ensured
- The organisation of recovery campaigns could be ensured
- Strategic locations where orphan sources are more likely to be found and significant nodal points could be identified. Moreover, the installation of detection and monitoring systems at the identified locations could be encouraged or regulated.

On the other hand, several good practices in force in Canada and the USA could advantageously be transposed at the European level for supporting the implementation of the Directive as well as the new EU Basic Safety Standards for protection against the dangers of ionizing radiation. These practices concern the following areas:

- Sealed Source Tracking System applied in Canada and the USA for reporting movement of sources.
- Reports of inspection available for public review.
- Training program assessed at the time of license application.
- Inspection priority code assigned to each license in the USA.
- Guide related to security measures to prevent loss, sabotage, illegal use or possession, illegal removal of sources while in use, transfer or storage.
- Record of the most recent leak test results for transferee in order to avoid transfer of leaking and contaminating source.
- Security assessment performed by public institutions.
7  POSITION OF THE INDUSTRY

7.1  Rationale

In the HASS Directive, a ‘holder’ is defined as any natural or legal person who is responsible under national law for a source, including manufacturers, suppliers and users of sources. Source suppliers and manufacturers are indeed important stakeholders in the whole process of HASS management. As key players, the point of view of source suppliers and producers on the requirements of the HASS Directive has been considered as highly valuable for the study. In this regard, contacts were taken with the International Source Suppliers and Producers Association (ISSPA). ISSPA is an association gathering companies which are international industry leaders in the manufacture, production and supply of sealed radioactive sources and/or equipment that contain sealed radioactive sources.

A list of questions was sent to ISSPA to be officially provided with the association's position. The answers received from ISSPA for the different provisions are reported below.

7.2  ISSPA’s position

7.2.1  Recommended working life

The useful life of a source is affected by the source design but also by the actual conditions of use. From manufacturer's perspective, it does not make sense to define a limitation of use by source design only. To reduce radioactive waste and to optimize dose rate, sources should be used as long as the encapsulation can be expected to be safe.

7.2.2  Requirements for holders

Article 6 of the HASS Directive requests that each holder of sources shall ensure that suitable tests, such as leak tests based on international standards, are undertaken regularly in order to check and maintain the integrity of each source.

Regarding the undertaking of regular leak tests based on international standards, ISSPA states that the source itself can usually not be leak tested in the field due to the high dose rate. It is usual to take wipes at critical places of the source container (e.g. shutter) and to consider the criteria of 1/10 of the activity limit of ISO 9978. Lower limits seem inappropriate as the influence of uncertainties becomes too high. If a source is really leaking a much higher contamination is expected. The frequency of leak testing should be set depending on the risk of leaking sources. Therefore the conditions of use have to be taken into account. A fixed period of leak testing for all sources is not adequate under the principle of dose optimization.

According to Article 5 of the HASS Directive the holder shall provide the competent authority with an electronic or written copy of all or part of the records without undue delay on the closure of such records when the holder no longer holds any sources.

From ISSPA point of view, this requirement does not make sense as long as the holder holds the license to use such sources; it should be related to the closure of the license. In addition, harmonised national electronic records would allow electronic data transfer on the one hand and, on the other hand, reduce the risk of non-conformance due to the manual entering of data.
7.2.3 Identification and marking

Article 7 of the HASS Directive requires that the supplier shall ensure that each source is identified by a unique number. This number shall be engraved or stamped on the source, where practicable. This number shall also be engraved or stamped on the source container. The manufacturer or the supplier shall ensure that the source container and, where practicable, the source are marked and labelled with an appropriate sign to warn people of the radiation hazard. 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 and that the markings and labels remain legible. The information shall include photographs of the source, source container, transport packaging, device and equipment as appropriate.

According to ISSPA, all manufacturers ensure that each produced source has a number and is marked with this number if appropriate (depending on the size of the source). Marking of container - engraved or stamped - is difficult because the containers are often used for different sources. The marking of transport containers is inapplicable and the marking of containers in which the source is changed frequently (e.g. Ir-192) is complicated. The appropriate method of marking should be settled by the manufacturer.

Article 7 also requests that the information shall include photographs of the source, source container, transport packaging, device and equipment as appropriate.

The requirement about the inclusion in the information of photographs of the source, source container, transport packaging, device and equipment as appropriate is inapplicable in ISSPA opinion. Taking pictures of active sources creates additional doses for the staff and requires additional efforts for the manufacturers/producers. The safety or security benefit of this requirement is not noticeable according to ISSPA.

7.2.4 Training and information

Article 8 of the HASS Directive specifies that the holder shall ensure that training in the field of radiation protection includes specific requirements for the safe management of sources. The information and training shall place particular emphasis on the necessary safety requirements and shall contain specific information on possible consequences of the loss of adequate control of sources. The information and training shall be repeated at regular intervals and documented, with a view to preparing the relevant workers adequately for such events.

To the ISSPA opinion, this special training is required by several other regulations and additional regulation seems therefore not to be efficient.

7.2.5 Take-back provisions

Article 6 requires that each holder of sources shall return each disused source to the supplier … unless otherwise agreed by the competent authority, without undue delay after termination of the use.

The request that each holder of sources shall return each disused source to the supplier makes sense from the safety and security perspective. It provides a solution to bring disused sources into a safe and secure haven. The take-back provisions limit for a source holder the time and the subsequent efforts to guarantee the source security. By returning the source, the holder transfers this responsibility to the supplier. Most of the suppliers offer the return of source, if the return is legally possible and if the user pays the costs at time of return. Unfortunately several issues complicate the practice:
Legal: in some states it is only allowed to send the source to the original supplier, not to a supplier who supplies a source to replace the disused source;

- Transport issues;
- The country of origin of the sources may be difficult to ascertain because the sources may contain components from multiple countries. Moreover, some companies have manufacturing facilities in several countries and the source certificate may be held by a single division of the company.

Three strategies exist for the long-term management of recovered disused radioactive sources:

- Recycling
- Long-term storage
- Disposal

If technically and commercially feasible, the recovered disused sources are recycled by the producers either by recovering the radioactive material, or by modifying the device for applications requiring lower activity sources or by retesting the source to extend its working-life. Reutilisation of disused sources (recycling) is the industry's preferred option because it reduces the amount of radioactive material that needs to be produced although this option must be cost effective and technically feasible for a commercial entity. However, as not all sources can be recycled, the main disadvantage of take-back provisions is that suppliers are misused as waste brokers. The practice puts therefore a burden on the supplier because the supplier takes the risk for the source disposal or for the management of waste resulting from source recycling or for other unexpected costs.

The long-term storage option is the less preferred option of the industry even if source manufacturers have robust security controls so that long-term storage at the source manufacturer facility is feasible. The concerns to take into account when considering long-term storage at manufacturer facility are:

- Liability issues associated with the quantities possessed
- Financial responsibility of eventual disposal
- Ultimate disposal path must be available because the disused sources will become waste if there is no possibility for recycling
- Site licensing capability and limits, security issues, etc.

Concerning the disposal option, many source manufacturers cannot offer the service to take back disused sealed radioactive sources as waste because:

- Transfer of radioactive waste is stringently limited
- Source manufacturers are usually not licensed to operate as waste manager
- Licensing and regulatory restrictions would greatly limit this option.

According to ISSPA, disused sealed radioactive sources should not be declared as waste as long as a long-term storage or disposal way is not defined and available.
7.2.6 Financial security

HASS Directive requires that “adequate provision, by way of a financial security or any other equivalent means appropriate, have been made for the safe management of sources when they become disused sources, including the case where the holder becomes insolvent or goes out of business” (Article 3). It also requests that “Member States shall ensure that a system of financial security is established or any other equivalent means to cover intervention costs relating to the recovery of orphan sources” (Article 10).

According to ISSPA, the person (company) which takes benefit from the source should ensure the financial security. It happens very rarely that a holder becomes insolvent or goes out of business. To avoid unnecessary bureaucracy it would be more efficient if the governments of the Member States would cover the intervention and disposal costs in such very seldom cases.

7.2.7 Recovery campaigns

Many companies have a policy of accepting back at the end of their useful life all sources that they have supplied as long as it is legally allowed. This is done under contract with the customers. About orphan sources, suppliers will work with and provide as much support as they can to the recovery of those sources.
8 LOSS OF CONTROL INCIDENTS IN EUROPE

One of the project tasks is the analysis of incidents in Europe due to a loss of control of radioactive sources. Two ways were followed to gather the available information about reported incidents:

- Through international organisations such as IAEA, Europol and Interpol that maintain databases on incidents or suspicious events,
- Through the questionnaire sent to the nuclear regulatory authority(ies) of each Member State.

8.1 Data from international organisations

In order to have access to information related to incidents with radioactive sources in Europe, requests were addressed to Europol, Interpol and IAEA, for both the IAEA’s Illicit Trafficking Database (ITDB) and the IAEA’s Incident & Emergency Centre (IEC). The answer of all these organizations was negative because of the confidentiality protection of the data. Alternatively it was asked about the possibility to receive some “anonymous” information concerning the following rather general topics:

- Radioactive sources most typically subject of loss of control
- Number of events with unauthorized access, loss and theft of radioactive sources in each Member State
- Number of incidents/accidents with harmful exposure to such sources
- Number of events as a consequence of malicious intent

Unfortunately, and even so, very limited information was provided by the aforementioned institutions.

Europol deplored not being more supportive due to the impossibility to share data outside their restrictive legal framework.

IAEA’s Incident & Emergency Centre indicated that it is not in a position to give the information because any information related to radioactive materials belongs to the country (authority) which is responsible for the safekeeping of the material. In addition, the IAEA gets the information only in case of transnational or trans-boundary impact and therefore IEC does not have information if there were no such consequences over several countries.

The IAEA ITDB is not at liberty to provide access to the database to any commercial enterprise or private company regardless of their contractual obligations. The ITDB upholds strict information classification and dissemination procedures of information contained in the database which is provided globally by the 120 Member States ITDB Points of Contact. The only information obtained from ITDB is that there are very few incidents, perhaps single digit numbers that have involved harmful exposure and even fewer cases involving malicious intent.

Nevertheless, the IAEA ITDB releases some information to the public in so called “fact-sheet” about incidents of nuclear and other radioactive material out of regulatory control. The data given below represents a cross-section of the aggregated ITDB data that is available for the public domain (2013 fact-sheet).
The ITDB System contained a total of 2331 confirmed incidents over the period 1993-2012.

Of the 2331 incidents, 419 are determined as unauthorised possession and related criminal activities. These incidents mainly involved potentially weaponsusable nuclear material.

615 incidents involved theft or loss. The majority of thefts and losses reported to ITDB involve radioactive sources used in industrial or medical applications. Devices containing radioactive sources can be attractive to a potential thief as they may be perceived to have a high resale or metal scrap value. The majority of industrial sources that are reported stolen or lost are those used for non-destructive testing and for applications in construction and mining. The majority of such sources use isotopes such as Ir-192, Cs-137 or Am-241. Those incidents reported in 2012 range from potentially lethal category 2 to significantly less hazardous category 5 sources. The information received emphasises the need to improve security measures. A significant proportion of incidents reported to the ITDB is related to the loss of sources used in diagnostic and radiotherapy applications. These are generally the least dangerous category 5 sources that pose a relatively low hazard to human health. Many hospitals also house and use high-activity category 1 sources such as those used in radiotherapy treatment. However, it is rare to receive a report of an incident involving a source used for these applications. The recovery rate for category 1-3 sources is high due to the concerted effort made by the authorities to recover them.

1244 incidents involved other unauthorised activities and events. The reporting of this kind of incidents, especially “unauthorised disposal” and “unauthorised movement” has risen steadily since 2003. The rise is related to the increased number of radiation portal monitoring systems deployed at national borders and scrap metal facilities. In recent years, a growing number of incidents involved the detection of manufactured goods contaminated with radioactive material. This indicates a persistent problem for some countries in securing and detecting the unauthorized disposal of radioactive sources. The most common source of such contamination is the material (in most cases, metal) from which the product had been manufactured. This material may have originated from the metal recycling industry and, in the process of being melted down, became contaminated with material from a radioactive source such as cobalt-60. Such contaminated metal, if used to manufacture household goods, could pose a potential health problem to unsuspecting consumers.

In the remaining 69 cases, the category of incident was not determined.

Interpol provides information on radioactive and nuclear matters based on the Rutherford report that covers incidents from 2007 to 2009. Over that period, the non-nuclear radioactive materials involved in criminal incidents were: americium-241 (two cases), americium-241 together with caesium-137 (three cases), and americium-241 together with iron-55, cadmium-109, cobalt-60 and nickel-63 (one case each). There were two further cases with an unidentified isotope. Criminal incidents took only a minor percentage (less than 8 per cent) of all reported incidents in 2007-2009. These included one investigative confiscation of low-enriched uranium in 2007, one attempted purchase of radioactive material in 2009, two attempted sales of depleted uranium in 2008 and of natural uranium in 2007, as well as three attempted scams, one in 2007 and two in 2009, in which no nuclear or radioactive material was actually available for sale. There were also one hoax threat in 2007 and 14 thefts: four in 2007, six in 2008 and four in 2009. Over 2007-2009, no cases involving the attempted use of radioactive material to injure or poison individuals were reported.
8.2 Data from Member States

From the data received, it can be concluded that the discovery of radioactive sources or contaminated items in scrap metal is by far the most frequent incident encountered. The detection occurs at scrap metal facilities but also at national borders. The main concerned isotopes are Cs-137 and Ra-226.

The second most frequent event reported by the MS is the discovery of orphan sources. Orphan sources were recovered at children playgrounds or public places, municipal dumps and during take-over of facilities or in nearly bankrupt companies. The orphan sources recovered are Ra-226, Co-60, Cs-137, Sr-90 and Pu-239 in smoke detectors.

Incidents with radioactive sealed sources also occur during operations. The sources involved are mobile sources of Co-60 and Ir-192 that are used in gammagraphy or in radiotherapy. Typical incidents are leaking sources, failure of source retraction, sources jammed out of device, etc. Such incidents are reported by Bulgaria, France, Germany, Italy and Poland.

Several cases of loss of sources are also mentioned in Ireland, Poland and Slovenia. The loss is generally discovered during inspections. The involved isotopes are Ra-226 and Co-60.

Thief of sources is only reported by Bulgaria with 13 incidents recorded over the period 1998-2010. Two cases of theft of HASS are reported in 2012:

- A radiography device loaded with Ir-192 source of 10 Ci was stolen in Sofia when the device was left unattended by a worker. The device was found within 24 hours and nobody was injured.
- Three level gauges loaded with Cs-137 sources (about 50 GBq each) were stolen from a factory. The gauges were dismantled by the thieves. Within 24 hours after the report of the theft, the police found the containers in a scrap yard and the sources in the area where the thieves live. The sources were recovered and transferred to a temporary storage and afterwards to the Novi Han repository. 35 people from the concerned area were under medical monitoring but no health consequences were noticed. The incident was classified on level 2 of the INES scale.

8.3 Countermeasures

After the loss or theft of a source, the best practices generally identified are as follows:

- Efficient information exchange between relevant stakeholders (authorities, emergency teams, etc.),
- Search investigation at potential locations,
- Public information in local or national media to warn potentially affected people,
- International information exchange.

In case a source is lost or stolen, the authority should search for other similar "vulnerable sources" used in the same practice(s) by other holders to promote awareness and to check whether adequate preventive measures are in place.
Once a source is detected, the most efficient counter-measures are identified as being:

- Immediate isolation of the source and of the area to prevent access by unauthorized persons,
- Dosimetric and contamination measurements by skilled experts,
- Removal of the source and transport for safe storage,
- Enquiry to identify the source holder,
- Efficient information exchange (local, national and international).

In Bulgaria, an annex to the national emergency plan is specifically dedicated to emergency cases with orphan sources. In such cases, an emergency team from the Nuclear Regulatory Agency, the Ministry of Health and the Ministry of Internal Affairs (civil protection and fire protection directorate) is formed. In addition, every user of radioactive sources must have an internal emergency plan that is reviewed by the nuclear regulatory body during the licensing process and during inspections. In case of incidents or accidents, the users must inform promptly the NRA and the Ministry of Internal Affairs. Facilities such as scrap yards, border check points, etc. must also elaborate an emergency plan taking into account the case where a source is discovered at their premises. To prevent the occurrence of incidents or accidents involving radioactive sources, different actions were performed in Bulgaria. For instance, campaigns for the collection of disused radioactive sources from past practices have been organised. During the period 2006-2009 about 5400 sources were recovered and transferred to the national repository in Novi Han. Monitoring portals were also installed on main scrap processing plants and on border crossing points. A guide dedicated to the monitoring of metal scrap and to the response and alarming procedures was developed and published on the NRA website. A simplified version of this guide was elaborated specifically for scrap yard workers and distributed among them. Lectures about sealed sources management, physical protection, emergency preparedness, etc. were also organised for scrap yard workers, users of radioactive sources, border police officers, etc.

In Spain, subsequently to the Acerinox radioactive source melting event that occurred in Algeciras in May 1998, several actions were taken. A protocol was established and signed between the involved stakeholders (Ministries, professional associations, radioactive waste management agency, Nuclear Safety Council ...). The protocol is a voluntary commitment subscribed by the industry and the administration that aims at establishing a national system for the prevention of risks arising from the presence of radioactive materials in scrap and in the products resulting from its processing. Metal recycling companies register for free, but on a voluntary basis, their own facility in the Protocol Register. By signing the protocol, each party takes several commitments that start automatically after signature. In this frame, the Ministry of Industry, Energy and Tourism has issued a generic authorization to transfer any radioactive material detected to the radioactive waste management agency, has created and maintains the register of inscribed companies, and manages whatever action in case of contamination or dispersion of radioactive material. The nuclear regulatory authority has committed to establish the radiological criteria and advice on issues relating to the radiation protection of people and the environment, to inspect the radiological surveillance, and to promote and coordinate training and information plans. The radioactive waste management agency is in charge of removing and taking custody of the radioactive materials detected in scrap when they exceed the exemption levels on the one hand and, on the other hand, of providing technical advice to the companies subscribing the protocol. On their side, the subscribing companies commit to:

- establish a radiological surveillance and control system for each facility at which scrap is processed and isolate whatever radioactive material might be contained in scrap;
- adopt the measures required to prevent dispersion and take the safety measures until removal by the radioactive waste management agency.
If a generalized contamination of the facility is detected, the nuclear regulatory authority shall be informed immediately. The regulatory body will assess the information provided and will inform the Ministry of Industry, Energy and Tourism. In addition, the nuclear regulatory authority will control urgent actions related to the protection of the workers and the public. All costs linked to the implementation of the protocol are covered by the subscribing companies, although they may pass them on to their scrap suppliers. However, the management of Spanish sources detected may be financed through the Residual Waste Management Fund; the activities of the nuclear regulatory body in this field are financed by specific taxes. Information is provided to workers of the metal recycling sector to present the protocol and to increase awareness. Training is also given to concerned workers to familiarise them with radiation risk and basic radiological protection as well as to train them in the use of radiation detectors and radiation protection equipment. The lessons learnt from the implementation of the protocol in Spain point out that:

- Emphasis should be placed on workers’ training since the “human factor” was behind all the incidents. A database including pictures of all events in which radioactive material has been found is being developed by the nuclear regulatory authority;
- The scope of the protocol must be extended to incorporate other industrial sectors, such as industries managing dust from steel facilities;
- It is necessary to improve the screening procedure to separate regular waste materials from those materials that are to be managed as radioactive waste;
- The facilities specifically devoted to fragment the scrap must have a portal detector at the entrance;
- Controlling outgoing products with a portal monitor is a useful method to detect radioactive contamination.

Based on the lessons learnt, the recommendations made by the nuclear authorities of the MS to keep radioactive sources under control and to safely manage incidental situations are:

- robust systems for accounting, controlling and ensuring traceability of radioactive sources throughout their life cycle, including rigorous follow-up for timely submission of all necessary reports;
- regular inspections and interaction between holders and regulatory body;
- strengthening requirements of physical protection in high-risk facilities;
- compulsory training of the personnel;
- strengthening border control to detect radioactive materials;
- exchange of information among the national competent authorities and international organisations;
- public information and awareness;
- preventive control in companies dealing with scrap metal;
- elaboration, maintenance and testing of pre-established plans for prevention of and response to incidents involving HASS, orphan sources and radioactive scrap.
9 POSSIBLE MEASURES TO IMPROVE HASS SECURITY

9.1 Introduction

While nuclear materials are under the strict control of the safeguard authorities, the control regime of radioactive sources available in the commercial, health-care and research sectors may be insufficient. Control has been lost over a small fraction of those sources, sometimes resulting in accidents of which some have had serious consequences. Besides, there is a growing concern about the possibility of terrorist or criminal use of such radioactive sources. Consequently, efforts are being made towards increased control, accounting and security of radioactive sources to prevent any malicious act or loss of control.

A set of reference documents is available (see section Reference Documents) to provide guidance for regulatory bodies and operators to set up their own security system, adapted to their specific situation.

Considering the half-life of radioisotopes and their commercial availability, about a dozen of radioisotopes are of potential security concern (Am-241, Cf-252, Cs-137, Co-60, I-131, Ir-192, Po-210, Pu-238, Pu-239, Ra-226, Sr-90) [4]. The radioactive materials of greatest security concern are commercial radioactive sources that contain relatively high activities. In addition to radioactivity the chemical and physical properties of a source also influence the security risks (e.g. Cs chloride powder which can be easily dispersed).

9.2 General principles

The States are responsible to provide for the physical protection of nuclear and other radioactive material and their associated facilities, to ensure the security of such material, including in transport, and to combat illicit trafficking and the inadvertent movement of such material [2].

The Operators, as the authorized entities, should have the primary responsibility for implementing and maintaining security measures for radioactive sources in accordance with national requirements. They should also ensure that their personnel and contractors are suitably trained and meet the regulatory requirements, which should include trustworthiness [2].

Security measures should not compromise the safety of individuals or the protection of the environment. Safety and security measures should be designed and implemented in an integrated manner [2].

9.3 Physical protection – Security system

In order to put in place a security system, international guidance suggests a graded approach using a set of security levels, and the security functions of deterrence, detection, delay, response and security management [2]. Indeed, the purpose of a security system is to deter adversaries from committing a malicious act or to minimize, through detection, delay and response, the likelihood of an adversary succeeding in completing such a malicious act.

Three basic principles in relation to physical protection are:
1. The principle of the graded approach. Its objective is to ensure that highest consequence sources receive the greatest degree of security. According to that principle, the threat against the particular material, equipment or nuclear material shall be taken as basis to design and construction of the physical protection system. It takes thus into account the evaluation of the threat environment, the relative attractiveness of a radioactive source, the nature of the source and potential consequences associated with its unauthorized removal or sabotage. Categorization of sources according to security levels (see [2]) helps to provide a common international basis for decision making.

2. The protection-in-depth concept requires the application of a complex system of principles, administrative measures and technical solutions built onto each other to ensure physical protection, where the system guarantees the realization of the required level of protection by a combination of various independent protection levels applied in a specific sequence.

3. The concept of equal protection means that the physical protection system shall provide approximately equivalent protection against each potential intrusion routes and tactics under any (i.e. environmental, meteorological, lighting) conditions.

The operation of the physical protection system of a nuclear facility, the use, storage and transport of nuclear and other radioactive materials, as well as the particular implementation of the deterrence, detection, delay and response physical protection functions shall be described in a physical protection plan.

In order to determine the methods how the requirements should be complied with and so, as to proceed smoothly and duly during the respective licensing and inspection procedures, the authority should summarize its physical protection recommendations in physical protection guidelines.

### 9.4 Management of risks

In order to manage the risks, it is crucial to assess the vulnerabilities of the sources and their potential consequences, and thus to examine all stages of the life-cycle of the sources (“cradle to grave”).

In addition to implementing physical measures to protect the radioactive material, it is important to clearly understand the threat, improve the organisations’ security culture, analyse internal threats and plan the response to an incident well before it occurs.

As recommended by the World Institute for Nuclear Security (WINS) [3], to help determining the most appropriate security measures, one should look at the following areas:

- Understand roles and responsibilities
- Develop a strong security culture
- Define and assess the threat environment
- Understand the targets for malicious acts and their vulnerabilities
- Apply a graded approach to security and provide defence in depth
- Design the security system
- Draft a security plan
- Protect sensitive info
- Develop an effective, coordinated response strategy
- Plan for end of life
The defence-in-depth or layered security approach is a mechanism to build up an increasingly strong system of radiological risk reduction [4]. In case an event unfortunately occurs, the mitigation of consequences (emergency response and decontamination) should also be addressed.

Thus, according to [4], to reduce the risk, reducing both likelihood and consequences should be considered, by making efforts on the following topics:

- Improving security of radioactive sources
- Decreasing the use of certain types of very potent or dispersible radioactive materials
- Enhancing regulatory controls
- Improving export controls
- Increasing government cooperation in intelligence sharing about threats
- Deploying radiation detectors and other means as « second line of defence »
- Rounding up disused and orphaned sources
- Developing improved disposal and recycling pathways for sources
- Developing and deploying better decontamination technologies
- Improving the training of emergency first responders
- Increasing the capacity for effective international response to radiological incidents

A basis for an efficient security system is a good tracking system.

A concrete example of how a security programme may be applied is given in the “Security of Nuclear Substances: Sealed Sources” [5], as reproduced in the following table (Security levels and security objectives).
## Study on the current status of radioactive sources in the EU

<table>
<thead>
<tr>
<th>Security program sub sections</th>
<th>Category 1 - high risk</th>
<th>Category 2 - high risk</th>
<th>Category 3 - medium risk</th>
<th>Category 4 and 5 - low risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access control</td>
<td>• restrict access to authorized user only</td>
<td>• restrict access to authorized user only</td>
<td>• restrict access to authorized user only</td>
<td>• source should be protected against unauthorized access and removal</td>
</tr>
<tr>
<td></td>
<td>• two-person rule (optimal)</td>
<td>• visitors, students, contractors must be escorted at all times by an authorized user</td>
<td>• visitors, students, contractors must be escorted at all times by an authorized user</td>
<td></td>
</tr>
<tr>
<td>Intrusion detection system</td>
<td>• must provide immediate detection and be linked to a ULC-certified control room monitored by an operator 24/7 or an equivalent mechanism (i.e., continuous surveillance by operator) for detection, assessment, and communication with response personnel in case of security event</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perimeter and/or physical barrier</td>
<td>• must be protected with at least two physical barriers (i.e., walls, cages, secure containers) to separate the source from unauthorized personnel and provide sufficient delay to allow for immediate detection, and for response personnel to intervene before the adversary can remove the source</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Security of storage</td>
<td>• secured with high quality padlock, high security lock or equivalent security system</td>
<td>• secured with high quality padlock, high security lock or equivalent security system</td>
<td>• secured with high quality padlock, high security lock or equivalent security system</td>
<td>• source should be stored in a secure container or location</td>
</tr>
<tr>
<td></td>
<td>• equipped with a minimum of one intrusion detection system or equivalent</td>
<td>• equipped with a minimum of one intrusion detection system or equivalent</td>
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<tr>
<td></td>
<td>• secure containers must be able to resist an attack by handheld tools</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Response protocol</td>
<td>• specific response protocol and contingency plan</td>
<td>• generic response protocol and contingency plan</td>
<td>• source should be protected against unauthorized access and removal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• contact local law enforcement</td>
<td>• must develop a procedure in case of lost, stolen or malicious act involving radioactive sealed source</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• effective response time</td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>• must develop a procedure in case of lost, stolen or malicious act involving radioactive sealed source</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintenance and testing</td>
<td>• maintenance and testing must be conducted at least every six months, and written records should be maintained</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Possible measures to improve HASS security

<table>
<thead>
<tr>
<th>Security program sub sections</th>
<th>Category 1 - high risk</th>
<th>Category 2 - high risk</th>
<th>Category 3 - medium risk</th>
<th>Category 4 and 5 - low risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility security plan</td>
<td>reviewed annually or when important changes are done at the facility</td>
<td>classified prescribed and/or sensitive and stored appropriately</td>
<td>reviewed on a regular basis or when important changes are done at the facility</td>
<td>prudent management practice</td>
</tr>
<tr>
<td></td>
<td>communicated on a need to know basis</td>
<td>indicate measures in case of increased threat</td>
<td>must be classified prescribed and/or sensitive and stored appropriately</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>communicated on a need to know basis</td>
<td></td>
</tr>
<tr>
<td>Personal trustworthiness or background checks</td>
<td>criminal records name check</td>
<td>reference, education and employment verification</td>
<td>reference, education and employment verification</td>
<td>reference, education and employment verification</td>
</tr>
<tr>
<td></td>
<td>drivers and contractors (i.e., carriers) with unescorted access to radioactive sources must undergo this verification</td>
<td>criminal records name check</td>
<td>criminal records name check (prudent management practice)</td>
<td></td>
</tr>
<tr>
<td>Information security</td>
<td>all prescribed information must be protected and be shared on a need to know basis</td>
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<tr>
<td>Security awareness program</td>
<td>all authorized users, including staff who transport radioactive sources, must receive security awareness training on a regular basis</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Vehicle security</td>
<td>vehicle must be equipped with anti-theft or vehicle disabler and intrusion detection system, or equivalent measures</td>
<td>vehicle must be equipped with a minimum of two technical barriers to prevent unauthorized removal of the radioactive source/device</td>
<td>vehicle must be equipped with anti-theft and intrusion detection system or equivalent measures</td>
<td>source should be protected against unauthorized access and removal</td>
</tr>
<tr>
<td></td>
<td>vehicle must be equipped with a minimum of two technical barriers to prevent unauthorized removal of the radioactive source/device</td>
<td>access must be restricted to authorized users only</td>
<td>vehicle must be equipped with a minimum of two technical barriers to prevent unauthorized removal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>drivers must be equipped with a means of communication in case of emergency</td>
<td>two-person rule (optional)</td>
<td>drivers and operators must undergo a trustworthiness verification</td>
<td></td>
</tr>
<tr>
<td></td>
<td>drivers and operators must undergo a trustworthiness verification</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Transportation security plan</td>
<td>must develop and submit a specific Transport Security Plan to CNSC for review and approval</td>
<td>must develop and maintain a generic Transport Security Plan</td>
<td>prudent management practices</td>
<td>source should be protected against unauthorized access and removal</td>
</tr>
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<td></td>
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</tr>
</tbody>
</table>
9.5 TMT Handbook

In relation with mitigation of consequences (emergency response and decontamination), it is worthy to mention the following initiative.

The TMT handbook (Triage, Monitoring and Treatment of people exposed to ionising radiation following a malevolent act) [6] is dedicated to emergency response organisations with functions to plan, coordinate and execute mitigating actions (field operations, medical treatment at the hospital, public health response). It has been developed in a European research project (2006-2009) under the FP6 Euratom programme by six European partners and the World Health Organization (WHO) and is freely available upon registration (http://www.tmthandbook.org/).

It provides guidelines for response to malevolent acts involving radioactive material such as:

- Radiological Exposure Device
- Radiological Dispersal Device
- Attack on transport of radioactive material
- Contamination of food and water supplies

It is based on:

- existing and new knowledge and recommendations
- international consensus on treatment alternatives
- interaction with and feedback from end users

9.6 Information from other international activities

The World Institute for Nuclear Security (WINS) workshop “Enhancing the security of the “front end” of the radioactive source life cycle” in 2012 concluded that the development of a security culture is mainly based on education and training. Regular assessments, visits and follow-up actions are needed to keep the people engaged. Co-operation between authorities is also required to establish harmonized systems. As for safety, regulations and enforcement by inspections will provide the structure to effectively implement security measures. Security culture is different between front-end (sources manufacturer, isotopes producer) and back-end (end user, e.g. hospital, well logging) of the source cycle. The security culture decreases in facilities where the source does not represent the main part of work. As a result, the security level is decreasing from isotope production, source production, device manufacturer, user, to transport.

Another topic discussed was the radiological dispersal devices (RDD). The high-risk sources are the ones which are portable, dispersible and containing a significant radioactivity. Based on the chart of radionuclides, the isotopes of concern regarding the security aspects are those with the following features:

- Half-life longer than 7 days and shorter than 100 000 years
- Commercially available
- Available in large quantities in sources

Taking into account these features, only about 14 radionuclides are considered: Co-60, Se-75, Sr-90, Cs-137, Tm-170, Yb-169, Ir-192, Po-210, Ra-226, Pu-238, Pu-239, Am-241, Cm-244 and Cf-252. This list has to be compared with the US commercial radionuclide inventory which gives in descending order: Co-60> Cs-137 & Sr-90 > Ir-192 > Am-241 > Se-75 > Pu-238 > Pu-239 > Cf-252 > Cm-244 > Ra-226. In the US, Co-60 sources are still used and
produced for medical applications (gamma-knife, breast tumour treatment) although linear accelerators are more and more used worldwide.

To increase the physical protection of sources, one option would be the reinforcement of the capsule itself. However, if the encapsulation is reinforced, it will increase attenuation and higher activity sources will be required. The option is to replace powder dispersible radionuclide by pellet, thin disk or glass (insoluble) but again the sources are then bigger for the same activity. For instance, the major risk is due to $^{137}$CsCl powder, which is a key material for terrorists. It represents a greater threat than other radionuclides and should be replaced by Cs under the form of pellet or glass to reduce the dispersion.

The replacement of radioactive sources by alternative devices is also a point of attention of the international security community. Alternatives exist such as linear accelerators and x-ray machines (also for sterilization), which are more and more used in countries with good power supply (blackouts must be avoided). However, it does not satisfy all the applications according to the source manufacturers.

One recommends establishing a security ranking of devices. Based on this ranking, design improvements of both devices and sources should be developed and implemented during the manufacturing.

The issue of transport was also addressed. The basic principles to be followed are:

- monitoring to detect orphan sources
- consent between importing and exporting governments
- continuous control during international transport

Current controls on highways for category 1 sources put in place in USA are:

- position tracking
- constant surveillance
- redundant communication between cabs and centres
- route notification
- coordination between consignor and consignee
- additional controls as required by national/local authorities

The main challenges encountered when transporting HASS are:

- high transportation costs may discourage some end-users from returning disused sources back to supplier
- delays/denials during transport increases vulnerability of the consignment
- lack of safe havens if transit is delayed prior to reaching consignee
- lack of harmonized transportation security regulations
10 CONCLUSIONS AND RECOMMENDATIONS

The number of HASS currently registered in Europe is more or less the same as in Canada and represents half of the US inventory. A total of 30 700 HASS is reported through the national inventories of 25 Member States (MS) in which 4 countries account for 70% of the total sources inventory and 63% of the European HASS Holders. Since the number of HASS in the EU MS ranges from only a few to several thousands, the practical implementation of the HASS Directive requirements is strongly variable among MS.

To assess the status of the HASS Directive implementation in Europe, compliance of the current situation prevailing in each MS with 17 major requirements of the HASS Directive was checked. The main conclusion is that the HASS Directive is well implemented in the MS. Only 1 requirement is overall rather poorly implemented and concerns the Article 9.4 of the HASS Directive related to the organization of recovery campaigns for orphan sources. Half of the MS have not organized such campaigns arguing that HASS are under control, the inventories are updated, no orphan sources have yet been discovered on their territories, detection means are installed at borders, etc. In addition, 5 requirements of the HASS Directive show points of attention in more than 30% of MS. The requirements requiring attention concern training and information of workers potentially confronted to orphan sources, legislative framework, control of HASS by the holder, identification and marking of HASS and long-term management of disused HASS.

The analysis has been pursued by evaluating the level of implementation of the HASS requirements. The objective of this second analysis is to identify the best practices, weak points and points of attention from the safety and security perspective (regulatory framework, prevention, detection and response). 43 items over the aforementioned 17 requirements of the HASS Directive were compared between MS. The objectivity of the analysis is ensured by the establishment of an evaluation grid with specific criteria and an assessment by 4 experts independently. The best implemented items at the European level are: availability of a complete central inventory of all sources above exemption levels (20 out of 27 MS), regular performance of inspections covering both safety and security issues (24/27), checking of all HASS records during inspections (19/27), mechanism of financial security for the long-term management of HASS financed by the holders or suppliers (20/27), identification of strategic location where orphan sources are likely to be found (23/27), availability of emergency team 24/7 (22/27) and establishment of on-site emergency plan for HASS holder approved by the authority (21/27). The identified weak points and points of attention were analysed in the same way and are the basis of the final recommendations.

Comparison of the legislations and strategies in force in Canada and in the United States with the requirements of the HASS Directive has been carried out to put in evidence the good practices which could be transposed at the European level. The criteria used to assess the different topics of both North-American legislations are those defined for the analysis at the European level. As a conclusion of this comparison, it appears that the European legislation is at least as well developed as the US/Canadian ones. Some good practices identified in the US and Canada could advantageously be transposed at the European level for supporting the implementation of the HASS Directive and the new EU Basic Safety Standards (Directive 2013/59/EURATOM). However the opposite is also true and some HASS Directive provisions could be implemented in the USA and Canada to improve the control over high-risk sources.

The position of the industry regarding the HASS Directive requirements was given by the International Source Suppliers and Producers Association. The industry is pleading for a harmonized implementation of international rules especially on an internal market like the European Union. The requested harmonization concerns shipments, HASS definition, harmonized national electronic records, identification and marking and long-term management of disused radioactive sources. Regarding the last point, the recycling of
disused source appears to be the industry's preferred option while long-term storage is the less preferred option.

With regard to the analysis on incidents in Europe due to a loss of control of radioactive sources, access to information was addressed to Europol, Interpol and IAEA. Because of the confidentiality protection of the data, very limited information was provided. The only information obtained from the Illicit Trafficking Data Base (ITDB – IAEA) representative is that there are very few incidents, perhaps single digit numbers, that have involved harmful exposure and even fewer cases involving malicious intent are reported. Interpol indicated that criminal incidents took only a minor percentage - less than 8 per cent - of all reported incidents in 2007-2009.

From the data received through the questionnaires, it can be concluded that the discovery of radioactive sources or contaminated items in scrap metal is by far the most frequent incident encountered. The detection occurs at scrap metal facilities but also at national borders. The second most frequent event reported by the responding MS is the discovery of orphan sources. Orphan sources have been recovered at public places (even at children's playgrounds), municipal dumps and during take-over of facilities or in nearly bankrupt companies.

Based on the lessons learnt, the recommendations made by the authorities of the MS to keep radioactive sources under control and to safely manage incidental situations are: systems for ensuring traceability of radioactive sources throughout their life cycle, regular inspections, requirements of physical protection in high-risk facilities, compulsory training of the personnel, border control to detect radioactive materials, exchange of information among the national and international competent authorities, public information, testing of pre-established plans for prevention of and for response to incidents involving HASS.

Based on the analysis of the HASS Directive implementation in the MS, several recommendations related to the most important weak points or points of attention identified in this project can be addressed in order to improve its implementation through the whole life cycle of HASS:

- The current definition of HASS can result in practical management concerns. For example significant efforts must be devoted to low risk sources, which is not in line with the graded approach principle. Moreover, the current activity limits are not coherent with the IAEA source categorization, causing difficulties with e.g. the implementation of the Code of Conduct and international transport. The associated recommendation would be the revision of the HASS definition by considering actual activity levels and limits in line with the IAEA source classification. This is transposed in the new EU Basic Safety Standards in which the HASS definition refers to current activity, not anymore to the activity at the time of manufacture or placing on the market. Awaiting the transposition of the new EU Basic Safety Standards Directive, MS 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 high-activity levels.

- To ensure the immediate notification of any modification of the HASS status, the national regulatory framework should define a maximum tolerated delay of a few days within which the relevant authority must be notified.

- 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 to ensure that
they were effectively performed and the outcomes of the tests have been taken into account by the holders.

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

- The concept of “undue delay” for removal of disused sources from users’ premises is implemented in Member States in very different ways. To avoid the risk of loss of control of disused HASS stored at the holder’s premises, the national regulation should set a reasonable maximal period of time for storing disused sources at holder’s premises after which the HASS must be removed either by return to supplier or placement in a recognized storage facility for radioactive waste or transfer to another authorized holder. Compliance with this requirement should be controlled during inspections and the necessary enforcement actions should be taken once noncompliance is observed. To avoid undesirable situations, adequate arrangements for the long-term management of disused HASS should be a prerequisite to authorisation for any practice.

- The arrangements to be made for the financial guarantees for management of disused HASS and orphan sources are widely interpreted by the Member States and vary from pure contractual arrangements over State guarantees to monetary deposits. The associated recommendation would be to clarify what are the acceptable financial guarantees and to what extent “the money” has to be physically available.

- Need for organising systematic or dedicated orphan sources recovery campaigns should be assessed in the MS which have not organised yet such campaigns. A first step to assess the need of recovery campaign would be the analysis of historical records available at the authority and at the manufacturers/suppliers. During inspections at facilities where disused/orphan sources are more likely to be found such as hospitals, universities, research centres, military sites, etc. deeper investigations in the premises using measuring devices could be performed for searching legacy sources possibly present on the site.

- 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, the organisation of training sessions should be obligatory according to national regulation. 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.
11 REFERENCE DOCUMENTS

4. Ensuring the Security of Radioactive Sources: National and Global Responsibilities - C. Ferguson (2012)
5. Security of Nuclear Substances: Sealed Sources – REGDOC-2.12.3 issued in May 2013 by the CNSC (Canadian Nuclear Safety Commission)
6. TMT Handbook, Triage, Monitoring and Treatment of people exposed to ionising radiation following a malevolent act (2009)
### 12 APPENDIX 1 EVALUATION GRID AND CRITERIA FOR EVALUATION

<table>
<thead>
<tr>
<th>#</th>
<th>Item</th>
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<tr>
<td>1</td>
<td>Regulatory authority</td>
<td>All responsibilities within one regulatory authority</td>
<td>One regulatory authority and some responsibilities with few Ministries</td>
<td>Responsibilities spread over several institutions</td>
<td>Overlapping of responsibilities between more than 1 regulatory authority</td>
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<tr>
<td>2</td>
<td>Implementation of HASS Directive</td>
<td>—</td>
<td>Full implementation reported</td>
<td>—</td>
<td>Not fully transposed</td>
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<td>3</td>
<td>Compliance with HASS definition or implementation in accordance with the definition</td>
<td>—</td>
<td>Same definition &amp; implemented accordingly</td>
<td>Different definition used or implementation not in accordance with the definition</td>
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**Part 2: Prevention & Deterrence**

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<td>4</td>
<td>All relevant issues are considered during licensing process</td>
<td>Practical experience with refusing authorization / Time limited license</td>
<td>All relevant topics are considered</td>
<td>Contradictory information</td>
<td>Not all relevant topics considered</td>
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<td>5</td>
<td>Maintenance of records by HASS holders</td>
<td>—</td>
<td>Maintenance of records required</td>
<td>Defective practical implementation</td>
<td>—</td>
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<td>6</td>
<td>Notification of records to the authority</td>
<td>Direct notification with tolerated delay defined in regulation</td>
<td>—</td>
<td>Tolerated delay not defined in regulation</td>
<td>No direct notification</td>
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<tr>
<td>7</td>
<td>Recorded information in compliance with data of Annex 2 of HASS Directive</td>
<td>—</td>
<td>Complete data are recorded</td>
<td>—</td>
<td>Partial data are recorded</td>
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<td>8</td>
<td>Central inventory available and complete</td>
<td>All sealed sources above exemption</td>
<td>Only HASS inventory</td>
<td>Database not designed to produce total inventory</td>
<td>No central registry even for HASS</td>
</tr>
<tr>
<td>9</td>
<td>Availability of registry to law enforcement authorities</td>
<td>At all times</td>
<td>—</td>
<td>Under request</td>
<td>Registry not available to police</td>
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## Study on the current status of radioactive sources in the EU

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<tr>
<td>10</td>
<td>Inspections</td>
<td>Unannounced inspections performed</td>
<td>Inspections regularly performed</td>
<td>Limited resources / Inconsistent inspection programme</td>
<td>No inspection</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Checking of records</td>
<td>Records of all HASS are checked during inspections</td>
<td>HASS records are checked during inspections</td>
<td>All HASS records are not systematically checked</td>
<td>No periodic inspection of HASS</td>
</tr>
<tr>
<td>12</td>
<td>Training of inspectors</td>
<td>Very specific &amp; detailed training</td>
<td>Adequate training</td>
<td>Partial or on-job training</td>
<td>Training not defined/documentation</td>
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<td>Scope of inspections</td>
<td>Inspections cover both safety and security</td>
<td></td>
<td>Only safety aspects are checked</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>System of penalties</td>
<td>System of penalties in place and practical experience with enforcement</td>
<td>System of penalties in place</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Performance of tests by HASS holders</td>
<td>Frequency is defined in regulation or authorization / Tests are carried out by accredited expert</td>
<td>Tests are regularly performed</td>
<td>Leak test are not systematically performed</td>
<td>No test or limited tests performed</td>
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<td>16</td>
<td>Verification of test performance by authority</td>
<td></td>
<td>Verification by the authority</td>
<td></td>
<td>Limited information on tests performed received by the authority</td>
</tr>
<tr>
<td>17</td>
<td>Definition of HASS holder’s training programme</td>
<td>Training programme defined or approved by the authority</td>
<td>Training programme defined by the holder with support of recognised organisations</td>
<td>Training programme defined by the holder</td>
<td>No training programme</td>
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<td>18</td>
<td>Recording of training courses for HASS holders</td>
<td>Training courses are documented &amp; comprehension test is organised</td>
<td>Training courses are documented &amp; no info on comprehension test</td>
<td>Training courses are documented but no comprehension test is organised</td>
<td>Training courses are not documented</td>
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### Appendix 1 Evaluation grid and criteria for evaluation

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<tr>
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<td>19</td>
<td>Repetition of HASS holder’s training</td>
<td>Yearly</td>
<td>Adequately repeated</td>
<td>Defined by the holder</td>
<td>No frequency defined or repeated at a 5 years frequency</td>
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<td>20</td>
<td>Staff trained</td>
<td>Exposed workers and management</td>
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<td>Defined by the holder</td>
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<td>Verification of training performance by authority</td>
<td>Check of training records by the authority and regular reporting by holder</td>
<td>Check of training records by the authority</td>
<td>—</td>
<td>Training records are not checked during inspection</td>
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<td>22</td>
<td>Documentation accompanying HASS</td>
<td>—</td>
<td>Documentation as required in HASS Directive</td>
<td>Documentation not in compliance with HASS directive requirements</td>
<td>—</td>
</tr>
<tr>
<td>23</td>
<td>Verification of documentation by authority</td>
<td>Documentation verified by the authorities or TSO</td>
<td>—</td>
<td>Documentation not verified</td>
<td>—</td>
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<tr>
<td>24</td>
<td>All sources on the territory have an ID</td>
<td>—</td>
<td>All sources have ID</td>
<td>Some historical sources are not properly identified with ID</td>
<td>Unreadable ID</td>
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<td>25</td>
<td>Control system of HASS transfer</td>
<td>Permit for each transfer needed</td>
<td>System of control in place but permit for each transfer not specifically required</td>
<td>Information on HASS transfer from holder records sent to authority once a year</td>
<td>Transfer not fully under control</td>
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<tr>
<td>26</td>
<td>Verification that recipient is authorised</td>
<td>—</td>
<td>Holder ascertains that recipient is authorised</td>
<td>—</td>
<td>Authority is informed by Recipient’s country authority</td>
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<td>27</td>
<td>Long-term management as prerequisite to authorisation</td>
<td>—</td>
<td>Long-term management is a prerequisite to authorisation</td>
<td>Contradictory information</td>
<td>Long-term management is not a prerequisite to authorisation</td>
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## Part 3: Detection

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<td>Maximum time for storage at holder's</td>
<td>Reasonable maximum storage</td>
<td>Authorization for storage required</td>
<td>Tolerated storage time at holder's</td>
<td>No time frame defined for storage /</td>
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<td></td>
<td>premises</td>
<td>time set in regulation</td>
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<td>premises too long (≥ 5 years)</td>
<td>storage at holder premise as long-term</td>
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<td></td>
<td></td>
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<td>solution</td>
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<tr>
<td>29</td>
<td>Financial security for long-term</td>
<td>Take back provisions &amp; financial</td>
<td>Take back provisions with financial</td>
<td>Take back provisions without financial</td>
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<td></td>
<td>management</td>
<td>arrangements by holder/nuclear industry</td>
<td>guarantee by State</td>
<td>arrangements</td>
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<td>Access to centralised storage facility</td>
<td>Centralised storage facility with</td>
<td>No information on storage facility</td>
<td>Centralised storage facility with</td>
<td>Lack of centralised storage facility</td>
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<td>adapted capacity</td>
<td>capacity</td>
<td>limited capacity</td>
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<td>31</td>
<td>Security measures</td>
<td>Specific security measures required by</td>
<td>Adequate security measures implemented</td>
<td>Specific regulation in preparation</td>
<td>Limited security measures</td>
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<td></td>
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## Part 4: Preparedness and response

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<td>32</td>
<td>Identification of strategic locations</td>
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<td>Identification in progress</td>
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<td>Strategic locations are not identified</td>
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<td>33</td>
<td>Detection means at strategic locations</td>
<td>Detection means are regulatory imposed</td>
<td>Detection equipment is present</td>
<td>Detection equipment is not installed at</td>
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<td></td>
<td>all strategic locations</td>
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<td>34</td>
<td>Organisation of recovery campaigns</td>
<td>Dedicated budget available</td>
<td>Recovery campaigns are organised</td>
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<td>Recovery campaigns are not organised /</td>
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<td></td>
<td>no budget available</td>
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<td>35</td>
<td>Financial security for orphan sources</td>
<td>Financial guarantee paid by Holders</td>
<td>Financial guarantee paid by nuclear</td>
<td>Financial guarantee paid by State</td>
<td>No financial strategy</td>
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<td>industry</td>
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<td>36</td>
<td>International cooperation</td>
<td>—</td>
<td>Participation to IAEA Illicit</td>
<td>No participation to ITDB but information</td>
<td>Lack of information exchange</td>
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<td>Trafficking Database</td>
<td>exchange when necessary</td>
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## Part 4: Preparedness and response
### Appendix 1 Evaluation grid and criteria for evaluation

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<td>National off-site emergency plan</td>
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<td>Organisation at the regional level</td>
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<td></td>
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<td>established</td>
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<td></td>
</tr>
<tr>
<td>38</td>
<td>Availability of emergency team</td>
<td>Emergency team available 24/7</td>
<td>Emergency team available on request</td>
<td>No pre-established emergency team</td>
<td>No emergency team</td>
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<td>39</td>
<td>On-site emergency plan for HASS holder</td>
<td>Emergency plan approved by the authority</td>
<td>Emergency plan required</td>
<td>Emergency plan required only for sources &gt; 1 TBq</td>
<td>No emergency plan</td>
</tr>
<tr>
<td>40</td>
<td>On site response and alarming procedures where orphan sources are likely to be found</td>
<td>Procedures approved by the authority</td>
<td>Procedures required</td>
<td>Procedures not required</td>
<td>No procedures</td>
</tr>
<tr>
<td>41</td>
<td>Training of persons potentially confronted to orphan sources</td>
<td>Training obligatory according to regulations</td>
<td>No regulatory requirement but training organised</td>
<td>—</td>
<td>No training organized</td>
</tr>
<tr>
<td>42</td>
<td>Repetition of training</td>
<td>Yearly</td>
<td>Regularly repeated</td>
<td>Repeated on voluntary basis / upon request</td>
<td>Not regularly repeated</td>
</tr>
<tr>
<td>43</td>
<td>Recording of training</td>
<td>Training course is documented &amp; comprehension test is organised / Training includes practical exercises</td>
<td>Training course is documented</td>
<td>Defined by the employer / partially documented</td>
<td>Training course is not documented</td>
</tr>
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13.1 Regulatory framework with respect to HASS

13.1.1 Regulatory authority

The Canadian Nuclear Safety Commission (CNSC) regulates the use of nuclear energy and materials to protect the health, safety and security of Canadians and the environment; and to implement Canada's international commitments on the peaceful use of nuclear energy. CNSC was established in 2000 under the Nuclear Safety and Control Act and reports to Parliament through the Minister of Natural Resources. The possession and movement of high-risk sealed sources are regulated by the CNSC.

13.1.2 Legislative framework

Under the Nuclear Safety and Control Act, the Commission has implemented regulations and by-laws.

The General Nuclear Safety and Control Regulations (SOR/2000-202) provide general regulations with respect to license applications and renewals, exemptions, obligations of licensees, prescribed nuclear facilities and equipment and information, contamination, record-keeping, and inspections. They apply to all nuclear facilities and CNSC licensees and applicants. The "Nuclear Substances and Radiation Devices Regulations - SOR/2000-207" provide requirements for the licensing and certification of nuclear substances and radiation devices, use of radiation devices and record-keeping. They apply to all nuclear substances, sealed sources, and radiation devices.

The Class II Nuclear Facilities and Prescribed Equipment Regulations provide requirements for the licensing and certification of Class II prescribed equipment (irradiator, teletherapy equipment, cyclotrons, etc.).

The Transport of Nuclear Substances Regulations also pertain to high-activity sealed sources although they are more broad-based regulations.

The Canadian regulatory control of sealed sources fully conforms to the requirements of the IAEA Code of Conduct:

- Effective national legislative framework
- Independent national regulatory body
- Regulatory system for authorizations
- National registry and tracking system for high-risk sources
- Effective control of import and export of high-risk sealed sources
- Adequately trained & qualified competent authorities

13.2 Prevention and deterrence

13.2.1 Authorization for practice with HASS

Pursuant to the Nuclear Safety and Control Act (NSCA), before any person or company can possess, transfer, import, export, use or abandon a nuclear substance, prescribed equipment or prescribed information, authorization from CNSC must be obtained. CNSC ensures that all general requirements of the Nuclear Substances and Radiation Devices Regulations - SOR/2000-207 and the Class II Nuclear Facilities and Prescribed Equipment Regulations as well as any other applicable regulations are met, including such things as methods, procedures and equipment that will be used, procedures in case of accident/incident, locations, role and responsibilities, duties and qualifications of workers, training program, proposed inspection program, leak tests at prescribed interval of time, calibration, dosimetry service.
Where the application concerns Category 1, 2 and 3 sources (code of conduct), additional specific requirements have to be considered: security equipment, procedures of the radiation safety officer service, duties and training, off-site/on-site communication equipment, threat and risks assessment, access control, measures to prevent loss or illegal use, emergency procedures, composition of source (radiation level, isotope, activity). The CNSC uses formal risk-informed regulatory processes to optimize resource allocation and decision-making across the entire nuclear regulatory program, in particular licensing and compliance activities related to radioactive sources.

A license Application Guide provides guidance to applicants on how to complete an application for a CNSC license for nuclear substances and prescribed equipment. There is a single application guide for all licenses related to nuclear substances and radiation devices. The division that licenses accelerators and Class II prescribed equipment and facilities also have application guides for their licensees. (http://www.nuclearsafety.gc.ca/eng/acts-and-regulations/regulatorydocuments/published/index.cfm)

13.2.2 Records keeping and updating

The National Sealed Source Registry (NSSR) enables the CNSC to build an accurate and secure inventory of sealed sources in Canada, starting with those that are classified as high-risk (HASS). The NSSR is a CNSC-managed national database that maintains inventory information on all categories of sealed sources in Canada. It contains detailed information on high risk (Categories 1 and 2) and some information on moderate (Category 3) to low-risk (Categories 4 and 5) radioactive sealed sources. Every licensee is required to keep and provide the records of each sealed source with model, serial number, activity, location, name of each worker and training, date of work, record of leak test, etc. This information is checked through annual compliance reports and through compliance inspections.

The CNSC also maintains a database containing inventory information submitted by licensees at the time of their annual compliance report. This incorporates Cat 3, 4 and 5 sources not captured in the NSSR.

The NSSR’s high-risk source tracking component, the Sealed Source Tracking System (SSTS), provides licensees and CNSC staff with an efficient, effective way to report and track the movement of high-risk sealed sources. Categories 3, 4 and 5, are not subject to mandatory tracking through the SSTS but are subject to reporting under CNSC regulatory oversight (licensing and compliance). The SSTS is an electronic add-on to the NSSR. The SSTS keeps track of movements of radioactive sealed sources from one location to another using the Internet. Licensees have the option of using the online reporting system or they can submit the tracking information “manually” via fax or email. This information is then added into the system by the CNSC staff.

13.2.3 National inventory

Canada’s NSSR contains inventory details of close to 60,000 sealed sources (cat. 1 to 5) and more than 2,500 licensees, not all of them would have data in the NSSR (for example, low risk sealed sources would not be captured in the NSSR).

The SSTS registered 53,083 individual transactions of all types throughout the year 2011. In 2011, the SSTS was tracking 2,777 Category 1 sources and 22,778 Category 2 sources.

13.2.4 Inspections and penalties

Guide and worksheet are established for licensees to ascertain that the CNSC’s general expectations regarding regulatory requirements are met. Such requirements would generally be assessed during inspections which concern radiation protection (dose control), training & qualifications, operational procedures (leak test), organization and management. In June 2012, the Nuclear Safety and Control Act was amended to allow the CNSC to establish an
administrative monetary penalty system. This system will provide the CNSC with an additional tool to address non-compliances.

In general inspections are announced, but inspectors do have the right to enter premises at any reasonable time to inspect (section 30(1) of the Nuclear Safety and Control Act). License inspection frequency is based on a risk informed decision making process where higher risk activities are inspected more frequently than lower risk activities. For example, industrial radiography licensees will be inspected at least on an annual basis whereas a licensee who only possesses an x-ray fluorescence device would be inspected on a much more infrequent basis. The scope of inspections can vary depending on the type of inspection being performed (field, records, program).

The CNSC has several options when addressing non-compliances including the issuance of written notices (action notices and directives), requests for information in accordance with section 12 of the General Nuclear Safety and Control Regulations (SOR/2000-202), issuing orders in accordance with the Nuclear Safety and Control Act, taking licensing action, prosecution and in the future, the administration of administrative monetary penalties. The final regulations related to the administrative monetary penalties are expected to be published in the Canada Gazette Part II during the summer of 2013.

All licensees possessing nuclear substances or prescribed equipment must also submit annual compliance report detailing information such as contacts, locations, inventories, changes in program, number of workers and dosimetry results.

13.2.5 Control of HASS by the holder

Leak test periodicity is defined for high risk sources.

Leak test requirements are detailed in Section 18 of the Nuclear Substances and Radiation Devices Regulations and in Section 19 of the Class II Nuclear Facilities and Prescribed Equipment Regulations. These sections detail frequency, limits and requirements upon discovery of a leak.

13.2.6 Source holders’ training

Training requirements for all users of sealed sources are assessed at the time of the license application. The Nuclear Substance and Radiation Devices Regulations state that industrial radiography licensees can only permit CNSC-certified personnel and supervised trainees to use exposure devices containing nuclear substances. Certified exposure device operator (CEDO) candidates must apply directly to the CNSC. To be eligible to apply for CEDO certification, the following four steps must first have been successfully completed: Vocational training course, Written examination, Apprenticeship program and Practical examination. For other than Certified Exposure Device Operators (CEDOs) and with respect to handling sealed sources, there are no specific regulatory requirements.

There are regulatory requirements for the certification of radiation safety officers who are responsible for Class II facilities and prescribed equipment.

13.2.7 Identification and marking of HASS

Section 20 of the CNSC Radiation Protection Regulations provides labelling requirements for containers and devices containing nuclear substances. There are currently no CNSC regulatory requirements for labelling of sources themselves although in general sources meet ISO and/or ANSI standards.
13.2.8 Transfers of HASS

The Sealed Source Tracking System (SSTS) provides licensees and CNSC staff with an efficient, effective way to report and track the movement of high-risk sealed sources (Categories 1 & 2) using Internet. Licensees can report the following activities online:

- Receipt
- Transfer
- Import
- Export

Only CNSC licensees who are authorized to possess high-risk sealed sources can use this system. These licensees must obtain an authorization code from their CNSC licensing officer.

Licensees using the system are required to provide:

- The date of transaction
- Serial number of source
- Where the source is coming from - CNSC license number (if applicable) and address
- Where the source is going - CNSC license number (if applicable) and address
- Model name/serial number of prescribed equipment (such as radiography camera, irradiator, teletherapy machine)
- Model/name of source assembly (in the case of radiography camera)

A licensee who transfers a sealed source shall provide the transferee with a record of the most recent leak test conducted to ensure he is not transferring a leaking source which could potentially lead to contamination.

Transfers and exports of high risk sealed sources must be reported at least 7 days before the actual shipment takes place. Receipts and imports must be reported within 48 hours of reception.

For sources that are not tracked in the sealed source tracking system, the expectation is that inventories will be kept up-to-date and submitted annually as part of the annual compliance report.

The CNSC is responsible for controlling the export and import of Category 1 and 2 radioactive sources (HASS). Through its role in implementing export and import control measures, the CNSC enhances national and international safety and security by ensuring that only authorized persons are recipients of Category 1 and 2 radioactive sources. The CNSC’s program is consistent with the Code and Guidance, which have the following objectives:

1. Achieving a high level of safety and security regarding Category 1 and 2 radioactive sources;
2. Reducing the likelihood of accidental harmful exposure to Category 1 and 2 radioactive sources or the malicious use of such sources to cause harm to individuals, society and the environment; and
3. Mitigating or minimizing the radiological consequences of any accident or malicious act involving Category 1 and 2 radioactive sources.

To satisfy the requirements of paragraphs 23-29 of the Code, concerning export and import controls, the CNSC reviewed and adapted its regulatory processes to ensure they conformed to the strengthened international norms.
The enhanced CNSC import and export control program for Category 1 and 2 radioactive sources is fully consistent with the provisions of the Code and Guidance. Canadian exporters are required to apply for and obtain an Export Licence from the CNSC prior to exporting Category 1 and 2 sealed sources. The program encompasses licensing, compliance, prior shipment notifications to importing States, State to State requests for import consent to import Category 1 radioactive sources, and the establishment of bilateral administrative arrangements.

To further assist Canadian exporters and regulatory counterparts in understanding the implementation of Canadian export and import controls, the CNSC has recently published INFO-0791 Control of the Export and Import of Risk-Significant Radioactive Sources.

13.2.9 Long-term management of disused HASS

The licensees are responsible for ensuring that their nuclear facilities and activities are operated, decommissioned and abandoned in a manner that protects health, security and environment. This responsibility includes making appropriate plans for the termination of licensed activities, including the termination of operations, the short- and long-term management of radioactive waste. Disused HASS are currently dealt with by the licensee. The expectation is that they would be safely and securely stored by the licensee until disposed of appropriately or until transferred to another licensee.

Different options are available: disused sources can be stored on site, transferred to another licensee, returned to the supplier/manufacturer, stored/disposed of to a licensed waste facility. The only condition to any of these options is that whatever entity ends up with the source must have a valid license which permits the possession of that source. In the case of storage on site, there is no time limit for storage. The expectation is that the sources will be securely stored at all times under a valid license that authorizes storage.

Decommissioning plans are considered as part of the application process and are considered individually based on the type of license issued. Expectations for decommissioning plans vary depending on the activity.

The Nuclear Safety and Control Act authorizes CNSC to require licensees to provide a financial guarantee as a condition of their license. This ensures that licensees have sufficient financial resources in place to ensure the safe termination of their licensed activity. Currently the requirement for financial guarantees has been limited to Class I nuclear facilities and uranium mines and mills. Discussion Paper DIS-11-01 outlines CNSC’s plans to broaden the financial guarantee program over the next two years, to require all sites and activities licensed by CNSC to have financial guarantees, including sealed source users.

Each case of bankruptcy is dealt with individually with the trustee that takes on the responsibility of the nuclear substances.

13.2.10 Security measures

The CNSC regulatory document “Security Measures for Sealed Sources” was published on May 30, 2013. This document sets out the minimum security measures required to prevent the loss, sabotage, illegal use, illegal possession, or illegal removal of sealed sources while they are in storage at the site of a licensed activity, in transport or being stored during transportation.
13.3 Detection

13.3.1 Detection of orphan sources

The CNSC has not performed a national threat assessment to determine strategic locations of portal monitors but it is currently being completed. The CNSC does not regulate portal monitor users and as such it is not compulsory to have portal monitors at any location.

Metal recycling facilities, steel producers and waste facilities make independent decisions about installing monitors at their facilities. Continuous outreach to metal recycling facilities and steel producers is done through their respective professional associations to reach as many members as possible (Canadian Association of Recycling Industries and Canadian Association of Steel Producers).

Canada Border Services Agency determines which ports/border crossings will be monitored by portal monitors. For cases where goods coming from overseas are setting off portal alarms at Canadian Port, Canada Border Services Agency (CSBA) informs the CNSC. In general, the shipments are returned to the point of origin by the importers following the discovery of contaminated goods in compliance with the applicable transport regulations.

13.3.2 Campaign for orphan sources recovery

There has not been any specific recovery campaign of disused sources in Canada for high-activity sealed sources. The only campaign for returning sources has been related to historic radium luminescent devices. There is no specific budget set aside for recovery campaigns.

The CNSC has internal procedures in place for dealing with reported events and specifically for the discovery of an orphan source. If a serial number can be obtained from the source or device, the CNSC will attempt to determine the owner of the source using its NSSR and its database of inventory information. If the owner can be found, the owner is responsible for the cost of recovery and/or disposal of the source. If an owner cannot be found, currently it is the responsibility of the “finder” to pay for the recovery and/or disposal of the source. However, it is important to note that this determination is examined on a case by case basis and the CNSC will step in to manage the situation if deemed necessary. The CNSC is still in discussions with our national radioactive waste facility to facilitate the management of these sources as required.

13.3.3 International cooperation and information exchange

The CNSC Report on Lost or Stolen Sealed Sources and Radiation Devices summarizes the information reported to the CNSC about the losses and thefts of licensable sealed sources and radiation devices. This report is published on the CNSC website and accessible to the public. It is updated within 3 business days of the discovery of a lost or stolen source.

The CNSC reports lost or stolen materials to the IAEA Illicit Trafficking Database. In addition, the CNSC will also inform:

- United States Nuclear Regulatory Commission (USNRC)
- Federal Provincial Territorial Radiation Protection Committee (FPTRPC)
- Canadian Steel Producers Association (CSPA)
- Canadian Association of Recycling Industries (CARI)
- Canadian Transport Emergency Centre (Canutec)

To assist the international implementation of the Code and Guidance in a harmonized manner, the CNSC has developed a model bilateral administrative arrangement and has entered into bilateral administrative arrangements with its international counterparts in various countries to ensure that imports and exports of Category 1 and 2 radioactive sources between Canada and these countries are conducted in a manner consistent with the Code and Guidance. These arrangements assist in harmonizing regulatory approaches for
authorizing imports and exports and facilitate the sharing of regulatory information related to such imports and exports.

The establishment of bilateral Administrative Arrangements is a key element of the CNSC’s regulatory control program for the import and export of Category 1 and 2 radioactive sources.

13.4 Preparedness and response

13.4.1 Emergency plans and procedures

All licensee organizations must be well-prepared to respond to emergencies, and to cooperate with local, provincial, federal and international authorities. Each licensee emergency procedures are assessed at the time of license application to ensure they meet the CNSC expectations. Emergency program will vary depending on the nature of the licensed activity.

The provinces and territories have their own emergency plans which address their specific needs. Federal, provincial and municipal coordination is a key element of all emergency plans in Canada. Health Canada is the lead federal government department for all matters related to the Federal Nuclear Emergency Plan (FNEP), CNSC and other agencies. It coordinates the federal emergency response with provincial and municipal government agencies.

In the event of an emergency involving a high risk source, there is a CNSC Duty Officer emergency telephone line. This person is on call 24/7 and will forward any emergencies to the appropriate group for them to be addressed. Each type of event has a decision tree as to who needs to be contacted.

The CNSC provides extensive training to law enforcement and emergency services organizations (First Responders) enabling them to address radiological events. Paragraph 10 of the Code calls for every state “to ensure that adequate arrangements are in place for the appropriate training of … its law enforcement agencies and its emergency services organizations.” In conjunction with other Canadian federal government departments, the CNSC provides the radiological/nuclear content of these courses, as part of a larger set of emergency preparedness procedures.

13.4.2 Training and information of persons potentially confronted with an orphan source

As the CNSC does not regulate portal monitor users, training requirements would be determined by the facility/agency using the systems. The CNSC does however provide outreach material.

The CNSC has been successful in the past with the development of information posters and documents that it has targeted to specific stakeholders involved in a particular issue.

In the case of orphan sources, metal recycling facilities and landfill sites are the stakeholders that come in contact with scrap and waste in which orphan radioactive sources can be found. The objective is to make these stakeholders more aware of the potential sources that they could encounter in their products, and of how to be capable in detecting, identifying, removing and disposing of these materials.

The poster and its associated brochure/pamphlet provide:

- guidance and response actions to be taken in the event that a radiation portal monitor alarm is activated
- safety aspects to consider when dealing with unidentified radioactive substances
- hazards and risk associated with nuclear substances and radiation devices
- information related to the detection of radioactive substances and radiation devices
They can be found and ordered on the CNSC website at: http://www.nuclearsafety.gc.ca/eng/readingroom/factsheets/alarm-response-guidelines.cfm.

Transport Regulations are in the process of adding exemption limits for nuclear substances found in waste, scrap, and other materials.

The CNSC will be undertaking a variety of outreach activities like postings on the web, newsletters, information sessions, and visits to sites where orphaned sources may be discovered.
13.5 Incidents and accidents in Canada

Between beginning 2005 and end 2012, no incident has occurred with Category 1 sources. Over the same period 13 events with Category 2 sources have been reported and 7 with Category 3 sources.

<table>
<thead>
<tr>
<th>Event Date</th>
<th>Event Type</th>
<th>Event Description</th>
<th>Source Category</th>
<th>Number of Sources or Devices Involved in the Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/07/2005</td>
<td>Stolen</td>
<td>Stolen vehicle containing exposure device involved in accident</td>
<td>Cat 2</td>
<td>(1X Exposure device). Recovered on July 5, 2005</td>
</tr>
<tr>
<td>25/07/2005</td>
<td>Loss</td>
<td>Exposure device not secured during transport and lost</td>
<td>Cat 2</td>
<td>(1X Exposure device). Recovered on July 25, 2005</td>
</tr>
<tr>
<td>22/11/2005</td>
<td>Loss</td>
<td>Exposure device left at jobsite</td>
<td>Cat 2</td>
<td>(1X Exposure device). Recovered on Nov 22, 2005</td>
</tr>
<tr>
<td>15/01/2006</td>
<td>Stolen</td>
<td>Vehicle containing exposure device stolen</td>
<td>Cat 2</td>
<td>(1X Exposure device). Recovered on Jan 16, 2006</td>
</tr>
<tr>
<td>04/08/2006</td>
<td>Stolen</td>
<td>Vehicle containing exposure device stolen</td>
<td>Cat 2</td>
<td>(1X Exposure device). Recovered on Aug 4, 2006</td>
</tr>
<tr>
<td>19/10/2006</td>
<td>Loss</td>
<td>Exposure device source unaccounted for after shipment</td>
<td>Cat 2</td>
<td>(1X Exposure device source). Recovered on Oct 30, 2006</td>
</tr>
<tr>
<td>02/02/2008</td>
<td>Stolen</td>
<td>Theft of vehicle containing 3 well logging sources</td>
<td>Cat 2</td>
<td>(3 X Logging sources of Am/Be, Cs-137 &amp; Th-232). Recovered on Feb 3, 2008.</td>
</tr>
<tr>
<td>15/05/2008</td>
<td>Loss</td>
<td>Unsecured exposure device lost during transport</td>
<td>Cat 2</td>
<td>(1X Ir-192 Exposure device). Recovered on May 15, 2008.</td>
</tr>
<tr>
<td>23/08/2010</td>
<td>Loss</td>
<td>Lost exposure device</td>
<td>Cat 2</td>
<td>(1X Exposure Device). Recovered on August 24,</td>
</tr>
<tr>
<td>24/08/2010</td>
<td>Found Nuclear Substance</td>
<td>Recovered lost device (Ref to event #1333)</td>
<td>Cat 2</td>
<td>(1X Exposure Device). Recovered on August 24, 2010. Refer to Event ID 1333</td>
</tr>
<tr>
<td>08/11/2011</td>
<td>Found Nuclear Substance</td>
<td>Unsecured radiation device found by member of public</td>
<td>Cat 2</td>
<td>(1X Ir-192 Exposure Device). Recovered on Nov 8, 2011</td>
</tr>
<tr>
<td>11/02/2006</td>
<td>Stolen</td>
<td>Vehicle containing two industrial fixed gauges stolen</td>
<td>Cat 3</td>
<td>(2X Fixed gauges). Recovered on Feb 12, 2006 and March 3, 2006</td>
</tr>
<tr>
<td>19/01/2007</td>
<td>Stolen</td>
<td>Vehicle containing three logging sources stolen</td>
<td>Cat 3</td>
<td>(3X logging sources). Recovered on Jan 19, 2007</td>
</tr>
<tr>
<td>08/02/2007</td>
<td>Loss</td>
<td>Fixed gauge discovered missing during storage cleanup</td>
<td>Cat 3</td>
<td>(1X Fixed gauge). Not recovered.</td>
</tr>
<tr>
<td>Event Date</td>
<td>Event Type</td>
<td>Event Description</td>
<td>Source Category</td>
<td>Number of Sources or Devices Involved in the Event</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------</td>
<td>-------------------------------------------------------------</td>
<td>-----------------</td>
<td>-------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>09/02/2007</td>
<td>Found Nuclear Substance</td>
<td>High level scrap alarm</td>
<td>Cat 3</td>
<td>(1 X Cs-137 well logging source) recovered on Feb 9, 2007 and traced to original licensed owner.</td>
</tr>
</tbody>
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14.1 Regulatory framework with respect to HASS

14.1.1 Regulatory authority
In the USA, the regulatory authority is the Nuclear Regulatory Commission which regulates the possession and use of radioactive sources, under the U.S. Atomic Energy Act 1954, as amended. The mission of the NRC is to license and regulate the Nation’s civilian use of by-product, source, and special nuclear materials to ensure the adequate protection of public health and safety, promote the common defence and security, and protect the environment. The NRC’s regulations are designed to protect both the public and workers against radiation hazards from industries that use radioactive materials. NRC is an independent agency and among other things, has primary responsibility for licensing, inspecting, regulating and enforcing the commercial use of radioactive materials. This Act also provides that the Commission may delegate portions of its regulatory authority to the governments of the 50 States to license and regulate by-product materials (radioisotopes); source materials (uranium and thorium); and certain quantities of special nuclear materials, provided that these governments have standards and guidelines that are adequate and compatible to the NRC’s regulatory program. Thirty-seven States, known as “Agreement States”, have entered into 274b Agreements (a reference to the Act) with the NRC. The regulatory organization responsible for overseeing these materials depends on the location of the sources. About a quarter of the possession licensees are administered by the NRC while the Agreement States administer the remainder of the licenses. The NRC has the jurisdiction for all import and export licensing of these materials.

Disposal of radioactive waste is a complex issue, not only because of the nature of the waste, but also because of the complicated regulatory structure for managing it. There are a variety of stakeholders affected, and there are a number of regulatory entities involved. Federal government agencies involved in radioactive waste management include: the Environmental Protection Agency, the Nuclear Regulatory Commission, the Department of Energy, and the Department of Transportation.

14.1.2 Legislative framework
The Atomic Energy Act, as amended, is the fundamental U.S. law on both civilian and military uses of nuclear materials.

NRC regulates the civilian use of nuclear and radioactive materials in medical, industrial, and academic uses through a combination of regulatory requirements, licensing, safety oversight including inspection and enforcement, operational experience evaluation, and regulatory support activities.

The NRC’s regulations most relevant to sealed sources and high-risk sources (HASS) are found in Chapter I of Title 10 ("Energy") Sections 30-39 and 110 of the Code of Federal Regulations. In the USA, high-risk sources are radioactive materials identified by the IAEA as being at or above (or aggregating to) category 2 source thresholds defined the IAEA Code of Conduct on the Safety and Security of Radioactive Sources.

14.2 Prevention and deterrence

14.2.1 Authorization for practice with HASS
The NRC and the Agreement States have issued general licenses for importing, exporting and holding radioactive materials that are deemed sufficiently safe for use by persons without special training in radiation safety. These general licenses are issued in the regulations themselves and may have requirements such as annual reporting associated with them. These general licenses do not require the submission of an application by the
user because they are issued by a broad regulation, and do not relieve a person from complying with other applicable NRC, Federal and State requirements.

However all the radioactive sources of highest security concern (Cat 1 and 2 and sources that aggregate to the Category 2 threshold) require specific licenses for use in the USA. Specific licenses are issued by either one of the Agreement States or the NRC and include the authorization to possess, use, transfer, and dispose of radioactive material associated with various types of use, i.e. industrial, academic, research and development, manufacturing, distribution, irradiators, well logging, industrial radiography, medical programs, various types of service (leak testing of sealed sources, calibration of instruments, servicing of devices, collection and repackaging of radioactive waste for final disposal), and transportation. Applicants must provide information on the type of use, form, and activity of the source, qualifications of users and radiation protection programs, training of personnel, as well as written operating and emergency procedures.

NRC reviews the application according to procedures and criteria documented in the Standard Review Plans for these license applications. If NRC approves the application, a license is issued. The license may contain certain conditions imposed by the NRC and agreed to by the licensee. The license is valid for a specific period of time; it requires application and routine inspection. Licensees pay annual and licensing fees as NRC is a cost recovery agency. Each licensee designates one or more employees, often typically a Radiation Safety officer (RSO), to oversee compliance with applicable NRC and Agreement State regulations, including security controls.

### 14.2.2 Records keeping and updating

Each licensee shall conduct a quarterly physical inventory to account for all sealed sources possessed under his license. The information required to be reported for a received high risk source is the following:

1. Name, address, and license number of the reporting licensee;
2. Name of the individual preparing the report;
3. Name, address, and license number of the person that provided the source;
4. Manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;
5. Radioactive material in the source;
6. Initial or current source strength in Becquerels (Curies);
7. Date for which the source strength is reported;
8. Date of receipt.

The sources inventory at the user’s premises will be checked during inspection.

### 14.2.3 National inventory

Thanks to the NSTS (National Sources Tracking System) the NRC implements a national source registry, as described in the Code of Conduct. NSTS is essential for national security. It is a secure, user-friendly, web-based database designed to track high-risk radioactive sources (Category 1 and 2 radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until they decay below the Category 2 threshold). NSTS enhances the ability of the NRC and Agreement States to conduct inspections and investigations, communicate information to other government agencies, and verify legitimate ownership and use of nationally tracked sources.

NSTS contains information on licensees who possess nationally tracked sources. This information is specified in 10 CFR 20.2207 and includes the name and address of the facility, the license number, and contact information (such as phone number and email address). Information on each tracked source includes the make, model, serial number, radioactive
material, and activity. The information recorded in the NSTS is considered sensitive to homeland security, and is designated for “Official Use Only”.

It is assessed that more than 75,000 high-risk radioactive sources are possessed by approximately 1,300 licensees.

**14.2.4 Inspections and penalties**

NRC’s Regional offices and Agreement States conduct typically unannounced and periodic inspections of licensed activities, using guidance from Inspection Manual Chapter 2800 and Inspection Procedures 87101-87250 to examine whether licensees are performing activities in accordance with license requirements. An inspection priority code is assigned to each radioactive material license. The priority code (i.e. 1, 2, 3, or 5) is the interval between routine inspections, expressed in years. The same priority code is assigned to all licenses that authorize that particular type of use. Priority Code 1 presents the greatest risk to the health and safety of workers, members of the public, and the environment.

These inspections cover areas such as training of personnel who use materials, radiation protection programs, inventory of sources at user’s premises, radiation dose records, and security of nuclear materials. The NRC issues reports to document inspection findings. These inspection reports may contain enforcement actions and follow-up inspection items. NRC makes the Inspection Reports available for public review through its electronic document retrieval system (ADAMS).

As part of the oversight process, the NRC or Agreement State can consider taking enforcement action for licensees who violate the regulations. These sanctions may include notices of violation, monetary fines, or orders to modify, suspend, or revoke a license or require specific actions because of a public health issue. The U.S. NRC and Agreement State programs are authorized to issue significant (escalated) enforcement actions to licensees, individuals, and non-licensees for failure to comply with agency regulations.

**14.2.5 Control of HASS by the holder**

Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities. Consolidated guidance about medical, academic, and industrial uses of nuclear materials is published in "Consolidated Guidance About Materials Licenses" (NUREG-1556, Volumes 1-21).

The specific control provisions related to the different sealed sources applications are compiled in the regulation and provide the information necessary to perform a safety evaluation of the sealed source. For example, persons specifically licensed to perform industrial radiographic operations are only authorized to use equipment that meets the requirements of 10 CFR Part 34. Therefore, during an evaluation of radiography equipment, the items listed hereafter must be addressed: transport containers, leak testing, labelling, maximum radiation levels.

The applicant must provide the maximum time interval between leak tests to be performed on the product. Typically, products are required to be leak tested at intervals not exceeding 6 months.

**14.2.6 Sources holders’ training**

In order to receive the special license dedicated to a defined application (for example radiography), the applicant submits an adequate program for training the workers. The applicant identifies and lists the qualifications of the individual(s) designated as the RSO and potential designees responsible for ensuring that the licensee’s radiation safety program is implemented in accordance with approved procedures. The RSO shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee’s program.
The National Nuclear Security Administration (NNSA), a separately organized agency within the Department of Energy (DOE), established a voluntary program in 2008 as part of its Domestic Material Protection Program to provide security upgrades, beyond what NRC requires, to U.S. commercial facilities that contain high-risk radiological materials. This NNSA-funded training is designed to teach facility personnel and local law enforcement officials on how to protect themselves and their communities when responding to alarms indicating the possible theft or sabotage of nuclear or radioactive materials.

14.2.7 Identification and marking of HASS

Hereafter is a listing of information in order of importance that needs to accompany the source:

- trefoil symbol and/or the words “CAUTION – RADIOACTIVE MATERIAL”
- engraved serial number (the serial number can usually be traced back to determine the original activity)
- isotope
- activity and date of assay
- the last known user of the source
- distributor's name or logo

This is important in trying to locate additional information concerning the source. Alternate distributors may also be identified in the registration certificate. NRC includes the sealed source model numbers together with isotope, activity and date of assay in its sealed source and device computerized tracking system (NSTS). This recorded information could assist trained personnel in responding to an incident involving the source.

14.2.8 Transfers of HASS

Imports, transfers and exports must be recorded in NSTS by close of next business day. When transferring sources within the United States, licensees are required to verify that the recipient is authorized to possess the source. Proof is normally provided in the form of a copy of the recipient's license. Licensing documents of the NRC and the Agreement States are not uniform, however. Consequently, verifying authenticity of licenses is a challenge. Moreover, for sources sold over the Internet, website operators serve as middlemen only, never taking possession of the source and thus not needing a license themselves. This presents a potential security concern.

14.2.9 Long-term management of disused HASS

When a radioactive source is no longer used, it may be returned to the manufacturer, transferred to another qualified licensee, sent to a commercial waste disposal site, or stored. There are no time limits for storage at user’s premises established in the regulations; licensees must stay under their possession limits (which includes the disused sources in long-term storage).

Long-term management options for the disused sources must not be specifically defined in the license application. There does not appear to be a consistent requirement for specifying how a licensee will dispose of a disused source. For California it is clearly stated that the licensee has to explain how the source will be disposed. The Texas commission seems to be not as direct about this requirement but it does have a place on its application for specifying whether an applicant is seeking a license for disposal.

Recycling and reusing of disused sources is a desirable practice, but only when consistent with safety and security considerations. Under present practices, the secondary market for disused sources is vulnerable to theft and diversion of sources and to the use of fraud to access them.

Many licensees return sources to the supplier (take-back options).
Greater than class C waste (class with $T_{1/2} > 5$ years) may not be disposed at the commercially operated near-surface disposal facilities. It includes large radioactive sources that are of the greatest concern from security and safety standpoints. Currently no disposal pathway for this waste exists. DOE has been storing this waste at an interim storage site at Los Alamos Laboratory (Off-Site Recovery project - OSR) awaiting a permanent repository. Funds for developing a permanent disposal plan have yet to be provided. A related issue affecting the viability of disposal options is the absence of a requirement that potential users of radioactive sources prepay for disposal costs. This possibility has been under consideration but would probably not be in the near future. As a result, licensees are usually uninformed of the costs and are unprepared to pay them.

14.2.10 Security measures

The events of 9/11 have put new emphasis on security to prevent the malicious use of radioactive material, such as in dirty bombs. The NRC has been working with its Federal and State partners, as well as the international community, to provide appropriate safety and security requirements for radioactive materials without discouraging their beneficial use.

Under NRC regulations, a licensee is required to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. Furthermore, licensees are required to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area. The regulations on security are generic with broad requirements. NRC is in the process to improve its regulation by implementing increased security measures (access controls, monitor and response). Physical protection requirements were issued by Order by US NRC in June/July 2010. These Orders were the basis in authoring a new regulation, 10 CFR Part 37 “Physical Protection of Byproduct Material,” that became effective in 2013. Subpart B deals with access controls, subpart C with physical protection during use and subpart D with physical protection during transport.

In addition to the new NRC security requirements, the DoE is proposing its support. On a voluntary basis, facilities may request a security assessment by the DoE of which representatives will come on site to evaluate the security level. DoE can also financially contribute to the costs for the security improvements decided by the operators for up to three years after installation, after which the facility must maintain the equipment themselves.

14.3 Detection

14.3.1 Detection of orphan sources

The Environment Protection Agency (EPA) has developed voluntary programs and training to help reduce the incidences of orphan sources in scrap metal and the potential for exposure of workers and the public and contamination of the environment. EPA and the Department of Energy's Oak Ridge National Laboratory (ORNL) are investigating technologies to improve tracking and monitoring of radiological materials (including sources) in commerce through real-world testing of the Radiological Source Tracking and Monitoring (RadSTraM) system.

The performance of a national threat assessment to determine the strategic location where detectors have to be installed is not under NRC’s jurisdiction. The Domestic Nuclear Detection Office (DNDO) of Department of Homeland Security (DHS) has worked on it in its role as the integrating agency that coordinates with DOE, EPA, NRC and other partners to develop and deploy a global nuclear detection to reduce the risk from the nuclear threat.

In January 2013, the Office of the Inspector General of the DHS issued a report, which contains this major finding: “The components do not fully coordinate or centrally manage the radiation portal monitor program to ensure effective and efficient operations. Specifically, Customs and Borders Protection (CBP) does not consistently gather and review utilization information to ensure that it is fully utilizing all radiation portal monitors. CBP does not always monitor and promptly evaluate changes in the screening environment at seaports to relocate
radiation portal monitors as necessary. Finally, DNDO and CBP do not accurately track and monitor their inventory of radiation portal monitors. Given the radiation portal monitors’ limited life and the lack of funding for new monitors, CBP and DNDO should better coordinate to fully utilize, promptly relocate, and properly maintain inventory to best use resources and to continue screening of all containerized cargo entering U.S. seaports. The components concurred with our three recommendations and will identify a single program office responsible for fully coordinating and centrally managing the program; establish guidelines to track and report the utilization of monitors at every seaport; and develop and document a formal collaborative process to ensure that monitor relocation is effectively planned and implemented to meet security needs at seaports.” (http://www.oig.dhs.gov/assets/Mgmt/2013/OIG_13-26_Jan13.pdf).

DNDO reported that there are currently 444 radiation portal monitors operating at seaports throughout the U.S.

14.3.2 Campaign for orphan sources recovery

Source recovery is an ongoing effort. A series of initiatives have been taken in that field since the 9/11 event.

The Off-Site Source Recovery Project (OSRP) is a U.S. Government activity sponsored by the National Nuclear Security Administration (NNSA) and carried out in the frame of the Global Threat Reduction Initiative (GTRI). It has a mission to remove excess, unwanted, abandoned, or orphan radioactive sealed sources that pose a potential risk to health, safety, and national security. It is managed at DOE’s Los Alamos National Laboratory. The sources recovered are Cs-137, Co-60, Sr-90, Am-241 and Pu-238. GTRI security experts have recovered more than 28 000 disused sources from over 600 sites in 49 states totalling 1 230 000 Ci registered for recovery (2012). The major issue is the lack of appropriate container to transport the recovered sources. GTRI’s budget for the OSRP is dependent upon budget allocation of DOE/NNSA, it fluctuates from year to year.

Conference of Radiation Control Program Directors (CRCPD) manages a Nuclear Regulatory Commission-funded program for disposing of found orphan sources: CRCPD National Orphan Radioactive Material Disposition Program. CRCPD and DOE/ National Nuclear Security Administration (NNSA) have created a program entitled 'Source Collection and Threat Reduction' (SCATR) to collect sources being stored and not used that could - as an aggregate - be used for malicious intent. DOE recognizes that the availability of disposal of such sources is limited and expensive; and has initiated this rare opportunity for licensees to have financial assistance in properly securing and disposing of these sources through this CRCPD program.

14.3.3 International cooperation and information exchanges

The NRC works with the International Atomic Energy Agency and licensees to protect radioactive material from theft and unauthorized access. In early 2009, NRC deployed its new National Source Tracking System, designed to track high-risk sources in the United States on a continuous basis. Licensees must promptly report lost or stolen risk-significant radioactive material.

NRC contributes to the IAEA Illicit Trafficking Database.

14.4 Preparedness and response

14.4.1 Emergency plans and procedures

The NRC is the Coordinating Agency for radiological events occurring at NRC-licensed facilities and for radioactive materials either licensed by NRC or under NRC’s Agreement States Program. As Coordinating Agency, NRC has technical leadership for the Federal government’s response to the event. If the severity of an event rises to the level of General
Emergency, or is terrorist-related, Department of Homeland Security (DHS) will take on the role of coordinating the overall Federal response to the event, while NRC would retain a technical leadership role. Other Federal agencies who may respond to an event at an NRC-licensed facility, or involving NRC-licensed material, include Federal Emergency Management Agency, the Department of Energy, the Environment Protection Agency, the Department of Agriculture, the Department of Health and Human Services, the National Oceanographic and Atmospheric Administration, and the Department of State.

In the event of an emergency due to an orphan source that threatens public health and safety the DOE, on request of the NRC, can recover and secure the source. This has happened 20 times involving over 500 sources since 1990.

The NRC and Agreement States have 24/7 emergency ‘hotlines’ that can be called when orphan sources are found and present a safety or security concern.

14.4.2 Training and information of persons potentially confronted with an orphan source

A National Nuclear Security Administration (NNSA)-funded training is designed to teach facility personnel and local law enforcement officials how to protect themselves and their communities when responding to alarms indicating the possible theft or sabotage of nuclear or radioactive materials.

The Environment Protection Agency has worked with state, federal, and industry organizations to develop a CD-ROM-based training program that helps workers at scrap metal yards identify and properly handle radioactive materials found in scrap shipments. The training program, entitled Response to Radiation Alarms at Metal Processing Facilities, is designed to prevent unwanted radioactive material (orphan sources) from entering scrap metal processing facilities. A similar CD has been developed also for industrial demolition sites where industrial gauges and devices containing radioactive sources are frequently found.

14.5 Incidents and accidents in the USA

The NRC’s Nuclear Material Events Database (NMED) contains records of events involving nuclear material reported to the NRC by NRC licensees, Agreement States and non-licensees. Annual NMED reports are compiled for public consumption and reported to the U.S. Congress. NMED includes categories for: (1) Lost/Abandoned/Stolen Material, (2) Medical, (3) Radiation Overexposure, (4) Release of Licensed Material or Contamination, (5) Leaking Sealed Source, (6) Equipment, (7) Transportation, (8) Fuel Cycle Process, and (9) Other.

Some statistics:

- U.S. businesses and medical facilities have lost track of nearly 1,500 pieces of equipment with radioactive parts since 1996, according to a new federal accounting of radiological material.
- In the past 5 years, the Nuclear Regulatory Commission reported that of the more than 1500 radioactive sources that have been reported lost or stolen in the U.S., less than half have been found. The NRC has also admitted that it stopped tracking radioactive sources by serial number in 1984.
- The US steel industry accidentally melted orphan sources during steel production on 22 occasions between 1983 and 2004 resulting in a quarter billion dollars loss.