

# RADIATION USER'S ORGANIZATION

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This Guide is valid as of 1 January 2012 until further notice.

It replaces Guide ST 1.4, Radiation users's organization, issued on 16 April 2004.

Helsinki 2011  
ISSN 0789-4368

ISBN 978-952-478-763-5 (pdf)  
ISBN 978-952-478-764-2 (html)

# 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

The safe use of radiation requires that the radiation users' organization and the respective responsibilities are functional and clearly specified.

This Guide presents the requirements concerning the radiation user's organization, the approval of the radiation safety officer and the appointments of experts and on-site radiation safety persons. This Guide applies to uses of radiation requiring a safety licence.

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

*Provisions concerning the radiation user's organization and the organization description are laid down in section 18 of the Radiation Act (592/1991). The requirements relating to the competences and radiation protection training of radiation safety officers and other persons in radiation users' organizations are presented in Guide ST 1.8.*

## 2 The radiation user's organization shall be specified in the organization description

The use of radiation requires a safety licence which can be applied for from STUK in writing. Functionally separate responsible units, in principle, require their own safety licence.

Prerequisites for a joint safety licence for several responsible units or places of use of radiation may include, for example, that the entity be manageable by one radiation safety officer, that the management system of the responsible units or places of use be the same, that the internal supervision of the practices be centralized, and that the user's organization be well documented with appropriately defined responsibilities. A joint safety licence requires that on-site radiation safety persons be appointed for places of use to support the radiation safety officer (see Chapter 4).

### 2.1 Scope of the organization description

The radiation user's organization shall be appropriate from the point of view of safety.

The safety licence application shall include the organization description of the radiation user's organization. The organization description is required to state

- how operations essential from the point of view of radiation safety are appropriately dealt with in each responsible unit and each place of use of radiation
- how the radiation safety officer manages the safety of all radiation practices as a whole.

The extent of the organization description shall be proportionate to the nature and extent of the practices as well as to the radiation safety related risks involved. In simple cases, the appointment of a radiation safety officer in the safety licence application suffices for an organization description. A more extensive organization description, specifying not only the radiation safety officer but also the matters referred to in Item 2.2, must be prepared for the following types of practice, at least:

- uses of radiation in health care
- regarding other uses of radiation, all category III practices and practices in which on-site radiation safety persons have been appointed to support the safety officer. The categories for certain practices are presented in Appendix B.

*Provisions concerning the safety licence and granting the safety licence are laid down in section 16 of the Radiation Act, and provisions concerning the application for a safety licence are laid down in section 14 of the Radiation Decree (1512/1991).*

### 2.2 Matters to be included in the organization description

An extensive organization description shall cover the following issues:

- the managerial and supervisory relations in the radiation user's organization and the flow of information to ensure safety in the place of use of radiation

- duties and responsibilities of the radiation safety officer (see Item 3.5)
- deputizing arrangements for the radiation safety officer, the deputy's duties and responsibilities, when a deputy is appointed (see Item 3.5)
- the number, duties and responsibilities of on-site radiation safety persons and their communication with the radiation safety officer, when such on-site radiation safety persons are appointed (see Chapter 4)
- the medical physics expert and his/her duties, when such an expert is appointed (see Chapter 5)
- the multi-professional liaison body organized by the radiation safety officer, the duties and responsibilities of its members and the intra-group communications, when such a body is established (see Chapter 5)
- the liaison body of the radiation safety officers and its duties, when such a body is established (see Item 3.1)
- the qualified expert and his/her duties, when such an expert is appointed (see Chapter 5)
- the description of the separate radiation protection unit and the division of the required duties between the unit and the radiation safety officer, when such a unit is established (see Chapter 5).

The organization description shall indicate the worker groups engaged in radiation work as referred to in the Radiation Act. It must also be indicated which of these groups include workers classified in category A.

The radiation safety officer is required to confirm his/her consent to serve in this capacity by his/her signature. The consent shall be sent to STUK appended to the organization description.

The medical physics expert and the qualified expert are required to confirm their consent to serve in these capacities by their signatures when they are appointed. The signed consent forms must be submitted to STUK upon request.

If, exceptionally, one safety licence is planned to cover more than one place of use of radiation or for more practices than one, the organization description shall, in a comprehensive manner, describe all of the organization relating to the use of radiation.

If, exceptionally, the radiation safety officer candidate is not employed by the responsible party, a contract shall be established between the responsible party and the radiation safety officer to delegate authority to the radiation safety officer in order to enable him/her to legally assume the responsibility for the safety of the practice.

Should a person employed by a different responsible party become a candidate for a radiation safety officer's post, the application shall include an appendix with a description of the radiation safety officer's duties, including a description of his/her working time arrangements approved and signed by the employer providing his/her full-time employment.

If certain radiation appliances are used independently (through renting them, for example) by the staffs of several responsible parties under their respective safety licences, the organization description shall include an appendix explaining the division of responsibilities to ensure radiation safety. The explanation shall make clear that all the responsible parties involved approve the arrangements for the responsibilities.

### **3 The responsible party shall nominate the candidate for the radiation safety officer's post**

The organization description appended to the safety licence application shall name the responsible party's candidate for the radiation safety officer's post, requesting approval for his/her appointment. Only one radiation safety officer can be appointed for one safety licence.

A copy of the certificate indicating that the candidate has passed the radiation safety officer's competence exam must be appended to the safety licence application. If the radiation safety officer candidate has already been appointed to be the radiation safety officer for a corresponding practice in another current safety licence, it suffices to state the matter and provide the number of the licence. STUK will authorize the candidate to act as the radiation safety officer if

the competence criteria presented in Guide ST 1.8 as well as the criteria presented in this Guide are all fulfilled.

### 3.1 Preconditions for radiation safety officers' work

Radiation safety officers shall be suited to their duties and able to communicate with staffs in places of use and also with any external persons conducting business there. In practice, in addition to Finnish or Swedish, this requires a good oral and written command of the working language in the place of use.

Persons to be appointed as radiation safety officers shall be aware of the required duties. Safety licence applications shall contain the candidates' signatures indicating consent to serve in the capacity of radiation safety officer. The appointment of a radiation safety officer does not in any way diminish the general obligation of the responsible party to ensure the safety of the practice and its compliance with the requirements of the Radiation Act.

Radiation safety officers shall be empowered to deal with the required duties in practice. They shall have the independent status and authorities appropriate to their duties. They shall have the authority, for example, to issue compelling orders to other workers and to discontinue the use of radiation if the safety of the practice is or if it could be compromised. Radiation safety officers' places of work, resources, use of time and other conditions shall be so arranged that they are able to attend to their duties as radiation safety officers in a manner consistent with the nature and scope of the use of radiation.

If the responsible party requests in the safety licence application that one radiation safety officer be allowed to take charge of several places of use of radiation or geographically large areas, or, exceptionally, that one radiation safety officer be approved for several safety licences, the responsible party shall be required to show reliably that the candidate will be, in practice, capable of dealing with the duties successfully. In such cases, the responsible party shall arrange and describe in an acceptable manner the following issues in respect of the use of radiation:

- the radiation safety officer's responsibilities specific to each use place, duties of the on-site

radiation safety person in each use place and supervision of the practices

- the radiation safety officer's duties and allocation of working time
- introduction of the radiation safety officer to the practices and conditions in the relevant places of use of radiation
- communication and reporting practices among on-site radiation safety persons, the radiation safety officer and the responsible party.

In certain cases such as in large health care units or industrial plants, one responsible party may hold several safety licences, each one appointing a different radiation safety officer. In such cases, in order to ensure communication, it may be necessary to form a liaison body consisting of these radiation safety officers.

*Radiation safety procedures at work places and reporting to the responsible party are discussed in Guide ST 1.6.*

### 3.2 Radiation safety officer employed by the responsible party

In principle, the radiation safety officer should be employed by the organization using radiation.

Exceptionally, a person can be approved for the radiation safety officer's post who fulfils the competence criteria of Guide ST 1.8 but is not employed by the responsible party. The condition for approval is that the appointed individual be able to regularly visit the relevant places of use of radiation to supervise the use, and be reachable by persons working in these places, should anything acute arise. Radiation safety officers external to the safety licence holder organization are acceptable in circumstances in which the use of radiation is minor and the use of radiation sources is not demanding from the point of view of radiation safety.

### 3.3 Radiation safety officers' places of work

In radiotherapy, the places of work of radiation safety officers shall be the same as the places of use of radiation.

In practices of categories I and II as well as in practices of category III other than radiotherapy, it is acceptable for radiation safety officers' places of work to be other than the places of use

of radiation only if the officer regularly visits the places of use to supervise the use of radiation and is reachable by persons working in these places, should anything acute arise. In such cases in order to ensure safety, it is required that one or more on-site radiation safety persons be appointed for the places of use (see Chapter 4).

### 3.4 Deputy radiation safety officer

Deputy radiation safety officers shall be appointed at least in

- radiotherapy
- nuclear medicine as practiced in type A or type B laboratories (see Guide ST 6.1)
- category III X-ray activities in health care
- industrial use of radiation in category III.

For other practices, deputies shall be appointed when safety so requires. Some practices may necessitate appointing more deputies than one if, for example, the actual radiation safety officer (or the deputy) is frequently absent.

The deputy radiation safety officer shall have authorities equal to those of the actual safety officer if the actual safety officer is not available.

### 3.5 Duties of the radiation safety officer

The responsible party shall specify in writing the duties of the radiation safety officer and the deputy radiation safety officer.

Typically, the radiation safety officer is tasked with the following duties:

- the identification of risks relating to the practices, safety assessments and anticipation of abnormal events
- promotion and maintenance of a good safety culture
- radiation safety and security arrangements in places of use of radiation including classification of working areas and workers involved in the use of radiation, implementation of all required radiation safety procedures, and the writing of use place specific safety instructions
- maintenance and continuous monitoring of radiation safety through e.g. the analysis of the results of individual monitoring and monitoring of working conditions
- radiation protection training and instructions for workers involved in the use of radiation

- communication with on-site radiation safety persons and the acquisition of the required expertise
- ensuring that the safety licence and the radiation user's organization are up to date
- reporting to the responsible party and proposing measures to improve safety
- implementing and supervising of actions in response to STUK's repair orders and informing STUK of relevant issues
- authorizing the use of a radiation appliance after repair and after it has been made sure that the appliance is in good operating condition; demanding radiation appliances for health care may necessitate hearing a medical physics expert as well
- dealing with abnormal events in places of use of radiation and reporting such incidents to STUK.

## 4 When is it required to appoint an on-site radiation safety person for a place of use?

The responsible party shall appoint an on-site radiation safety person for a place of use of radiation when the respective radiation safety officer is responsible for several places of use or geographically large areas. On-site radiation safety person shall also be appointed for places of use in the exceptional case that one person alone is the radiation safety officer referred to in several safety licences.

When on-site radiation safety persons are appointed, the organization description is required to describe the division of work among the radiation safety officer and the on-site radiation safety persons as well as their respective authorities, duties and communication practices. The tasks of on-site radiation safety persons shall include, for example, supervising the safety of practices and ensuring everyone's compliance with guidelines and regulations in their everyday work.

An on-site radiation safety person is required to have radiation protection training appropriate for the duties and a good knowledge of the

practices applied in the place.

In industrial radiography, an on-site radiation safety person shall have the competence of a radiation safety officer.

*More detailed requirements concerning on-site radiation safety persons as required for industrial radiography are available in Guide ST 5.6.*

## **5 The responsible party shall be obligated to acquire sufficient expertise**

In addition to the radiation safety officer, the responsible party shall employ the services of other experts.

### **Medical physics expert**

In uses of radiation in health care, the responsible party shall appoint a medical physics expert (or experts, if necessary) for radiotherapy, nuclear medicine and X-ray practices of category III. The responsible party shall ensure that the medical physics expert is qualified as required under the relevant statutes and that the expert has had the required supplementary training in radiation protection.

In nuclear medicine, the medical physics expert shall always be available to visit the site when called. The medical physics expert shall always be personally involved in radiotherapy dose planning, quality assurance and activities pertaining to radiation protection.

Medical physics expertise shall be used in X-ray practices in health care for the planning and monitoring of radiation protection, optimization, quality assurance and radiation dose measurements. In X-ray practices of categories I and II, medical physics expertise is required for expert opinions or counsel when practices are begun or essentially changed, or when problems are encountered in radiation protection, optimization of practices, quality assurance or radiation dose measurements.

Medical physics expertise can be used effectively in multi-professional liaison bodies

organized by radiation safety officers. Such bodies may comprise, in addition to a radiation safety officer and a medical physics expert, e.g. a nurse or nurses, a physician, and a specialist in equipment technologies. The need for such bodies shall be assessed by the responsible party after hearing the views of the radiation safety officer and, when needed, the medical physics expert.

### **Physician responsible for procedure**

In uses of radiation in health care, the responsible party shall appoint a physician to be responsible for any procedure or examination involving exposure to radiation, ensuring that this physician is qualified as required under the relevant statutes and that the expert has had the required supplementary training in radiation protection.

### **Physician issuing referrals for procedures involving exposure to radiation, physician interpreting the results, and person performing procedures involving exposure to radiation**

In uses of radiation in health care, the responsible party shall ensure that physicians issuing referrals for procedures and examinations involving exposure to radiation as well as physicians interpreting the results and persons performing these procedures are qualified under the relevant statutes and have had the required supplementary radiation protection training.

### **Medical practitioner responsible for medical surveillance**

The responsible party shall ensure that the medical surveillance of workers in category A is conducted by a medical practitioner ascertained by a competent authority<sup>\*)</sup> to be qualified to perform such surveillance, and that the medical practitioner has had the required supplementary training in radiation protection.

### **Qualified expert and radiation protection unit**

For exceptionally demanding uses of radiation it may be necessary to appoint not only a radiation

<sup>\*)</sup> At the time of approval of this Guide, STUK.

safety officer but also a qualified expert\*\*), or to form a radiation protection unit in order to arrange the radiation protection of workers and other individuals exposed to radiation. Orders relating to this matter will be issued in the safety licence if necessary.

STUK approves the qualified expert and radiation protection unit upon proposal by the responsible party.

If the medical practitioner or an expert is not employed by the responsible party but the work is to be performed under an external contract, a good practice of ensuring the meeting of the competence and supplementary training requirements is to state them in the contract document.

*Provisions concerning medical physics expertise are laid down in the Ministry of Social Affairs and Health Decree (423/2000), sections 15 and 26; provisions concerning the physician responsible for procedure and the performer of procedure as well as their competence and radiation protection training are given in Chapter 5 of the same decree.*

*Qualifications of persons working in radiation user's organizations and their radiation protection training are given in Guide ST 1.8. More detail concerning the radiation protection training of health care staff is available in Guide ST 1.7.*

*Provisions concerning the competence of medical practitioners responsible for medical surveillance of category A workers are laid down in section 13 of the Radiation Decree and discussed in more detail in Guide ST 7.5.*

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\*\*) Qualified expert is a term from Directive 96/29/Euratom. In Finland, the duties of a radiation safety officer generally include the duties of a qualified expert so that a specific qualified expert is not necessarily needed.

## 6 Changes in the radiation user's organization shall be reported

If the radiation safety officer changes or if any changes occur in the division of responsibilities given in the organization description, STUK shall be notified of the changes within two weeks of their entry into force. However, it is considered a good practice to inform STUK of any changes in advance.

For the sake of the smooth continuation of the radiation safety officer's duties, it is recommended that the responsible party and the radiation safety officer agree in writing that the radiation safety officer

- when intending to relinquish the radiation safety officer's duties, gives at least one month's notice prior to the discontinuation point
- when relinquishing the radiation safety officer's duties, undertakes to attend to these duties temporarily until a successor has been appointed
- participates in familiarizing his/her successor with the radiation safety officer's duties
- ensures that the notifications to STUK concerning the change of the radiation safety officer are prepared appropriately and on time.

*Provisions concerning notifications of changes to STUK are laid down in section 16 of the Radiation Decree (1512/1991), and they are also discussed in Guide ST 1.6.*

## APPENDIX A

### Definitions

#### **On-site radiation safety person**

A key person appointed for a place of use of radiation by the responsible party, tasked with supporting the radiation safety officer in the supervision of activities in this place of use in order to ensure the safety of operations and compliance with relevant radiation safety guides.

#### **Medical physics expert**

An expert in radiation physics and radiation technology pertaining to uses of radiation in health care for the purpose of radiation protection of persons undergoing examinations and treatment. The expert provides advice where necessary or attends in person to duties pertaining to dose planning, measurement of radiation exposure, optimization of practice, quality assurance, and radiation protection.

#### **Organization description**

A written description of a radiation user's organization.

#### **Qualified expert**

A person ascertained as competent by STUK and possessing the training and physical, technical and radiochemical knowledge to perform dose evaluations, and who is capable of issuing advice and arranging for radiation protection and for the verification of the operating condition of the equipment, instruments and meters used in such protection.

#### **Use of radiation**

Use of radiation sources in medicine, industry, research and education, and manufacture of and trade in radiation sources, and related activities such as possession, safekeeping, servicing, repair, installation, import, export, storage, transport, and rendering radioactive waste harmless.

#### **Radiation user's organization**

Arrangements concerning the duties, supervisory relations and interpersonal flow of information

regarding persons engaged in the use of radiation and the management of the safety of the practice.

#### **Radiation protection unit**

An operating unit formed by the responsible party, the duty of which is to perform separately specified radiation protection functions and to provide special advice.

#### **Category (of workers)**

Category A shall include those workers whose effective dose caused by their work exceeds or may exceed 6 millisieverts (mSv) per year or for whom the equivalent dose for the lens of the eye, skin, hands and feet is or may be greater than three tenths of the dose limits laid down for these tissues for workers. Category B shall include those workers engaged in radiation work who are not classified as category A workers.

#### **Party running a radiation practice (the responsible party)**

The holder of a safety licence, any business or sole trader, enterprise, corporation, foundation or institution which uses radiation sources in its operations, or any employer or self-employed person engaged in radiation practices. When the responsible party is not a physical person (but is e.g. a limited liability company, foundation or municipality), the party responsible for the operation as a whole is the party with the highest authority in the organization.

#### **Category (of practices)**

Classification of practices involving exposure to radiation on the basis of their potential risks. The greater the risk, the higher the category.

#### **Radiation safety officer**

A person in charge, appointed by the responsible party to handle the practical activities to ensure the safe use of radiation, to maintain the safety, and to correct any defects.

## **APPENDIX B**

### **Categories for radiation practices**

#### **Health care practices**

##### **Category I**

- Limited X-ray practices involving
  - bone mineral density measurement devices
  - conventional dental X-ray appliances (devices by which images are created on intraoral imaging receptors, panoramic tomography equipment and cephalostats)
- Veterinary X-ray practices involving
  - conventional X-ray equipment
  - dental X-ray appliances
- Practices involving
  - such sealed radiation devices that do not allow radiation outside the device during any type of use other than minor leakage radiation (max. 1  $\mu\text{Sv/h}$  at 10 cm from the surface of the device).

##### **Category II**

- X-ray practices involving
  - conventional X-ray equipment
  - mammography equipment
  - cone beam computed tomography (CBCT) devices
- C-arm practices involving
  - mobile fluoroscopy equipment
- X-ray practices outside X-ray departments involving
  - mobile conventional X-ray equipment
- Screening in category I or II practices
- Use of sealed sources (other than sealed sources in categories I and III)
- Use of unsealed sources
  - C-type laboratory
- Installation, repair and servicing of radiation appliances and radiation sources in category I or II practices
- Clinical trial use of radiation appliances in category I or II practices
- Veterinary X-ray practices involving
  - computed tomography equipment
  - fixed fluoroscopy equipment
- Research and teaching using X-ray appliances in category I or II for health care practices.

##### **Category III**

- Demanding X-ray practices and interventional radiology involving
  - computed tomography equipment
  - fixed fluoroscopy equipment
- Screening in category III practices
- Radiotherapy
- Nuclear medicine involving
  - computed tomography equipment
  - unsealed sources in B- or A-type laboratories

- high-activity sealed sources<sup>\*)</sup>
- Installation, repair and servicing of radiation appliances and radiation sources in category III practices
- Research and teaching using X-ray appliances in category III for health care practices
- Clinical trial use of radiation appliances in category III.

## **Practices in industry, research, education and trade**

### **Category I**

- Practices involving
  - such sealed radiation devices that do not allow radiation outside the device during any type of use other than minor leakage radiation (max. 1 µSv/h at 10 cm from the surface of the device)
  - sealed sources in education with activities of max. 100-fold compared to the exemption values
- Trade, import or export of smoke detectors or similar products used as consumption goods.

### **Category II**

- Practices involving
  - industrial radiometric measuring appliances (including high-activity sealed sources<sup>\*)</sup> with fixed installations)
  - sealed sources other than those used in category I and III practices
  - shielded and unshielded X-ray equipment
  - unsealed sources in C-type laboratories
  - wide-scale use of radiation appliances and radiation sources in category I (practices in several locations and/or towns)
  - radiation appliances and radiation sources in category I used for exhibition purposes in public places
- Trade, import or export of radioactive materials (other than practices in category I)
- Installation, repair and servicing of radiation appliances and radiation sources in category I or II practices.

### **Category III**

- Practices involving
  - high-activity sealed sources<sup>\*)</sup> (excluding fixed radiometric measuring appliances)
  - calibration tracks or equivalent
  - particle accelerators
  - mobile fluoroscopy equipment
  - unsealed sources in B- or A-type laboratories
- Practices involving shielded imaging rooms in places of use of radiation or equivalent shielding structures
- Radiography
- Tracer tests outside laboratories
- Installation, repair or servicing of radiation appliances and radiation sources in category III practices
- Manufacture and assembly of sealed sources.

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<sup>\*)</sup> High-activity sealed source, see Guide ST 5.1.