

# Radiation Safety Requirements for Radionuclide Laboratories

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# Authorisation

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.

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.

Translation. Original text in Finnish.

This Guide includes the requirements relating to the implementation of Council Directive 96/29/Euratom; OJ No. L 159, 29.6.1996, p. 1.

# 1 General

In order to ensure the safe use of radioactive substances, it is important that attention is paid, already when planning a laboratory or other place of radiation use, to the radiation safety requirements arising from the nature of the work and the radionuclides used. The underlying principles to be taken into account in the planning are that it is safe to work in the laboratory, discharges of radioactive substances into the environment remain minimal both in normal and abnormal conditions, and that the passage of radioactive substances from the laboratory into the hands of unauthorised persons is prevented.

According to section 26 of the Radiation Act (592/1991), the safety requirements affecting safety in the use of radioactive substances that are to be taken into account in the planning of laboratories and other premises, will be confirmed by the Radiation and Nuclear Safety Authority (STUK).

This guide lays down the requirements for laboratories and storage rooms in which radioactive substances are used or stored as unsealed sources. In addition, some general instructions concerning work in radionuclide laboratories are set out.

# 2 Laboratory Classification

By radionuclide laboratory is meant a laboratory in which radioactive substances are handled as unsealed sources.

Radionuclide laboratories are classified as laboratories of type C, B or A. The type of laboratory required for a specific operation is determined on the basis of the radiotoxicity class of the radionuclides used, the activity handled at any one time, and the nature of the work involved. In radionuclide laboratories the controlled and supervised areas, as specified in ST Guide 1.6, shall also be defined and delineated.

When radioactive substances are handled using conventional chemical procedures, the laboratory shall be equipped in such a manner as to comply with the requirements of laboratory type C, B or A in accordance with the activity limits specified in Table I. If the activity handled at one time is less than the exemption limit given in ST Guide 1.5, no structural radiation safety requirements will be set for the laboratory.

**Table I.** Definition of the laboratory type on the basis of the radiotoxicity class of the radionuclides used and the activity handled at any one time.

Radionuclide radiotoxicity class <sup>*)</sup>	Laboratory type and activity used at any one time		
	Type C	Type B	Type A <sup>**)</sup>
Radiotoxicity class 1	< 0.5 MBq	0.5 MBq–0.5 GBq	> 0.5 GBq
Radiotoxicity class 2	< 5 MBq	5 MBq–5 GBq	> 5 GBq
Radiotoxicity class 3	< 50 MBq	50 MBq–50 GBq	> 50 GBq
Radiotoxicity class 4	< 500 MBq	500 MBq–500 GBq	> 500 GBq

<sup>\*)</sup> The radiotoxicity classification for the most common radionuclides is given in the Appendix.  
<sup>\*\*)</sup> Maximum activities are laid down in the safety licence.

In a type C laboratory with efficient air-conditioning and a fume cupboard or other handling box suitable for the work in question, the maximum activities may be tenfold compared to those specified in the second column of Table I. For radionuclides belonging to radiotoxicity classes 3 and 4, STUK may approve (with the same preconditions) an even higher activity limit (the safety licence and laboratory specific activity limit).

The activity limits in Table I are applied by multiplying them by coefficients derived from the radiation hazard connected with the work. The coefficients for various operations are as follows:

Storage of radioactive liquids	100
Uncomplicated handling of liquids	10
Conventional chemical handling	1
Complicated handling of liquids where there is a danger of splashing or vaporisation, as well as uncomplicated handling of dry matter, and animal experiments	0.1
Handling of dry matter with a danger of dust formation	0.01

In a type C laboratory, for instance, the maximum permissible activity of radionuclides in radiotoxicity class 2 stored as unsealed sources is 500 MBq, but the activity handled at any one time must not exceed 0.5 MBq if, depending on the nature of the work, radioactive material could be spread by either evaporation or splashing.

## 3 Radiation Safety Requirements Concerning Laboratory Structures and Equipment

### 3.1 Type C Laboratory

A type C laboratory is intended for the handling of low activities. The structures and the equipment in the laboratory are similar to those of a modern, well-planned chemistry laboratory. The radiation safety requirements for a type C laboratory are as follows:

- With regard to the fire safety and the fire-technical requirements of the structural elements, the laboratory must fulfil the requirements set out for rooms and premises in special use specified in the Finnish Building Regulations, Section E1 “Structural Fire Safety” and E2 “Fire Safety of Production and Storage Buildings”.
- 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 and alkalis and organic solvents. Joints and gaps shall be filled so as to obtain a smooth, easy-to-clean surface.
- The walls and the ceiling shall be made of materials that have a smooth surface and are easy to clean.
- The working areas may be equipped with only the minimum furniture needed, the coatings of which do not accumulate dust and are easy to clean.
- According to need, separate waste bins are to be provided for liquid and solid radioactive waste, and the bins shall be labelled with an ionising radiation symbol.
- If liquid radioactive wastes are discharged into the sewage system, there shall be a separate sink for this purpose, which shall be labelled with an ionising radiation symbol.
- There shall be a washbasin for washing hands. The faucets of the basin should pref-

erably be operable by the arms or legs/feet, or in some other way without having to touch the faucets.

- The laboratory shall be furnished with a sign indicating a danger of radiation.
- It shall be possible to ventilate the laboratory sufficiently. The distance between the intake and exhaust openings shall be sufficient to prevent exhaust air from flowing back into the intake opening.
- 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 fume cupboard. The flow rate of air at the working opening of the cupboard shall be at least 0.5 m/s when the height of the opening is 30 cm. Any faucets connected to the cupboard shall be operable from outside the cupboard.

### 3.2 Type B Laboratory

A type B laboratory is designed especially for the handling of radioactive substances. In addition to what is stated above about type C laboratories, a type B laboratory must fulfil the following additional requirements:

- The laboratory must have a vestibule with a washbasin and space for changing and keeping protective clothing.
- The floor coating shall be unbroken and extend at least 10 cm up the walls. All lead-throughs for piping shall be insulated.
- The floor and working benches shall be strong enough to support the assembly of a sufficient radiation shield around the radiation sources using, for instance, lead bricks.
- The faucets of the washbasin used for washing hands shall be operable by the arms or legs/feet, or otherwise without having to touch the faucets.
- When locked, the windows must not be openable 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 that are most subjected to contamination.

- The laboratory shall be equipped with a sufficient number of fume cupboards or glove boxes. The exhaust air shall be led outside via a separate exhaust duct. The exhaust air shall normally be filtered.
- The exhaust air filter shall be located as close to the fume cupboard or glove box as possible in such a manner as to prevent the radioactive substances, accumulating in the filter, from constituting a radiation danger to the environment and to allow easy replacement of the filter. The exhaust blower shall be located close to the exhaust opening 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.

The prior inspection procedure, which is dealt with below, is not generally required for a type B laboratory.

### 3.3 Type A Laboratory

A type A laboratory is intended for the large-scale use of radioactive substances. The maximum amounts of radioactive substances used in type A laboratories are specified in the safety licence, taking into account the environmental conditions, the laboratory's safety systems, the properties and activities of the radionuclides to be used, and other factors linked to radiation safety.

Plans for a type A laboratory shall be submitted to STUK for inspection prior to the start of construction. In the plan, the following matters concerning the environment, the use of laboratory and the structures and the safety arrangements shall, at the very least, be presented for the appraisal of safety:

- a map of the region showing the location of the installation
- residential and working premises in the near environs of the installation
- utilisation of soil and waters in the environs

of the installation (e.g. agricultural land, water supplies, wells etc.)

- a description of the operations, including the radionuclides and their activities to be used
- layout of the rooms in the laboratory (plan drawings)
- heating, plumbing and ventilation arrangements (especially the filtering of exhaust air)
- structural materials (summary of construction method)
- a description of the treatment and discharge of radioactive wastes
- a description of the radiation meters to be used for the protection of workers and the environment, and of their calibration
- an evaluation of the exposure levels of residents living in the vicinity of the installation associated with the worst accident scenario.

Detailed radiation safety requirements for a type A laboratory are laid down separately, on a laboratory-specific basis, for each laboratory depending on the information presented in the plan. Final approval for the start-up of operations is granted in the safety licence. A precondition to the licence may be an inspection before the start-up of operations for example.

### 3.4 Radiopharmacy Laboratory

It shall be taken into account in relation to a radiopharmacy laboratory that both the Drug Act and the Radiation Act regulate the operations. The manufacturing and storage of radiopharmaceuticals in the laboratory shall comply with the Good Radiopharmaceutical Practice (GRP), which includes conditions ensuring sterile manufacturing and radiation protection. As far as the laboratory and patient rooms are concerned, the following radiation safety requirements shall be fulfilled:

- A radiopharmacy laboratory must comply with the special requirements of a type C or B laboratory (items 3.1 and 3.2). Ready-to-use radiopharmaceuticals may, however, also be handled, injected or stored in other laboratory rooms suitable for such purposes.

- For administering therapeutic doses, there shall be a separate room with a floor coating as specified in item 3.1.
- There shall be a separate patient room for those patients receiving therapy who are staying at the hospital. Furthermore, the access of such patients to public areas shall be restricted until the radioactive substances in their bodies no longer constitute a radiation hazard to other persons.

## 4 Storage of Radioactive Substances

Radioactive substances shall be stored in such a manner as to prevent them from constituting a radiation hazard to the environment or passing easily into the hands of unauthorised persons. As far as the fire safety of the storage facility is concerned, the requirements specified in item 3.1 shall be taken into account. In addition, the following requirements shall be fulfilled when arranging such storage:

- The radiation shielding of the storage facility shall be sufficient to ensure that the annual radiation dose accruing from stored radioactive substances does not exceed 1 mSv for people other than those engaged in radiation work. The dose rate outside the storage room should not be more than 2.5  $\mu$ Sv/h.
- The storage room shall be lockable, and it must not be used for any other purpose. The storage room shall be furnished with a sign indicating a danger of radiation.
- The storage room shall be organised such 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.
- If radioactive substances may be released into the air, it shall be possible to ventilate the storage sufficiently.

## 5 Surface Contamination Limits

In radionuclide laboratories and other places where radiation is used, the amount of radioactive substances on the various surfaces shall not exceed the surface contamination limits specified in Table II. If the surface contamination limits are exceeded, measures are to be taken to remove or isolate the contamination. 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 special protective measures.

The surface contamination limits do not apply to the inner surfaces of fume cupboards and other similar handling areas, such as glove boxes, nor contamination protectors which are used in addition to the standard protective clothing when working in contaminated areas. In such cases, however, the contamination shall be kept as low as reasonably possible. In a radionuclide laboratory there shall be a radiation meter, which is suitable for the measurement of surface contamination.

When determining surface contamination, the amount of both fixed and non-fixed contamination is to be taken into account. Surface contamination is determined as the average activity over an area of not more than 100 cm<sup>2</sup>. The smear method is set out in standard SFS 4574.

## 6 General Instructions Concerning Laboratory Work

When using unsealed sources, attention shall be paid not only to the external radiation exposure but also, and in particular, to the internal radiation exposure, which may be caused by contaminated air and working benches or other surfaces. The passage of radioactive substances out of the laboratory or into the hands of unauthorised persons shall be prevented. Below is a list of general regulations for working in a radionuclide laboratory:

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

**Table II.** Surface contamination limits.

Radioactive substance	Working areas and tools		Workers	
	Controlled area <sup>*)</sup> Bq/cm <sup>2</sup>	Supervised and other area Bq/cm <sup>2</sup>	Clothing Bq/cm <sup>2</sup>	Skin Bq/cm <sup>2</sup>
Radionuclides in radiotoxicity class 1	4	0.4	0.4	0.2
Other radionuclides	40	4	4	2

<sup>\*)</sup> The definition and the requirements for the controlled area are set out in ST Guide 1.6.

- Workers handling radioactive substances must wear adequate protective clothing. Such protective clothing must not be worn outside the laboratory.
- It is not permitted to eat, drink, smoke or make up in a radionuclide laboratory. Neither is pipetting by mouth permitted.
- Work involving the handling of volatile or dusty radioactive substances shall be carried out in a fume cupboard or glove box.
- If the work carries a specific risk of contamination, it is preferable to avoid working alone in the radionuclide laboratory, especially after regular working hours.
- During work stages with a risk of contamination, working surfaces shall be covered with a material preventing the spread of contamination.
- When handling radiation sources radiation shielding (syringe shields, lead shields etc.) shall be used whenever possible.
- Radiation sources shall be labelled so that they are easily identifiable.
- Tools and equipment needed for preventing the spread of radioactive substances and removing contamination shall be available at all times.
- The dose rate of external radiation and the amount of contamination in the radionuclide laboratory shall be monitored at appropriate intervals, and always when considerable contamination of workbenches or other surfaces, the air of the laboratory, working clothes or tools is suspected.
- A record shall be kept of incoming shipments containing a radioactive substance and of stored radioactive substances.

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

## 7 Bibliography

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- 5 NLN Publication No. 26. Radiopharmacy. Preparation and Control of Radiopharmaceuticals in Hospitals. Nordiska Läkemedelsnämnden, Upsala, 1989.
- 6 Guidance Notes for the Protection of Persons against Ionising Radiations arising from Medical and Dental Use. National Radiological Protection Board, 1988.
- 7 DIN 25425, Teil 1. Radionuklidlaboratorien. Regeln für die Auslegung.
- 8 DIN 25425, Teil 2. Radionuklidlaboratorien. Grundlagen für die Erstellung betriebsinterner Strahlenschutzregeln.
- 9 SFS 4575. Measurement of radioactive surface contamination. Smear method (smear test, wipe test). (in Finnish)

**Appendix**

**RADIOTOXICITY CLASSIFICATION OF THE MOST COMMONLY USED RADIONUCLIDES**

<b>Group 1</b>						
Pb-210	Po-210	Ra-226	Ra-228	Ac-227	Th-228	Th-230
U-232	Pu-238	Pu-240	Pu-241	Pu-242	Am-241	Cm-244
Cf-252						
<b>Group 2</b>						
Co-60	Ge-68	Sr-90	Ru-106	Ag-110m	I-124	I-125
I-131	Cs-134	Cs-137	Ce-144	Sm-151	Eu-152	Bi-210
<b>Group 3</b>						
C-14	Na-22	Na-24	P-32	P-33	S-35	Cl-36
K-43	Ca-45	Sc-46	Mn-54	Fe-52	Fe-55	Fe-59
Co-57	Co-58	Ni-63	Cu-67	Zn-62	Zn-65	Ga-67
Ga-72	As-73	As-76	Se-75	Br-82	Rb-84	Rb-86
Sr-82	Sr-85	Sr-89	Y-88	Y-90	Zr-95	Nb-95
Mo-99	Ru-103	Pd-103	In-111	Sn-113	Sb-124	Sb-125
Te-132	I-123	I-132	Ba-133	Ba-140	La-140	Ce-141
Pm-147	Sm-153	Gd-153	Ho-166	Tm-170	Yb-169	Ta-182
W-185	W-187	W-188	Re-186	Os-191	Ir-192	Au-198
Hg-197	Hg-203	Tl-204	Pu-237			
<b>Group 4</b>						
H-3	C-11	F-18	Cr-51	Mn-56	Cu-64	Ga-68
Tc-99m	In-113m	Dy-165	Pt-193	Tl-201		

The radiotoxicity classification for those radionuclides which are not listed in the table will be provided whenever necessary by STUK.