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THE GERMAN RADIATION PROTECTION INFRASTRUCTURE WITH EMPHASIS ON THE SAFETY OF RADIATION SOURCES AND RADIOACTIVE MATERIAL

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Abstract. Through federalism, Germany has a complicated but well functioning regulatory infrastructure for the safety and security of radiation sources based on a clear legal system. The main features of this infrastructure include the legal framework, the authorization and control systems and the responsibilities of different regulatory authorities, which this paper will describe. In connection with the legal framework, the provisions to control the import/export of radiation sources are briefly discussed and some information is given about the registries of sources. Protection and response measures related to unusual events concerning radiation sources, including orphan sources, will be cited. Also, the education and training of different target groups and punitive actions are touched upon in the paper. Conclusions will be drawn for future national and international actions.

INTRODUCTION

One of the major findings of the conference on Safety of Radiation Sources in Dijon 1998 [1] was that an effective national regulatory authority operating within a suitable national infrastructure is a key element for safety. Besides an efficient regulatory system, the radiation safety infrastructure includes relevant laws, regulations and guidelines, supporting experts or expert groups and services [2].

The experience of more than 40 years of the widespread use of radiation sources in research, industry and medicine in Germany shows good practice. For some decades (since 1976 in West Germany, and 1965 in East Germany) a systematic registration of all unusual events in the use and transport of radioactive material and of the loss and find of radiation sources has taken place. Although in Germany good practice has been established in these decades, 700 incidents have been registered since 1991 (after reunification) mostly without any radiation exposure of individuals. Nevertheless, these events have sometimes had a potential for a non-negligible exposure. Therefore, it is important to register and to analyse events deviating from normal operation or, for near misses, to recognize potential exposures in the initial phase and, if necessary, to initiate measures at an early stage, especially for losses and finds.

The German governmental system is a federal system of 16 independent federal states (Länder). An overview is shown in Fig. 1. A regulatory infrastructure on the supreme level and also on the subordinate level supported by a clear legal system ensures the safety and security of radiation sources.

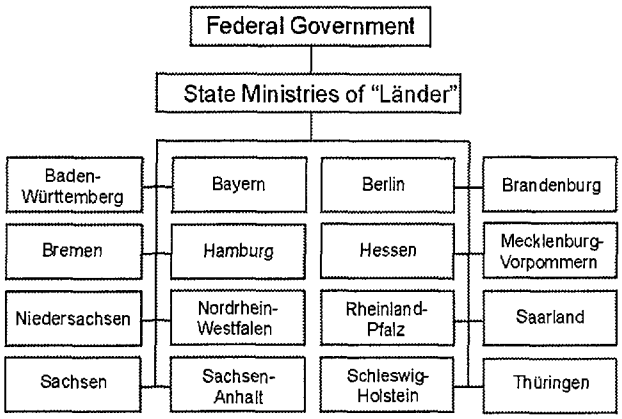

Fig. 1. German federal system.

REGULATORY INFRASTRUCTURE

Legislation
In Germany, there are typically three levels of binding regulations in the field of radiation protection, especially for the safety of radiation sources outside nuclear industry:

Laws:	Atomic Energy Act (AtG)
Ordinances:	Radiological Protection Ordinance (StrlSchV)
	X-ray Ordinance (RöV)

Guidelines:	e.g.
(Codes of Practice)	Education and training
	Licence specimen for gamma radiography
	Check of sources tightness
	Type approval *)
	Contamination control on leaving contamination areas *)

*) in preparation

Guidelines are binding for the competent "Länder" authorities and transposed via licence obligations or supervising procedures to the user of radioactive sources. In accordance with the German constitution, the "Länder" governments are responsible for the implementation of the laws in behalf of the federal Government. The federal Government has to ensure uniform implementation and legality, called expedience supervision. Fig. 2 shows a comprehensive survey.

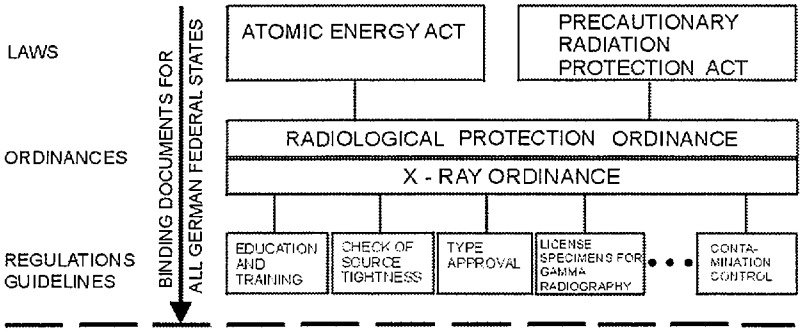

Fig. 2. Legislation concerning safety of radiation sources.

Primarily, the Atomic Energy Act stipulates legal requirements in general for radiation protection and detailed ones for safety and security of the peaceful use of nuclear energy. The purpose concerning radiation protection of this act is:

- to protect the life and health of human beings and property against the hazards of nuclear energy and the harmful effects of ionizing radiation/radioactive sources and to compensate damages caused by nuclear energy or ionizing radiation;
- to prevent danger to the internal or external security of the Federal Republic of Germany arising from the application or release of nuclear energy and fissile material;
- to guarantee the performance of the international duties of the Federal Republic of Germany in nuclear energy and radiological protection.

In the Atomic Energy Act, the responsibilities of different administrative authorities are laid down. The provisions of the Act are amended by the further above mentioned ordinances.

The purpose of the Radiological Protection Ordinance is the regulation of principles and requirements for precautionary and protection measures which are applied at utilization and influence of radioactive materials and ionizing radiation from artificial and natural origin to protect people and the environment against the dangers arising from ionizing radiation, within the framework of the AtG. This ordinance regulates the following practices concerning the safety of radiation sources:

- the use of radioactive substances, which means all parts of the authorization process including the establishment of dose limits for workers and the public;
- the purchase of radioactive substances, their delivery, the transportation and transboundary movement;
- the licensing and operation of state and federal facilities for taking possession and for disposal of radioactive waste;
- the licensing and operation of facilities to produce ionizing radiation (accelerators, energy >5 keV), except for X-ray units;
- the addition of radioactive substances in the production of consumer products, drugs, pesticides and fertilizer and the activation of these products.

The X-ray Ordinance covers the operation of X-ray units and other electrical equipment emitting ionizing radiation due to accelerated electrons at a potential difference of more than

5 keV and up to 3 MeV. This group of sources is not covered by the topic of the conference and therefore it will not be considered in this report.

Following these laws and ordinances, a number of binding regulations and guidelines were specified and had to be implemented by the "Länder" authorities. In the ongoing process to amend our radiation protection legislation converting the EURATOM Directive 96/29 [3], these regulations have to be revised.

Regulatory Authorities
The *Federal Ministry for Environment, Nature Conservation and Nuclear Safety* is accountable for the enforcement of the Atomic Energy Act, the Radiological Protection Ordinance and the X-ray Ordinance. It regulates the radiation protection through "administration by order" and is responsible for the expedience supervision. All international co-operation and co-ordination is organized the Ministry, which may delegate the implementation of tasks.

To solve important scientific problems and to prepare political decisions in the field of radiation protection, the Ministry for Environment, Nature Conservation and Nuclear Safety has an independent advisory body – the German Radiological Protection Commission. This commission issues recommendations for topical problems in radiation protection which can be implemented in regulations.

The various responsibilities for nuclear safety and the radiation protection, including the safety and security of radiation sources, are laid down in the Atomic Energy Act. In general *competent administrative authorities of the "Länder"* empowered by their "Länder" governments are responsible for implementation of all laws, ordinances and guidelines concerning radiation protection.

Federal institutions are responsible only for:

- Import and export
  The import and export of radiation sources is regulated by the Federal Export Office (BAFA) and supervised by the Federal Ministry of Finances (esp. customs offices).
- Transport of high activity sources (>10^{12} Bq)
  The licensing process of the transport of high activity sources has to be conducted by the Federal Office for Radiation Protection except for the transport with ships and on railway and the supervision is performed by the competent "Länder" authorities (e.g. traffic police) or the Federal Railway Office.

The tasks of the "Länder" authorities are authorization (notification, registration, licensing), supervision (inspection), surveillance (environment, external and internal occupational exposure), approval of training, prototype approval and interim storage of radioactive waste.
The licensing authority is not necessarily the same as the authority for supervision. The "Länder" government can engage different administrative offices with these tasks, such as

- The State Office for Environmental Protection
- Mining authorities
- District administrations
- The State Office for Maintenance of Industrial Health and Safety Standards.

Altogether, nearly 80 competent "Länder" authorities work in radiation protection in the 16 "Länder". Fig. 3 gives an overview of the regulatory authorities.

Within the German radiation protection infrastructure, each of the "Länder" has its own "micro-infrastructure". This structure with its peculiarities mentioned above demands measures for harmonization of all regulatory aspects. Therefore, a *Joint Radiation Protection Committee,* which representatives of "Länder" authorities and of the Federal Ministry (BMU) attend, was founded. In regular meetings, this committee discusses topical radiation protection issues, participates in the preparation of ordinances, regulations and guidelines and in the implementation of licensing, inspection and enforcement items. Practically, all regulatory authorities closely follow the decisions of this committee, thus taking on nearly binding obligations.

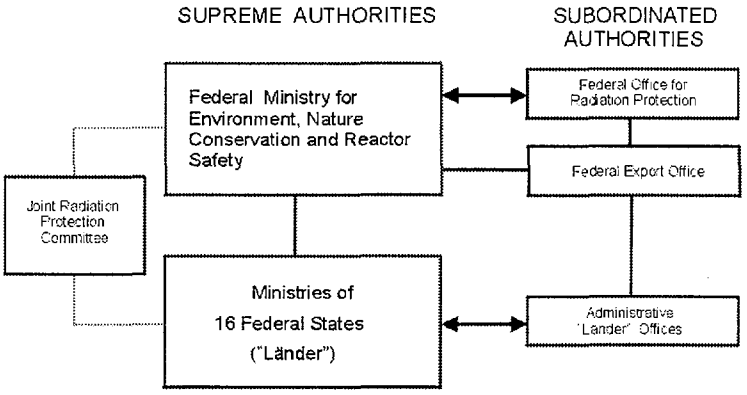

Fig. 3. Regulatory authorities concerning radiation sources.

The Federal Office for Radiation Protection (BfS) established by law in 1989 as an authority subordinated to the BMU is responsible for the:

- scientific support for the ministries;
- licensing of transports of nuclear material and high activity sources (mentioned above);
- central dose registry;
- quality assurance of surveillance in the Länder.

Important tasks concerning the quality assurance, calibration, prototype approval of radioactive sources and transport containers are solved centrally by the Federal Institute of Physics and Metrology (PTB) and the Federal Institute for Material Research and Testing (BAM).

Furthermore, the Federation and the "Länder" are supported by institutions like Technical Agencies (TÜV) and those providing expertise, e.g. large research centres, universities, private companies, employers and trade unions.

In addition to the competent authorities in all "Länder", six approved dosimetric services for external personal dosimetry and about 24 services for bioassay and body counting are established in Germany. The licensing authority stipulates which dosimetric service has to be used by the licensee.

AUTHORIZATION

In 1999 in Germany, about 20 000 licences covering practices with radioactive substances in non-nuclear fields were registered. Roughly, this number corresponds to an average of about 12 000 licensees. Half of them use only sealed radiation sources in medicine, research, teaching and industry. The application of sealed sources in industry (level gauges, density gauges, gamma radiography) is the most common practice (see Fig. 4). [4]

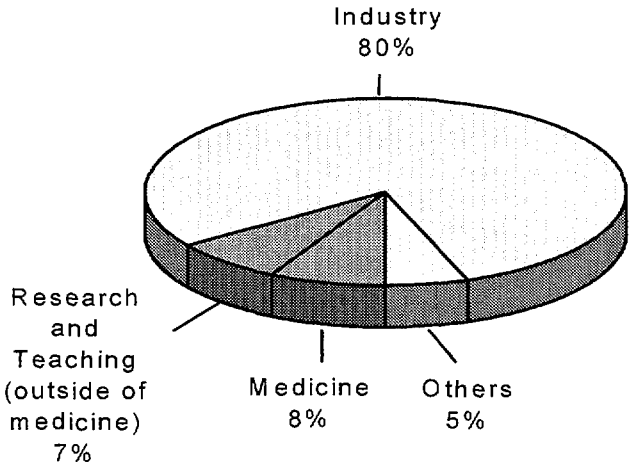

Fig. 4. Licensees of sealed sources.

Because of the presently running process for implementation of the EURATOM Directive 96/29 into the German radiation protection legislation both modi operandi – hitherto and in future – will be shortly explained.

In the past, *registration and licensing* were practised for the use of radiation sources. The registration process is managed predominantly through notification. The main criterion for registration of the use of radioactive substances is the activity, which must not exceed the exemption level for the radionuclide by a factor of 10; otherwise a licence would be necessary. Instruments or equipment containing a radioactive source with higher activity may be registered only if they have a *prototype approval* in accordance with the Radiological Protection Ordinance; otherwise — here, too — a licence is necessary. The legal procedure for the type approval is regulated by the Radiological Protection Ordinance and the preconditions are laid down there. The type approval granted by the competent "Länder" authority in one state is valid for all "Länder". The Federal Government envisages to centralizing the type approval at its Federal Office for Radiation Protection in the course of implementation of the new EURATOM Basic Safety Standards.

The efforts for licensing radiation practices vary broadly depending on the radiation protection problems and potential hazards encountered. Some applications need only a standardized licence with the stipulation of the legally responsible person, qualified experts, details about the source and the device, storage and waste specifications, dose assessment for radiation workers and for the public etc. For more complex radiation practices, independent experts and scientific institutions have to be involved in the licensing process.

Inspections

An essential component of the radiation protection infrastructure to increase the safety of radiation sources is the inspection which is conducted, announced and unannounced, by the competent "Länder" authorities. At an early stage, the inspection allows corrective measures if radiation safety requirements are violated, e.g. to avoid the loss of control over a radiation source. Mostly the inspection is carried out according to a checklist which is adapted to the application in consideration of all legal obligations and other safety requirements. [5] The decentralized inspections are effective especially because of their high frequency and the close contact to the licensee.

NATIONAL PROVISIONS

Registries/Inventories

An important tool for well functioning and effective supervision is a radiation protection registry where all information about the licensee, the licensed practice or the licensed device, the properties of the source, their registration number, the present stay etc. are stored. On such a basis, the supervision and analysis issues can be handled efficiently (e.g. an inspection plan can be prepared precisely, technical parameters are available immediately, search/identification of an orphan source is supported more effectively). Each of the German "Länder" has an extensive registry or a number of registries of significant radiation sources. A good example of such a database exists in Hessen [6].

The purpose of this database is mainly to:

- record all licences concerning the use of sealed and unsealed radioactive substances, the construction and operation of installations to produce ionizing radiation (accelerators, afterloading, irradiators, gamma radiography);
- evaluate the licensing facts and produce a current overview;
- assess the annual utilization of the granted licences (purchase, existence, delivery and residues of radioactive substances);
- collect information for radiological calculations.

Experience has shown that a centralized database in each of the "Länder" is an optimal administrative solution to achieve the objectives mentioned, also being close enough to the administrative authority and its licensees for prompt updating and management.

On the basis of the "Länder" registries, the Ministry for Environment, Nature Conservation and Nuclear Safety in pursuance of the expedience supervision continuously renews a central database with information on devices with sources of higher activity, e.g. for afterloading and for medical and technical gamma irradiation and the licensees. For instance presently 217 afterloading devices are in operation in the different "Länder" with following activities:

Ir–192	200–1000 GBq	(85%)
Cs–137	30–100 GBq	(10%)
Co–60	150–250 GBq	(1%)
Sr–90	1.5–10 GBq	(4%).

160 high activity sources (30–500 TBq) — mainly Co-60 and only a few Cs-137 — are in use for medical therapy.

Transboundary movement

Because border control is no longer practised within the European Union (EU), it has been necessary to find a solution for continuing the information about the transboundary movement of radiation sources and waste. A system is now installed which demands a priori declaration about a planned transboundary movement of sealed radiation sources. The obligations are set out in the Euratom Regulation 1493/93 and compliance is mandatory for all member countries of the EU. The German Government empowered the Federal Export Office (BAFA) with supervision.

The movement of a radiation source into a non-member country of the EU can be conducted without prior authorization if the source has an activity lower than a factor of 10^8 of the exemption limit in accordance with the Radiological Protection Ordinance and if notification is given to the competent authority. Notification deadlines are prescribed in the ordinance.

Furthermore, facilities, institutions, offices etc. have to notify the import at their competent authority. For cross checking the correctness of possession, licence and use, BAFA regularly sends information to the competent authorities about the transboundary movement (import and export) of all radiation sources. For example, 585 high activity sources (>1,86 TBq) were imported in 1998 from 12 countries and 296 sources were exported into 40 countries. The following Table 1 gives an overview of the main nuclides [7].

Table 1. Exported and imported radiation sources with A >1,85 TBq

Nuclide	Number of sources	
	Imported	exported
Ir–192	179	176
Cs–137	40	17
Se–75	178	85
Co–60	188	18

Education and training

Since 1982, guidelines on the education and training of qualified experts in radiation protection exist, supplemented in 1990 by the regulations on the education and training of qualified experts in nuclear installations. In addition the regulation on radiation protection in medicine contains specific commitments in that field.

Depending on the intended task/work (e.g. the use of radiation sources), the regulation prescribes the training which the expert has to have: its content, type and minimal duration (in hours). The regulations also prescribe that a training course, including the detailed training programme and the names of the lecturers for the different training groups has to be approved by the competent "Länder" authority. In this way, quality control is possible by the regulatory authority and should also be reinforced by inspections. In pursuance of their expedience supervision, the Federal Ministry for Environment, Nature Conservation and Nuclear Safety publishes a list of all approved training courses annually. Presently, nearly 150 organizers of approved radiation protection training courses exist in Germany [8].

Moreover, many other courses, workshops, seminars, colloquia and practical training are held which are not approved. These events are target group oriented, for instance for workers in facilities of the recycling and steel industry or for customs officers.

Abnormal events and emergencies

Part of all licences concerns emergency preparedness. The user itself has to draw up an emergency plan, make available response measures and inform the workers involved in the radiation practice about the emergency measures and train them in response actions.

On the federal level, a network of 12 regional radiation protection centres exists for the medical treatment of persons who have been unpredictably exposed to ionizing radiation. The staff of these centres are trained regularly. In addition, many scientific institutions and also the employers and trade unions responsible for dealing with accidents and occupational diseases and their compensation support these centres, for instance by providing measuring methods.

Recovery of control of orphan sources

To recover the control of orphan sources, Germany has a number of possibilities – on the one hand different facilities for detecting or searching for sources and, on the other hand, equipment for reducing the likelihood of the occurrence of a large scale event.

Nearly all melting facilities (steelworks) and most scrapyards in Germany are equipped with measuring systems to detect orphan sources or contamination. These are stationary truck and railway wagon facilities, mobile measuring devices and, to a lesser extent, also devices for laboratory measurements for slag, dust and melts. Ship monitors are rare but in such cases, detectors are installed at the cabin of the crane. Furthermore, the truck lock in the port of Hamburg is equipped with big plastic detectors (2 x 25 l). At the border crossings to Eastern Europe, customs use stationary detectors in car locks (plastic 1l) and also mobile devices. Additionally, up to 10 mobile measuring cars are working on streets and highways (NaJ(Tl) detectors).

These controls are not legally regulated. For the transport of dangerous goods, a limit of 5 μ Sv/h at the outside of a vehicle is prescribed. In the Joint Radiation Protection Committee, the regulatory authorities and customs authorities agreed to an intervention level of 1 μSv/h for further measurements and investigations at the border lines.

The following alarm values are used in Germany [9]:

Customs, Hamburg port	4 μSv/h natural activity
	10 nSv/h artificial activity
Customs	1 μSv/h (mobile detectors)
Recycling industry	10...15 nSv/h total
	8.... 10 nSv/h artificial
Steel industry	8.... 15 nSv/h total
	6.....8 nSv/h artificial
Incinerating plants	1 μSv/h total
	200 nSv/h artificial

These values are restrictive (from the radiological point of view), only valid for internal control by industry and, as mentioned above, not prescribed by regulations. The competent authority is informed about finds.

Last year in incinerating plants, nine events were registered where radioactive material was detected. In the recycling and steel industries (including scrapyards), 11 events were notified where radioactive sources were found (e.g. 2 Cs-137 sources with 2.22 GBq and 2.77 GBq in scrap) [4].

To date, no controls have been prescribed by the European Union for delivery from a non-member country. Agreements are necessary.

For searching for a high activity orphan source in the open country and for a rapid estimation of widespread contamination of the environment, helicopters of the German Federal Border Police equipped with sensitive gamma ray spectrometric systems are available at short notice[10]. For technical support, e.g. to get a source back under control, some companies are equipped with state-of-the-art facilities such as remote control tools.

Management of disused sources

In general, the management of disused sources in an individual case is prescribed in the licence. Disused sources should be returned to the producer. This should be part of the contract between producer and user. In cases where such a return is not achievable, the source has to be given to one of the authorized State facilities for waste storage ("Landessammelstelle") or to other approved facilities of companies for waste management, or to be sold for recycling.

Information about incidents with radiation sources

Licensees are obliged to notify incidents with radiation sources. The competent authorities have to register unusual events in the use of radiation sources and to report about it to their "Länder" Ministry and to the Federal Ministry for Environment, Nature Conservation and Nuclear Safety, which carries out expedience supervision. The Ministry is responsible to inform all other relevant "Länder", Ministries and bodies about the event, the conclusions drawn and the lessons learned. Information about unusual events is published annually.
The procedure will be demonstrated by an example:

In 1997 a source Cs-137 with an activity of around 200 GBq was found on a scrapyard in Sachsen-Anhalt. The first notice was given by the owner (he discovered it by monitoring at the site) to the competent authority, which initiated — in close co-operation with the Federal Ministry for Environment, Nature Conservation and Nuclear Safety — the necessary measures and informed all relevant bodies. The Ministry took subsequent steps of information exchange with the other "Länder" (searching for former holder) and concerned neighbouring countries (manufacturer, transporter), the EU Commission and the IAEA. So far, the former holder of the source has not been identified.

National punitive actions

The Atomic Energy Act and the subsequent ordinances contain regulations for the event of an infringement of the law or rule. An infringement is committed by anyone who, for example:

- runs a practice with radioactive materials without a licence;
- does not comply with all regulations of the Radiation Protection Ordinance and the obligations in the licence.

These infringements can be punished with fines of up to DM 100 000.

In addition, the "Criminal Code of the Federal Republic of Germany" has regulations for the punishment of all severe violations of licence conditions or unauthorized activities with radiation sources and radioactive materials during use, transport, supply, import, export or disposal.

The misuse of ionizing radiation to cause damage or injuries to another person is punished by imprisonment from six months to ten years and, for certain serious misuses, by imprisonment for not less than five years. Attempted exposure of people to ionizing radiation is punishable by imprisonment for not less than five years, and more serious offences by life imprisonment or imprisonment for not less than ten years. Planning and preparing such criminal activities is punishable by imprisonment from six months to ten years.

The "Foreign Trade Ordinance" 22 November 1993 provides that any person who exports goods enumerated in the list related to nuclear energy without any authorization wilfully or negligently, or markets such goods as part of transit trade, or who organizes a prohibited transit of such commodities, is liable to a fine up to DM 500 000.

CONCLUSIONS

- The German system for radiation protection is strongly meshed because it has developed over a period of more and more widespread use of radioactive substances. Even through the German radiation protection system is functioning well, it would be recommendable for countries about to set up a radiation protection system to establish a centralized system for the safety of radiation sources, especially those countries with few practices.
- In countries with a frequent and extensive use of radioactive substances, it could be advantageous to work with a decentralized system especially for licensing and inspection of practices concerning radiation sources. Such a solution is more efficient because of proximity to the user of the source, local knowledge about special details etc.
- Otherwise, a registry of those sources which have the potential to create severe hazards when uncontrolled should be built up at least by the competent regulatory authority and preferably should be centralized nationally. Search operations can be supported and international co-operation and assistance is easier [11].
- Furthermore, it would be preferable for the safe management of radiation sources, to develop guidelines for the measurement and evaluation of radioactivity in recycling materials which could be a binding document for all "Länder" and based on unified international recommendations and agreements.
- For decentralized systems, an advisory body like the Joint Radiation Protection Committee is important to harmonize decisions and actions of the authorities responsible for authorization of practices with radiation sources and to disseminate information about experience.

- To recognize danger or potential hazards caused by radiation sources at an early stage, the establishment of a centralized national registration and information system of incidents and accidents concerning radiation sources (outside the INIS information system) is advantageous. A unique scheme for registration increases the quality of information, evaluation and feedback. Also, the necessary subsequent dissemination of the lessons learned will be broader and continuously.

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