

RADIATION SAFETY WHEN USING UNSEALED SOURCES

1	GENERAL	3
2	RISK ASSESSMENT IS THE BASIS FOR PLANNING	3
3	CLASSIFICATION OF RADIONUCLIDE LABORATORIES	3
4	REQUIREMENTS CONCERNING THE STRUCTURES AND EQUIPMENT OF RADIONUCLIDE LABORATORIES	4
4.1	General design principles	4
4.2	Type C laboratory	4
4.2.1	Fire safety	4
4.2.2	Surface materials and furniture	5
4.2.3	Ventilation	5
4.2.4	Water and sewerage equipment	5
4.3	Type B laboratory	6
4.4	Type A laboratory	6
4.5	Request for preliminary statement	6
4.6	Storage room for radioactive substances	7
4.7	Facilities for a nuclear medicine unit	7
4.7.1	General	7
4.7.2	Handling rooms for radiopharmaceuticals and patient rooms	8
4.8	Tracer tests performed outside of the laboratory	8
4.8.1	Radiation safety requirements	8
4.8.2	Notifications to STUK	8
5	SURFACE CONTAMINATION	9
6	WORKING WITH UNSEALED SOURCES	9

This Guide is valid as of 1 May 2016 until further notice.

It replaces Guide ST 6.1, Radiation safety when using unsealed sources, issued on 17 March 2008.

Helsinki 2016

ISBN 978-952-309-331-7 (pdf)

ISSN 0789-4716

ISBN 978-952-309-332-4 (html)

7	TRANSPORT OF RADIOACTIVE SUBSTANCES	10
7.1	Transport preparations and reception of radiation sources	10
7.2	Transporting radiation sources by road	11
8	ABNORMAL EVENTS	11
8.1	Preparation for abnormal events	11
8.2	Procedure in case of an abnormal event	11
8.3	Reporting of abnormal events	11
APPENDIX DEFINITIONS		

Authorization

The Radiation Act stipulates that the party running a radiation practice is responsible for the safety of the operations. The responsible party is obliged to ensure that the level of safety specified in the ST Guides is attained and maintained.

Under section 70, paragraph 2, of the Radiation Act (592/1991), STUK – Radiation and Nuclear Safety Authority (Finland) issues general instructions, known as Radiation Safety Guides (ST Guides), concerning the use of radiation and operations involving radiation.

Translation. In the event of any differences in interpretation of this guide, the Finnish and Swedish versions shall take precedence over this translation.

1 General

In order to ensure the safe use of radioactive substances, it is important that attention is paid, already when planning the place of radiation use, to the radiation safety requirements arising from the nature of the work and the radionuclides used. The underlying principle of the planning is to ensure that working with unsealed sources is safe. It is also important that the discharges of radioactive substances into the environment are as low as possible even during possible abnormal events and that unauthorized access to radioactive substances is prevented.

This Guide sets forth the radiation safety requirements for radionuclide laboratories, storage rooms of radioactive substances and tracer tests performed outside of laboratories. The Guide also contains general instructions for working with unsealed sources and for the transport of radioactive substances.

The definitions of the terms used in the Guide are presented in the Appendix.

Section 26 of the Radiation Act (592/1991) contains provisions concerning the right of the Radiation and Nuclear Safety Authority (STUK) to confirm the safety requirements to be taken into account during the planning of the facilities. Guide ST 1.10 discusses the planning of premises of use for radiation sources. The requirements for security arrangements at a radionuclide laboratory are set forth in Guide ST 1.11. Guide ST 6.2 concerns the processing of radioactive wastes and discharges generated by the use of unsealed sources. Section 23 of the Radiation Decree (1512/1991) contains provisions concerning the discharges of radioactive substances. Guide ST 1.6 discusses the classification of workers within radiation work. Guide ST 7.1 discusses monitoring of radiation exposure. Guide ST 7.5 concerns the arrangement of medical surveillance for occupationally exposed workers.

2 Risk assessment is the basis for planning

The party running a radiation practice (hereinafter referred to as the “responsible party”) shall identify the risks related to the activities in advance and perform a risk

assessment. Purposeful facilities shall then be planned on this basis. The assessment shall take into account external radiation (including doses to the hands and the eyes), internal radiation, contamination risk, stay time in the laboratory, security arrangements and the potential for and consequences of abnormal incidents. Risks shall be reassessed if the conditions change considerably.

3 Classification of radionuclide laboratories

Radionuclide laboratories are classified as laboratories of type C, B and A.

The laboratory type required for a specific operation is determined by

- the radionuclides used
- the activity handled at any one time
- the nature of the work involved.

Working areas shall, where necessary, be classified as controlled areas and supervised areas.

The radionuclide laboratory shall be equipped to comply with the requirements of laboratory type C, B or A, in accordance with Table 1. If the activity handled at any one time is less than the exemption value given in Guide ST 1.5, no structural special requirements will be set for the laboratory.

Table 1. Definition of the laboratory type on the basis of the radionuclides used and the activity handled at any one time.

Laboratory type	Activity handled at any one time
Type C	≤ 10 -fold exemption value ^{*)}
Type B	$\leq 10^4$ -fold exemption value ^{*)}
Type A	$> 10^4$ -fold exemption value ^{*)}
*) The amount of activity as given in Guide ST 1.5.	

The activity limits presented in Table 1 shall be applied when radioactive substances are handled using conventional chemical procedures. The following coefficients that depend on the type of the work are applied to the values presented in Table 1:

- **0.1**; Especially hazardous work with a danger of splashing or vaporization (e.g. animal experiments, complicated handling of liquids, handling of dry matter)

- **10**; Uncomplicated handling (e.g. the dilution of stock solutions)
- **100**; Storage of radioactive substances.

A facility that is only used for the storage of radioactive substances is not classified as a radionuclide laboratory. The requirements concerning storage of radioactive substances are described in detail in item 4.6.

Section 32 of the Radiation Act (592/1991) contains provisions concerning the division of working areas into controlled areas and supervised areas. The requirements for the controlled areas and supervised areas are set forth in Guide ST 1.6 and examples of the classification of areas are provided in Appendix B to Guide ST 1.6.

4 Requirements concerning the structures and equipment of radionuclide laboratories

4.1 General design principles

The design of a radionuclide laboratory shall take into account the radiation protection of the workers and the other persons (the members of the public). Operations shall be planned and executed in such a manner that the radiation exposure caused by the use of radiation is as low as reasonably achievable (principle of optimization). However, the plan that is selected for execution on the basis of the optimization study shall be such that the effective dose caused on persons other than those engaged in radiation work is not expected to exceed 0.3 mSv per year (dose constraint). If the operations are appropriately optimized, the doses are usually clearly lower than the dose constraint.

The following factors shall also be considered when planning the use of unsealed sources:

- Moving of radioactive substances on site shall be kept to a minimum by locating those premises between which radioactive substances need to be moved close to each other.

- The premises shall be appropriately protected. Special attention shall be paid to radiation shielding in premises used for handling or storing radionuclides that emit gamma or neutron radiation.
- The premises shall be designed in a manner that can prevent unnecessary residence and movement within them.
- Unauthorized access to the radionuclide laboratory and the storage of radioactive substances shall be prevented.
- The management of radioactive waste shall be organized in a manner that does not cause a radiation hazard.
- If the nature of the practice requires minor discharges of radioactive substances into the air, sewage system or otherwise into the environment, then special care shall be taken to ensure that the quantities of substances thus discharged remain below the activity limits imposed by STUK and as low as can reasonably be achieved.
- Any abnormal events shall be taken into account in the planning of the operations.

4.2 Type C laboratory

A type C laboratory is intended for the handling of low activities. The structures and equipment in a type C laboratory are similar to those of a modern, well-planned chemistry laboratory. The radionuclide laboratory shall have sufficient space for safe working. The radionuclide laboratory shall also be furnished with a sign indicating a radiation hazard. Sufficient radiation shielding and personal protective devices shall be available. No offices or other similar work areas that are not necessary for the laboratory functions shall be placed within the laboratory premises. The requirements set forth in items 4.2.1–4.2.4 also apply to type C laboratories.

Guide ST 1.3 discusses warning signs for the premises of use of radiation sources.

4.2.1 Fire safety

With regard to the fire safety and the fire-technical requirements of the structural elements, the laboratory shall fulfil the

requirements set out for premises, as specified in The National Building Code of Finland, Section E1 “Structural Fire Safety in Buildings” and for premises in special use E2 “Fire Safety of Production and Warehouse Buildings”.

4.2.2 Surface materials and furniture

All the surface materials and furniture of the radionuclide laboratory shall be selected in a manner that makes them easy to clean. Attention shall also be paid to the following matters:

- The floor and the surfaces of working benches shall be made of materials impermeable to moisture and resistant to ordinary chemicals, such as dilute acids, alkalis and organic solvents.
- Joints and gaps shall be filled.
- The walls and the ceiling shall be made of materials that have a smooth surface.
- The working areas must be equipped with only the minimum furniture needed, the coatings of which do not accumulate dust and are easy to clean.

4.2.3 Ventilation

Ventilation shall be planned and implemented according to the requirements set for laboratories in the National Building Code of Finland, Section D2 “Indoor climate and ventilation of buildings”. The following features shall also be considered when planning the ventilation of the radionuclide laboratory:

- The ventilation in the laboratory shall be sufficient. The ventilation for radionuclide laboratories shall always be planned on a per-case basis.
- The distance between the intake and exhaust openings of the ventilation system of the building shall be sufficient to prevent possibly contaminated exhaust air from flowing back into the intake opening.
- If necessary, a filter shall be installed in the intake duct in order to reduce impurities in the inside air of the laboratory and to clean any possible backflow.
- The need to filter the exhaust air shall be considered case by case. It depends on the nature of the work, the radionuclides used and on their chemical and physical form as well as the chemical and physical form of the possibly

contaminated air. If it is necessary to filter the exhaust air, the filter shall be located in such a manner that the radioactive substances accumulating in the filter do not constitute a radiation hazard to the environment and that the filter is easy to replace.

- The need for the radiation shielding of the exhaust duct and filters shall be considered, and shielding shall be installed if necessary.
- Exhaust air from inside the premises, fume cupboards, glove boxes or other similar protective cupboards shall not be recycled if there is a possibility that radioactive substances can be discharged into the air; the air must be fed outside by means of a separate exhaust duct.
- The exhaust duct shall be designed in a manner that prevents radioactive vapour from condensing inside it.
- If necessary, the exhaust duct shall be furnished with a sign indicating a radiation hazard.
- The ventilation drawings shall indicate which ventilation ducts come from the radionuclide laboratory.

If due to the nature of the work, it is probable that radioactive substances will pass into the air, the laboratory shall be equipped with a sufficient number of fume cupboards, glove boxes or similar protective cupboards for handling radioactive substances. The following requirements shall apply to these cupboards:

- The air flow rate at the work opening of a fume cupboard shall be at least 0.5 m/s when the height of the opening is 30 cm.
- The exhaust blower shall be located so as to ensure negative pressure in the exhaust duct.
- The fume cupboards and glove boxes shall be equipped with a light indicating when the blower is in operation.

4.2.4 Water and sewerage equipment

The following factors shall be taken into account concerning water and sewerage equipment:

- If liquid radioactive wastes are discharged into the sewage system, there shall be a separate sink for this purpose. The sink shall be labelled with a sign indicating a radiation hazard.

- The sewage pipes from the radionuclide laboratory should lead directly into the main sewage pipe. Inside the building, they should not be connected to any other sewage pipes than those coming from radionuclide laboratories.
- When necessary, the sewage pipes from radionuclide laboratories shall be furnished with a sign indicating a radiation hazard.
- Preventing backflow is recommended.
- A washbasin shall be available for washing hands. The faucets of the basin shall be operable without having to touch them (e.g. faucets that operate with a motion detector or faucets that can be used with the arm).

4.3 Type B laboratory

In addition to what is stated above about type C laboratories, a type B laboratory shall fulfil the following additional requirements:

- The facilities for the use and storage of radioactive substances shall be sectioned into a separate fire compartment if a fire within the laboratory or storage rooms can lead to a discharge of radioactive substances that causes substantial radiation doses to the workers or the members of the public or the contamination of the environment.
- The laboratory shall have a vestibule (enclosed space) with a washbasin as well as space for changing and keeping protective clothing and for contamination measurements.
- The laboratory shall be furnished with the necessary equipment for cleaning possible contamination.
- The floor coating shall be unbroken and extend at least 10 cm up the walls.
- All pipe penetrations shall be sealed.
- The floor and the working benches shall be strong enough to bear the weight of a radiation shield assembled from lead bricks, for example.
- The locking of the windows shall be such that windows cannot be opened without a separate key.
- The laboratory shall be furnished with mechanical ventilation which maintains the air pressure in the handling area, during the use of radioactive substances, slightly lower than that in the surrounding area,

in order to ensure that air flows towards those areas of the room, which are most subjected to contamination. The pressure difference between the areas shall be 10 Pa at a minimum.

- A method shall be available for confirming the pressure difference between the areas.

4.4 Type A laboratory

A type A laboratory shall fulfil the requirements set above for type B and C laboratories. In addition, STUK lays down radiation safety requirements for each type A laboratory on a laboratory-specific basis, depending on the information presented in the plan submitted by the responsible party. The maximum activities for radionuclides used in a type A laboratory are defined in the safety licence.

4.5 Request for preliminary statement

If the planned operations can be expected to cause discharges into the environment (air, water systems, soil), a preliminary statement shall be requested from STUK concerning the plan before construction is started. Even when discharges are not anticipated, a statement shall be requested when the plan concerns a type A laboratory or another type of large-scale use of radioactive substances. The request for statement shall present the following matters, at a minimum:

- The location of the plant (regional map)
- Housing and business premises in the vicinity of the plant, with the number of persons
- Soil and water use in the vicinity of the plant (farming, water supply, wells and similar facilities)
- A description of the operations, the radionuclides used and their activity levels
- Room arrangements in the laboratory (layout drawings)
- HVAC arrangements (in particular, the filtration of exhaust air)
- Building materials (building practice report)
- Report on the management and discharges of radioactive waste
- Report on the radiation meters used for protecting the workers and the environment and their calibration

- An estimate of the radiation exposure caused to the workers and to the representative person
- A description of any possible abnormal events and preparation for them
- An estimate of the radiation exposure caused to the workers and to the representative person due to the possible abnormal events.

Final approval for starting operations will be issued in the safety licence and the inspection performed at the site.

The request for preliminary statement is also discussed in Guide ST 1.6.

4.6 Storage room for radioactive substances

Radioactive substances and wastes shall be stored in such a manner as to prevent them from constituting a radiation hazard to the environment or passing into the hands of unauthorized persons. If significant quantities of radioactive waste are generated, a separate storage room for radioactive waste might be needed.

The shielding of the storage room for radioactive substances and waste shall be planned and implemented in a manner that complies with the optimization presented in item 4.1 and the related dose constraint. Furthermore, the following requirements shall apply to the storage room:

- As regards the fire safety of the storage room for radioactive substances, the requirements specified in items 4.2.1 and 4.3 shall be taken into account.
- With regard to the surface materials and furniture, the requirements specified in item 4.2.2 shall be taken into account.
- The storage room for radioactive materials must not be used for any other purpose.
- The storage room shall be furnished with a sign indicating a radiation hazard.
- The storage room shall be organized so that each radiation source can be taken into and out of the room without causing any danger.
- Solutions which may develop excessive pressure shall be stored in such a way that

there is no danger of radiation even if the container or package is broken.

- The storage room shall be designed in a manner that effectively prevents the spreading of radioactive substances into other premises.
- If radioactive substances may be discharged into the air, the air pressure in the storage room shall be lower than in the surrounding rooms.

The number of unsealed sources in the storage shall be kept as low as possible.

4.7 Facilities for a nuclear medicine unit

4.7.1 General

A unit where radioactive substances are used as unsealed sources in nuclear medicine examinations and/or treatments typically include:

- handling room for radiopharmaceuticals
- a room for changing clothes (vestibule)
- a room for carrying out cell labelling
- a room for administering radiopharmaceuticals to patients
- a waiting room for patients
- for patients, a room for changing clothes and a toilet
- imaging room
- a storage room for radiation sources
- a storage room for radioactive waste
- possibly a room for measuring samples
- a patient room for those receiving radionuclide therapy.

The patient room of patients who have received radionuclide therapy may need to be radiation-shielded to protect other patients and workers. Radiation shielding of the imaging room may also be necessary in order to prevent radiation sources outside the room from disturbing the functioning of the imaging device.

Guide ST 1.6 shall be followed when dividing areas into controlled areas and supervised areas. Guide ST 1.10 discusses the planning of radiation shielding for X-ray equipment.

4.7.2 Handling rooms for radiopharmaceuticals and patient rooms

The handling rooms for radiopharmaceuticals and patient rooms shall meet the following radiation safety requirements:

- A laboratory that is used for the handling of radiopharmaceuticals shall meet the requirements set for a type B laboratory (see items 4.2 and 4.3 in this Guide). The storage and injection of ready-to-use radiopharmaceuticals is allowed also in other suitable premises.
- For administering radionuclide therapy, there shall be a separate room with a floor coating as specified in item 4.2.2.
- The surfaces of the room intended for administering radiopharmaceuticals and the imaging room shall be easy to clean.
- There shall be a separate patient room for those patients receiving ^{131}I therapy who are staying at the hospital. The patient room shall be equipped with its own toilet and washing facilities. The patient room shall be furnished with a sign indicating a radiation hazard.

The Finnish Medicines Agency (Fimea) supervises radiopharmaceuticals and Fimea regulation 6/2012 contains provisions concerning the use of radiopharmaceuticals. The National Supervisory Authority for Welfare and Health (Valvira) regulates the manufacture and entry on the market of health care equipment and supplies based on the Medical Devices Act (629/2010).

4.8 Tracer tests performed outside of the laboratory

Radioactive substances are also used as unsealed sources in tracer tests performed outside of the laboratory.

4.8.1 Radiation safety requirements

Tracer tests performed outside of the laboratory shall take into account the requirements set forth in item 4.1 (planning of the use of unsealed sources). Furthermore, the following radiation safety requirements shall apply to tracer tests:

- The requirements for the discharge of radioactive substances into the environment also apply to tracer tests performed outside of the laboratory. If necessary, the meeting of

the requirements shall be demonstrated by means of calculations (effective dose caused by the tracer tests to a representative person, taking into account the external and internal dose) or by monitoring the discharges.

- If the radiation safety officer cannot actively supervise the safety of the tracer test, an on-site radiation safety person shall be appointed to ensure the radiation safety of the test. The radiation safety officer and the on-site radiation safety person shall be trained as radiation safety officers in the use of unsealed sources in industry, research and education in accordance with Guide ST 1.8.
- Controlled areas and supervised areas shall be separated within the test area. For example, the controlled areas shall be separated by barricade tape and marked with a sign indicating a radiation hazard.
- Unauthorized access into the controlled area shall be prevented.
- Written instructions shall be available for the tracer tests and they shall include radiation protection instructions as well as instructions for abnormal events.
- If the unit undergoing the tracer test has a radiation safety officer, they must be notified of the tracer test. It is especially important to note the radiometric measuring devices that may have been installed in the process subjected to the tracer test.
- After the tracer test, measurements shall be employed in order to ensure that there is no contamination in the area.
- Tracer tests using radioactive substances are forbidden in drinking water networks.

In addition to the requirements presented above, STUK may set other requirements or limitations for an individual tracer test.

Guide ST 6.2 discusses the discharge of radioactive substances into the environment. Guide ST 1.8 sets forth the training and qualification requirements for the radiation safety officer and the other persons working in the radiation user's organization.

4.8.2 Notifications to STUK

An advance notification of tracer tests shall be made to STUK at least two weeks prior to the

date of the tracer test. The advance notification shall be made in writing and it must contain at least the following information:

- the holder and number of the safety licence and the radiation safety officer
- the place and time of the tracer test
- the purpose of the tracer test and its legal justification
- the radionuclide used, including its chemical and physical form
- the total activity used in the tracer test, the number of measurements to be taken, the activity used in a single measurement and an analysis of the amount of radioactive substances discharged into the environment
- an estimate of the effective dose caused to a worker and a representative person
- an estimate of the effective dose that may be caused to a worker and a representative person as a result of an abnormal event.

5 Surface contamination

Good working practices, regular cleaning and contamination measurements are important for keeping the contamination at a low level on the premises. A record shall be maintained regarding the cleaning and contamination measurements at the premises. Measures are to be taken to remove or isolate the contamination if the surface activity in the radionuclide laboratory and in other places of radiation use exceeds the limits specified in Table 2. If the working site, tools or clothing cannot be decontaminated sufficiently, their use shall be restricted and the passage of radioactive substances into the body and their dispersal into the environment shall be prevented by other measures.

The surface activity limits apply neither to the inner surfaces of fume cupboards and other similar handling areas, nor to contamination protectors, which are used in addition to the standard protective clothing when working in contaminated areas. In these cases, as well, contamination shall be kept as low as reasonably possible.

When determining surface activity, the amount of both fixed and non-fixed contamination is to be taken into account. The surface activity is determined as the average activity over an area of 100 cm², if possible.

The monitoring of working conditions at the workplace is also discussed in Guide ST 1.6. Determining surface contamination is presented in standard ISO 7503.

6 Working with unsealed sources

When using unsealed sources, attention shall be paid not only to the exposure caused by external radiation but also to the exposure caused by internal radiation, which may be caused by contaminated breathing air, working benches or other surfaces. The passage of radioactive substances out of the laboratory or into the hands of unauthorized persons shall be prevented.

Below is a list of general working instructions:

- Unauthorized people are not to be admitted into the radionuclide laboratory.
- The radionuclide laboratory must be kept clean.
- Tools which are used for handling radioactive substances shall be cleaned after use and kept separate from other tools and instruments.

Table 2. Surface activity limits when using unsealed sources. [22]

Radioactive substance	Workplaces and tools		Workers	
	Controlled area*) (Bq/cm ²)	Supervised*) and other areas (Bq/cm ²)	Clothing (Bq/cm ²)	Skin (Bq/cm ²)
Alpha emitters	4	0,4	0,4	0,2
Beta and gamma emitters	40	4	4	2

*) The definitions of and requirements for controlled and supervised areas are set out in Guide ST 1.6.

- A sufficient number (to be decided depending on the nature of the operations) of suitable contamination and radiation meters shall be available in the laboratory.
- Workers handling radioactive substances shall wear adequate protective clothing. Such protective clothing must not be worn outside the laboratory.
- Eating, drinking, smoking or applying make-up is forbidden in the radionuclide laboratory. Pipetting by mouth is prohibited.
- Work involving the handling of volatile or dusty radioactive substances shall be carried out in a fume cupboard, glove box or other similar protective cupboard.
- If the work carries a specific risk of contamination, working alone in the radionuclide laboratory should be avoided.
- During work stages with a risk of contamination, working surfaces shall be covered with a material preventing the spread of the contamination.
- When handling radioactive substances, radiation shielding (syringe shields, lead shields or equivalent) shall be used whenever possible.
- Whenever possible, automatic equipment shall be used in the handling of radioactive substances in order to improve radiation safety and to reduce the number of human errors.
- Radiation sources shall be labelled so that they are easily identifiable. The labelling shall at least include the radionuclide, its activity, the date when the activity was measured and the person who measured it. For unsealed sources, the total volume or activity concentration shall also be indicated (activity per unit of volume, for example).
- Tools and equipment needed for preventing the spread of radioactive substances and removing contamination shall be available.
- The dose rate of external radiation and the amount of contamination shall be monitored at appropriate intervals. Contamination measurements shall be carried out after finishing work and always when considerable contamination of working benches or other surfaces, the air of the laboratory, working

clothes or tools is suspected. The results of the measurements shall be documented.

- A record shall be kept of incoming shipments containing a radioactive substance and of stored radioactive substances.
- A record shall be kept of radioactive wastes and discharges.

In addition to what is stated above, any laboratory-specific special regulations and instructions shall be followed.

Guide ST 7.1 provides instructions concerning measurements for the purpose of monitoring of working conditions.

7 Transport of radioactive substances

The transport of radioactive substances has been exempted from the need for a safety licence by virtue of the Radiation Act. However, the Radiation Act lays down general obligations for a safety licence holder who commissions the transport of radioactive substances or imports such substances. Any transport of radioactive substances must comply with the legislation on the transport of dangerous goods.

7.1 Transport preparations and reception of radiation sources

The consignor of a radioactive substance is responsible for the appropriate preparations of the transport. The consignor may be the safety licence holder or a party authorized by the safety licence holder. When consigning radioactive substances for transport, the consignor is responsible for ensuring the following, among other things:

- The radioactive substance is correctly classified (UN number and title).
- The transport package and its markings meet the set requirements.
- The mode of transport is appropriate from a safety perspective.
- The carrier has all the documents and instructions required by the regulations (consignment note, any additional instructions).

If radioactive substances are sent by air, the qualifications of the consignor and packer must be approved by the Finnish Transport Safety Agency.

The responsible party must ensure that employees receiving radioactive substances have been sufficiently trained and instructed for their task. Transport packaging containing radioactive substances must not be unnecessarily stored in the reception facilities.

7.2 Transporting radiation sources by road

A safety licence holder may transport their own radiation sources by road. In such cases, the licence holder must meet the obligations of the carrier and driver, including the following:

- The driver has the necessary qualifications for the transport of dangerous goods (a valid ADR certificate or awareness training, if necessary).
- The vehicle has the markings for the transport of radioactive substances, if necessary.
- The vehicle has the equipment and safety instructions required by the regulations.
- The shipments have been loaded safely.
- The damage, loss and unauthorized seizure of radioactive substances has been effectively prevented throughout the transport.

For more information about the transport of radioactive substances, see the guides *Radioaktiivisten aineiden kuljetus* (Transport of radioactive materials) [17] and *Turvajärjestelyt radioaktiivisten aineiden tiekuljetuksissa* (Security arrangements in the road transport of radioactive materials) [18], published by STUK.

The transport of dangerous substances is regulated by the Act on the Transport of Dangerous Goods (719/1994) and regulations issued by virtue of the Act. Detailed requirements for transport by road are specified in the Finnish Transport Safety Agency's order TRAFI/4541/03.04.03.00/2015. By virtue of Section 11 of the Radiation Act, the transport of radioactive substances constitutes use of radiation. The transport of radioactive substances has been exempted from the need for a safety licence by virtue of Section 17 of the Radiation Act. The safety licence holder's liability for transport and damage in transport are regulated by Sections 29–30 of the Radiation Act. The ADR

certificate is regulated by the Government Decree on the Driving Authorization of the Drivers of Dangerous Goods (401/2011). Awareness training is regulated by a Finnish Transport Safety Agency's order, Annex A, Special regulation S12.

8 Abnormal events

8.1 Preparation for abnormal events

The responsible party shall identify in advance the possible hazardous abnormal events associated with the use of radiation sources. Furthermore, the responsible party must prepare for the possibility that the radioactive substance is stolen or damaged maliciously. The responsible party shall plan and implement the operations in a manner that minimizes the likelihood of abnormal events. The responsible party shall also ensure that the information concerning the abnormal event is relayed within the organization, allowing it to reach the responsible party and the responsible individuals.

Steps shall be taken to prepare for potential abnormal events by such means as issuing written instructions on how to act in case of abnormal events to workers engaged in duties involving radiation sources, and by reserving sufficient equipment for the isolation of an area and the removal of contamination, for example.

8.2 Procedure in case of an abnormal event

In case of an abnormal event, all feasible measures shall be taken to decrease the radiation exposure, to prevent the spread of contamination and to restore radiation safety. The causes of the abnormal event shall be identified. Actions shall be taken in order to prevent the occurrence of similar events.

The causes of the event shall also be analyzed for near misses that involve a substantial potential risk, and the implementation of corrective actions shall be considered.

8.3 Reporting of abnormal events

Abnormal events must be reported to STUK without delay. The report shall indicate the following:

- the responsible party (safety licence holder) and the radiation safety officer

- the name and contact details of the person submitting the report
- the time and place of the event
- description of the event
- information on persons exposed to danger and an estimate of their possible radiation exposure
- information on radioactive substances that were discharged into the environment
- immediate actions taken due to the event.

If necessary, a written report concerning the abnormal event shall be submitted to STUK. In addition to the foregoing details, the written report must also give an account of the causes and consequences of the abnormal event (particularly of possible radiation exposure) and of the measures taken to prevent similar events in the future.

Reporting of abnormal events to STUK is regulated by Section 17 of the Radiation Decree (1512/91). Further details concerning the procedure in case of abnormal events and the reporting of such events to STUK are set out in Guide ST 1.6. Additionally, Guide ST 1.11 discusses intentional damage to or theft of radioactive substances and the required reports.

The obligation of professional users of medical devices and accessories to report hazardous situations to the National Supervisory Authority for Welfare and Health is regulated by the Medical Devices Act (629/2010).

Literature

1. DIN 25425-1. Radionuklidlaboratorien - Teil 1: Regeln für die Auslegung. Berlin: Deutsches Institut für Normung.
2. DIN 25425-2. Radionuklidlaboratorien - Teil 2: Betriebliche Strahlenschutzanweisungen. Berlin: Deutsches Institut für Normung.
3. International Atomic Energy Agency. Safe handling of radionuclides. IAEA Safety Series No. 1. Vienna; IAEA; 1973.
4. International Atomic Energy Agency. Applying radiation safety standards in nuclear medicine. IAEA Safety Reports Series No. 40. Vienna; IAEA; 2005.
5. International Atomic Energy Agency. Nuclear medicine resources manual. Vienna: IAEA; 2006.
6. International Atomic Energy Agency. Radiotracer generators for industrial applications. IAEA Radiation Technology Series No. 5. Vienna: IAEA; 2013.
7. International Commission on Radiological Protection. The 2007 recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Annals of the ICRP 2007; 37 (2–4).
8. International Commission on Radiological Protection. Radiological protection in medicine. ICRP Publication 105. Annals of the ICRP 2007; 37 (6).
9. ISO 7503-1:1988. Evaluation of surface contamination – Part 1. Beta-emitters (maximum beta energy greater than 0.15 MeV) and alpha-emitters. Geneva: International Organization for Standardization.
10. ISO 7503-2:1988. Evaluation of surface contamination – Part 2: Tritium surface contamination. Geneva: International Organization for Standardization.
11. ISO 7503-3:1996. Evaluation of surface contamination – Part 3: Isomeric transition and electron capture emitters, low energy beta-emitters ($E_{\beta_{\max}} < 0,15 \text{ MeV}$). Geneva: International Organization for Standardization.
12. ISO 17873 : 2004. Nuclear facilities – Criteria for the design and operation of ventilation systems for nuclear installations other than nuclear reactors. Geneva: International Organization for Standardization.
13. ISO 2889 : 2010. Sampling airborne radioactive materials from the stacks and ducts of nuclear facilities. Geneva: International Organization for Standardization.
14. Finnish Medicines Agency (Fimea). Operation of a hospital pharmacy and medicine centre. Regulation 6/2012. Fimea (18 December 2012).
15. Madsen MT et al. AAPM Task Group 108: PET and PET/CT Shielding Requirements. Med. Phys. 2006; 33 (1): 4–15.

16. Medical and Dental Guidance Notes, 2002. A good practice guide on all aspects of ionising radiation protection in the clinical environment; Prepared by the Institute of Physics and Engineering in Medicine (IPEM) with the support of NRPB, HSE, Health Departments, Environment Agencies. York; IPEM: 2002.
17. STUK. Radioaktiivisten aineiden kuljetus. STUK opastaa/Syyskuu 2012. (Transport of radioactive materials. Advice from STUK/ September 2012.) 2. revised edition. Helsinki: Radiation and Nuclear Safety Authority of Finland; 2013.
18. STUK. Turvajärjestelyt radioaktiivisten aineiden tiekuljetuksissa. STUK opastaa/ Kesäkuu 2015. (Security arrangements for road transport of radioactive materials.) Helsinki: Radiation and Nuclear Safety Authority of Finland; 2015.
19. The Ministry of the Environment's decree on the structural fire safety in buildings. Issued 6 April 2011. E1 The National Building Code of Finland.
20. The Ministry of the Environment's decree on the fire safety of production and warehouse buildings. Issued 22 March 2005. E2 The National Building Code of Finland.
21. The Ministry of the Environment's decree on the indoor climate and ventilation of buildings. Issued 30 March 2011. D2 The National Building Code of Finland.
22. International Atomic Energy Agency. Safe Handling of Radionuclides. IAEA Safety Series No. 1. Vienna: IAEA; 1973.

APPENDIX

DEFINITIONS

Surface activity

Surface activity, A_s , is the activity A of a radioactive substance on a given surface in the area under inspection, divided by the area S of this surface:

$$A_s = \frac{A}{S}.$$

The unit for surface activity is $\text{Bq}\cdot\text{m}^{-2}$.

Unsealed source

A radioactive substance that is not a sealed source.

Representative person

An individual in the population group most exposed to a certain radiation source, whose dose is representative for individuals in this group.

Tracer test

A test during which a substance that does not normally belong into a flow process is fed into the process and the progress of this tracer substance is then followed.

Surface contamination

Contamination of a radioactive substance on a surface.

Radiopharmaceutical

All medicines that, when ready to use, contain one or more radionuclides for a medical purpose.

Sealed source

A radioactive source wherein the radioactive substance is permanently enclosed inside a capsule or in a solid form; the purpose is to prevent the spreading of radioactive material under normal conditions of use.