

OPERATIONAL RADIATION SAFETY

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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. 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 and 90/641/Euratom; OJ No. L 349/21, 13.12.1990.

1 General

The party running a radiation practice (hereafter the responsible party) must ensure the safety of workers and other persons in the place where radiation is used. This Guide presents the essential radiation safety measures required for ensuring safety.

This Guide shall apply to the use of radiation and, where applicable, to other radiation practices.

The Radiation Act (592/1991) and the statutes based on it apply to the use of radiation and to practices in which exposure to natural radiation may occur.

Requirements for the practices referred to in the Nuclear Energy Act (990/1987) are presented in the YVL Guides, also issued by the Radiation and Nuclear Safety Authority (STUK).

2 The responsible party shall be responsible for safety

The responsible party shall be responsible for the safety of the use of radiation. The use of radiation shall fulfil the principles of **justification**, **optimization** and **limitation**. All operations shall be planned and implemented so as to keep the exposure of workers and the public as low as reasonably achievable according to the optimization principle; neither shall practice-specific or source-specific **dose constraints** given in the ST Guides be exceeded. Dose constraints shall be used as the maximum limits when optimizing protection against radiation emitted by certain sources. The purpose of dose constraints is, also, to ensure that the total radiation doses arising from different practices do not exceed the dose limits prescribed in the Radiation Decree.

The general duty of care of the responsible party to ensure radiation safety for workers and other persons is prescribed in chapter 4 of the Radiation Act. The principles of optimization, justification and limitation are prescribed in section 2 of the Radiation Act. Dose limits are given in chapter 2 of the Radiation Decree

(1512/1991). The provisions concerning STUK's authorization to set dose constraints are issued in paragraph 2, section 7 of the Radiation Decree.

2.1 Practices shall be planned and risks shall be identified in advance

The responsible party shall plan and implement all radiation protection measures necessary. In matters concerning radiation safety, the responsible party shall be required to ensure that it possesses the expertise required with respect to the nature and extent of the practice. Sufficient expertise and qualified staff shall be acquired in good time prior to commencing the practice. When radiation safety measures are being planned and implemented, the responsible party shall consult the radiation safety officer. When necessary, other experts shall also be consulted in advance, such as a medical physics expert for medical use of radiation, and a qualified expert in other uses of radiation when such an expert has been nominated. Guide ST 1.4 describes in more detail who may function as medical physics experts and qualified experts. The medical practitioner responsible for medical surveillance shall be consulted in matters relating to the health of workers engaged in radiation work.

Radioactive materials shall be taken into account in the rescue and safety plan of a place where radiation is used. When necessary, other authorities such as fire and rescue authorities shall be consulted as well.

The responsible party shall also be liable for the safe use of radiation and for the observation of radiation legislation and the related regulations in those situations in which the practical tasks relating to radiation safety measures have been assigned to nominated experts.

The responsible party shall take care of the following matters, for example:

- The magnitude of the radiation exposure to which workers are subjected and the factors affecting it shall be investigated in advance for the optimization of radiation safety measures in all working situations. The investigation shall also take into account the possibility of exceptional working conditions.
- All workers shall be protected from radiation by appropriate arrangements.

- Workplaces shall be classified into controlled areas and supervised areas, where appropriate.
- Workers who may be exposed to radiation shall be classified either into category A or B.
- Risks relating to the safety of the practice shall be identified and their significance shall be assessed.
- Possible abnormal events relating to the practice as well as any abnormalities with significance from the viewpoint of safety shall be identified in advance to the extent possible. The potential exposure arising from identified events shall be assessed. Assessment results shall also be utilized in the classification of work areas and workers engaged in radiation work (see chapters 3 and 4).
- The occurrence of abnormal events shall be prevented as effectively as possible. Procedures necessitated by abnormal events shall be planned in advance (see chapter 7) and recorded in operation instructions.
- Monitoring of radiation exposure in accordance with Guide ST 7.1 and medical surveillance in accordance with Guide ST 7.5 shall be arranged for workers who may be exposed to radiation.

If the use of radiation is extensive or the radiation sources in use are high-activity, risk assessment results and risk preparation plans shall be presented in the safety licence application. In those cases, the radiation shielding plans concerning the places in which radiation is used should also be sent to STUK for an advance statement before implementation. This concerns, for example, accelerator facilities, irradiation equipment or irradiation plants, laboratories of type A, radiotherapy rooms and rooms used for industrial imaging in which the intention is to use a particle accelerator or a high-activity sealed source. During the planning and preparation phase of the practice, the responsible party may ask STUK for an advance statement concerning the safety of the practice, the place of use or the radiation source. The final approval for the use of radiation with possible additional terms and conditions shall be granted in the safety licence decision and at the inspection conducted at the place of use.

If radioactive material or equipment containing radioactive materials are used in the practice, the responsible party shall present a plan in the safety licence application showing how care shall be taken of the radioactive waste or decommissioned radiation sources previously contained in the equipment. Plans shall conform to Guides ST 5.1 (sealed sources) and ST 6.2 (unsealed sources).

The responsible party shall inspect the installation of radiation sources and the facility plans in advance; the responsible party shall also inspect and approve all new radiation sources and any changes to radiation sources. The responsible party shall verify through inspection prior to the commissioning of any radiation sources or facilities that all installations and changes are safe and conform to radiation safety requirements. When acquiring radiation appliances and radiation sources, it shall be ensured that they are suitable for the purpose for which they are acquired and conform to applicable regulations.

Monitoring of radiation exposure is treated more fully in Guide ST 7.1 and medical surveillance in Guide ST 7.5 by STUK. Design principles and shielding requirements for places of use of radiation are presented in Guide ST 1.10.

2.2 Radiation user's organization is a part of the management system

The use of radiation requires a valid safety licence unless the practice is specifically exempted from the safety licence requirement.

The responsible party shall form an effective radiation user's organization for the purpose of using radiation. The tasks and responsibilities of persons belonging to the radiation user's organization shall be defined clearly. The radiation user's organization shall be documented and kept up-to-date. This can be done as a part of the **management system** of the organization operating the radiation practice. Management system is also called quality system.

The functioning of a management system relating to the use of radiation and the respective quality assurance practices shall be assessed regularly, and instructions and procedures shall be changed when necessary. Any problems

observed in the safe use of radiation shall immediately be reported to the responsible party. It is good practice that the radiation safety officer discusses the performance and the development needs of the radiation user's organization with the responsible party at least once a year. This will enable the responsible party to make the decisions required to improve the safety of the practice and to change procedures and instructions.

The safety licensing procedure, exemptions from safety licensing and the notification obligation of licence-exempt practices are treated in more detail in Guide ST 1.1. The grounds for exemptions from the safety licence are presented in Guide ST 1.5. The radiation user's organization is discussed in Guide ST 1.4, and quality assurance procedures are discussed in practice-specific ST Guides.

2.3 Changes in practices shall always be reported

The responsible party must ensure the safety of the use of radiation and that it conforms to requirements at all times, including when the practice undergoes changes. It is good practice that all fundamental changes to the practice be reported to STUK before their implementation. The responsible party shall request an amendment to the safety licence before implementing any solutions in the following cases:

- extending the practice to a type of practice other than that stated in the safety licence
- change to the place in which a radiation appliance or a radiation source is used (a new place of use or changes to existing structures)
- commissioning of a new radiation appliance or radiation source.

Notifications of other changes, such as changing the radiation safety officer, a change in the radiation user's organization, or the discontinuation of the use of radiation either in part or in total, must be sent to STUK within two weeks of the change (see section 16 of the Radiation Decree).

2.4 Practices shall be monitored

The responsible party shall regularly inspect:

- sufficiency and condition of radiation shieldings and protective devices
- warning devices, alarm appliances and the respective systems as regards radiation appliances and places in which radiation is used, as well as the condition of safety appliances
- radiation meters and radiation alarm devices; it is also required that such devices be calibrated and tested according to Guide ST 1.9.

The responsible party shall arrange for continuous monitoring of the practice so that all radiation exposure greater than that anticipated and all abnormal events are detected quickly and acted upon without delay (see chapter 7). For the purpose of monitoring the practice and with respect to the nature and extent of the practice, the responsible party shall set **investigation levels** for regularly monitored radiation quantities or other relevant measurable quantities. The procedures and actions must be defined in writing that shall be implemented at the place in which radiation is used if an investigation level is exceeded. Setting the investigation levels and defining the respective procedures is a natural task for the radiation safety officer with the assistance of a medical physics expert or a qualified expert.

Investigation levels may be set, for example, for an individual measurement result concerning radiation exposure or radiation level, or for a certain parameter value of a radiation appliance. Investigation levels comprise, for example:

- the reading of an employee's personal dosimeter
- the result of a working condition monitoring measurement, such as the dose rate at a certain workplace, or the contamination level of the surfaces of the workplace, or the dose in a certain job
- the dose rate outside the place of use or storage of the radiation sources
- the measurement result showing the radiation output of a radiation appliance
- the reading of a discharge monitor (regarding isotope production or some other fundamental handling of unsealed sources).

The radiation safety measures listed in item 2.1, designed for ensuring safety, shall be reassessed at certain intervals, for example, annually. In addition, the identification of abnormal events and fundamental deviations as well as the assessment of potential exposure shall be repeated at regular intervals or every time a change is implemented in the practice or work methods. Assessments and assessment results shall be recorded. Operation instructions shall be updated or renewed when necessary.

The setting and use of investigation levels in individual monitoring is described in Guide ST 7.1 and, in more general terms, in the IAEA publication Safety Series No. 115.

2.5 Discharges shall be monitored

Those facilities in which radionuclides are produced or unsealed sources are handled extensively are required to have the necessary surveillance equipment to measure radioactive discharges in order to protect the environment and the public. Discharges shall be restrained and discharge monitoring measurements shall be arranged in accordance with the terms and conditions of the safety licence. Monitoring measurements shall be performed if the amount of discharges could exceed the values given in Guide 6.2 allowing for any possible abnormal events.

The condition of the technical equipment in use shall be checked, and the measuring equipment used for discharge monitoring shall be regularly calibrated in accordance with the quality assurance system. In addition, flawless operation and appropriate use of all equipment shall be ensured.

Additional instructions on discharges, the measuring of discharges, and other procedures for environmental protection are available in Guides ST 6.1 and ST 6.2.

2.6 Care shall be taken of all decommissioned radiation sources

All decommissioned radiation sources and radioactive waste shall be taken care of appropriately.

Decommissioned sealed sources shall not be purposelessly stored on premises where radiation

is used. Such storing is temporarily allowed if it is intended that the source be recommissioned. Decommissioned sealed sources which have no more use, or are not expected to have any more use, shall be returned to the supplier. Sources may also be returned to a party who, in accordance with the waste management plan concerning such sources, is bound to receiving them after their use. Radiation sources containing short-lived radionuclides may, however, be stored for aging in a safe storage in the place where radiation is used. STUK shall approve such storage when granting the safety licence or inspecting the practice.

A decommissioned X-ray unit or another unit producing radiation electrically shall be returned to the supplier or scrapped appropriately. The device may also be assigned to another responsible party, but such a party must be instructed to acquire a safety licence before using the device. It is good to state the matter in the assignment contract or in the sales contract. A device which is to be scrapped shall be made inoperable, and all markings indicating ionizing radiation or a radiation hazard shall be removed. The environmental legislation and the legislation concerning hazardous substances give provisions on the appropriate disposal of toxic or hazardous substances contained by such appliances.

When the practice is discontinued, the responsible party shall ensure that no radioactive materials or appliances containing them remain on the place where radiation was used. If unsealed sources were handled in the place where radiation was used, the responsible party shall use appropriate contamination measurements to ensure the purity of the rooms, furniture, appliances and goods on the premises. Contamination measurements shall not be necessary if only very short-lived radionuclides were in use and it can be shown by calculations that there can be no more contamination.

3 Workplaces in radiation work shall be classified

In radiation work, workplaces shall be classified into controlled areas and supervised areas, where appropriate. The classification shall take

into account the nature of the use of radiation sources, the estimated annual doses caused by the practice, the hazard of contamination and the potential exposure. In addition, attention shall be paid to the possibility of an abnormal event which might result in radiation exposure high in comparison with the exposure caused by normal operations.

3.1 How are controlled and supervised areas defined?

Such working places and other areas shall be defined as **controlled areas** in which:

- during regular or temporary stay, the effective dose for a worker exceeds or may exceed 6 mSv per year, or the equivalent dose to the lens of the eye 45 mSv per year, and the equivalent dose to the hands, feet and skin 150 mSv per year, allowing for the possibility of a work-related incident resulting in abnormal radiation exposure;
- due to a radiation and contamination hazard, working requires special safety instructions and procedures.

Such areas are classified as **supervised areas** which are not controlled areas but in which the annual effective dose of a worker may exceed 1 mSv, or the equivalent dose to the lens of the eye may exceed 15 mSv, or the equivalent dose to the hands, feet or skin may exceed 50 mSv.

At a place of work, depending on the nature of the work, areas may be classified only as controlled or only as supervised, or they may be unclassified. These areas can be located completely separate from each other. The classification of an area as controlled or supervised can also be made temporarily for the duration of a specific procedure. Examples of the classification of working areas are presented in Appendix B.

In working areas, the precautionary and protective arrangements required shall be in the correct proportion to the risks arising from the practice. The rooms in which radiation is used and the safety appliances relating both to the rooms and the radiation appliances shall conform to practice-specific ST Guides.

Instructions necessary for work and radiation protection in controlled and supervised areas

shall be given by the responsible party following consultation with the radiation safety officer, with the medical physics expert in matters of medical use of radiation, and with the qualified expert in other practices, when such an expert has been nominated. If necessary, the medical practitioner responsible for medical surveillance shall also be consulted.

The classification of areas into controlled and supervised areas shall be made and the respective instructions shall be created when the safety licence application is submitted; both shall be inspected on the premises in the context of STUK's inspection.

The classification of controlled and supervised areas is prescribed in section 32 of the Radiation Act. Examples of the classification of areas are presented in Appendix B.

3.2 What is required of a controlled area?

The following presents the minimum requirements for a controlled area:

- The area shall be delineated, and access to it shall be restricted to those individuals with appropriate training who are required and essential for the work in the area and fully aware of the safety instructions to be observed as well as the radiation or contamination hazards associated with staying or working in the area.
- Anyone working in a controlled area repeatedly or for long periods must be at least 18 years old. Students and apprentices in the ages of 16–17 may participate in the use of radiation sources in these areas insofar as it is necessary for their vocational training (see item 4.2).
- Radiation sources in the area containing radioactive materials shall be marked so that the markings show the essential information and hazards concerning each radiation source, such as the radionuclide and its activity, the date the activity was determined, dose rate, contamination hazard, etc.
- The area must be marked. It is good practice to use a specific "Controlled Area" sign which also displays a warning sign indicating radiation hazard. A specific sign is not required, however, if the markings

show otherwise that the area is controlled. In the context of medical use of radiation, an acceptable marking consists of, for example, the marking “X-Ray examination room” or “Radiotherapy room”. In an operating room or hospital ward or in industrial use of radiation, an acceptable marking consists of a sign set up for the time of irradiation to indicate the radiation hazard.

- The warning markings, alarm lights and acoustic signals in use shall clearly indicate any radiation sources in operation.
- Unauthorized access to the area shall be prevented by structures, safety interlocks or access control.
- Workers in the area shall be given written working and safety instructions appropriate to the nature of the work, including instructions for immediate measures in the case of an abnormal event. The controlled area and working conditions shall be regularly controlled in accordance with the written procedures.
- Workers in the area shall use personal protective devices and protective clothing necessary for the work.
- Workers shall use personal radiation alarms if such radiation sources are used in the area which, in the case of an abnormal event, could cause radiation exposure great in comparison with the exposure caused by normal operation. Alternative measuring arrangements are allowed in established practices with fixed radiation appliances and well-shielded rooms to enable workers to detect, without delay, any exceptional increase in radiation exposure.
- If radioactive materials with a hazard of contamination are used in the area, appropriate measurements shall be taken and purification procedures conducted to prevent the spread of contamination via workers, tools and other goods both inside the area and when exiting it. Those leaving the controlled area must have the possibility to measure and remove contamination from the skin, clothes and objects carried.
- Radiation exposure monitoring shall be arranged for workers in the area in accordance with Guide ST 7.1.

The controlled area may be temporarily visited by persons other than the trained persons mentioned in the previous paragraph, such as guests, under the following conditions:

- The visit to the area is essential.
- The visit takes place under the supervision of a trained person.
- The visitors are given the appropriate guidance and instructions prior to entering the area.
- The radiation exposure of the visitors is monitored appropriately, for example, with a continuously operating radiation meter or a dosimeter read immediately after use.
- All visitors and the doses they receive are recorded for the radiation safety officer to monitor regularly.

If necessary, an investigation level shall be set for visitors’ exposure in accordance with item 2.3.

3.3 What is required of a supervised area?

The following presents the minimum requirements for a supervised area:

- Monitoring of working conditions must be arranged for the area in accordance with Guide ST 7.1.
- Contamination measurements must be conducted regularly when using unsealed sources.
- Radiation sources in the area containing radioactive materials and the related hazards must be marked appropriately. When necessary, the area must be equipped with signs indicating that it is supervised.
- Workers must be given instructions on working in the supervised area, on the use of the radiation sources and on the related radiation hazards.
- The delineation of the area and the adequacy of the protective measures must be ensured by regular checks and measurements.

3.4 Radiation safety measures and security arrangements shall be planned comprehensively

The premises on which radioactive materials are used and stored shall enable the safe use of such materials. All persons must be protected from unnecessary radiation exposure. Radioactive

materials, radiation appliances containing them and devices producing radiation electrically shall be protected against loss and damage, and they shall not be allowed in the possession of unauthorized parties or otherwise misused.

Security arrangements aim at preventing any sources from being damaged, lost, possessed by an unauthorized party or misused. Security arrangements may include, for example:

- regular inspections to ensure that radiation appliances and radioactive materials are in place and undamaged; the contents and intervals of inspections shall be defined in the respective plan; all inspection results shall be documented
- procedures to ensure that appliances and sources do not come into unauthorized possession when they are received, assigned or transferred
- bookkeeping on all receipts and assignments of appliances and sources
- structural barriers to keep unauthorized persons from appliances and sources
- access control to and from rooms containing appliances and sources
- according to the nature and extent of the practice, reliability assessments of persons in charge of the use of radiation
- storing plans, procedural instructions and other similar documents concerning security arrangements in a way that prevents unauthorized persons from gaining possession of them.

Radiation safety measures and security arrangements shall be planned and implemented comprehensively so that the best overall solution from the point of view of safety, covering both aspects, is reached. The extent of the security arrangements shall take into account all foreseeable risks in accordance with the nature and extent of the practice. If necessary, STUK will issue more detailed requirements on security arrangements in connection with safety licensing and inspections.

Security arrangements for high-activity sealed sources are described in Guide ST 5.1.

4 Workers shall be protected

4.1 Workers performing radiation work shall be classified into categories

Prior to commencing any work, workers performing radiation work shall be classified into either category A or B (Radiation Decree, section 10). The classification of a worker shall be checked at defined intervals and at a minimum when the worker's job description changes or the practice undergoes significant changes.

Category A shall include those workers whose effective dose caused by their work exceeds, or may exceed, 6 mSv per year, or the equivalent dose to the lens of the eye 45 mSv per year, and the equivalent dose to the hands, feet or skin 150 mSv per year. The classification shall be made allowing for the possibility of work-related potential exposure. Persons working repeatedly or for long periods in controlled areas shall be classified into category A.

Category B shall include those workers performing radiation work who are not classified as category A workers.

Workers whose exposures to radiation are so minor that they need not be classified into either category, A or B, shall be protected according to the same principles as individuals belonging to the public.

Examples of the classification of workers into category A are presented in Appendix C.

The suitability of a worker to be classified as a category A worker shall be ensured in an appropriate medical examination. These examinations may be performed by such doctors only whom STUK has deemed qualified to perform medical examinations of category A workers.

Provisions concerning the classification of workers into categories A and B are given in section 32 of the Radiation Act and in section 10 of the Radiation Decree.

4.2 Persons under 18 years in age shall not be assigned to radiation work

Persons under 18 years in age shall not perform radiation work. However, students or apprentices

aged 16 but under 18 may participate in the use of radiation sources insofar as it is necessary for their vocational training (see the Radiation Act, section 37).

Persons under 18 years in age shall not be classified as category A or B workers. However, apprentices and students in the ages of 16–17 who in the course of their studies are obliged to use radiation sources shall be protected according to the same principles as category B workers.

The effective dose of students and apprentices in the ages of 16–17 shall not exceed 6 mSv per year. The equivalent dose to the lens of the eye shall not exceed 50 mSv per year, and the equivalent dose to the hands, feet or any part of the skin shall not exceed 150 mSv per year.

The working conditions and protective measures for apprentices and students 18 years or over in age shall be arranged in the same way as the working conditions and protective measures for category A and B workers. The dose limits of workers performing radiation work apply to these students and apprentices, as well. The rights and responsibilities of apprentices and students in matters relating to radiation safety are the same as those of workers engaged in radiation work.

5 Workers shall be trained and introduced to their tasks

The responsible party is obliged to arrange training and introduction to their duties for workers, appropriate to the nature of the practice and to the conditions at the workplace (the Radiation Act, section 36). Training given to each worker must be recorded. If the responsible party does not have the resources or sufficient expertise to arrange training, training can be outsourced to external experts.

The responsible party shall give information on the health risks involved in their work to all workers and those apprentices and students who in the course of their studies are obliged to use radiation sources. Information shall be given on general radiation safety arrangements and on the special features of each worker's own

work and working conditions. Information shall also be given on the importance of complying with requirements relating to technology, health and administration. The key roles in providing information and training shall be filled by the radiation safety officer, the medical practitioner responsible for medical surveillance, the medical physics expert in matters of medical use of radiation, and in other uses of radiation, the qualified expert, if one has been nominated.

Women shall be informed of the importance of notifying the relevant party of a pregnancy early. It shall be emphasized in particular that external radiation exposure and radioactive contamination of the body may pose a hazard for the foetus. A breastfeeding mother must be informed that contamination may pose a hazard for the breastfed baby. A female worker must notify the responsible party and the medical practitioner responsible for medical surveillance, or the medical practitioner who performed her pre-employment examination, of her pregnancy immediately after it has been confirmed, in accordance with Guide ST 7.5.

The responsible party shall arrange for training in general principles of radiation protection to be given to workers engaged in radiation work, as well as to apprentices and students. Workers, apprentices and students shall be instructed in safe working practices and given instructions as to actions in the case of abnormal events. In giving training and instructions, it shall be emphasized that workers are obliged to attend to their radiation safety and to that of others and to comply with orders and instructions issued.

Provisions on the training and instruction of workers are given in section 36 of the Radiation Act. The requirements on the qualifications of persons working in radiation user's organizations and on the radiation protection training required for competence are presented in Guide ST 1.8. The qualification requirements for healthcare staff involved in the use of radiation are presented in the Decree of the Ministry of Social Affairs and Health on the medical use of radiation (423/2000), and the content-related objectives of radiation protection training are presented in Guide ST 1.7.

6 Outside workers shall also be protected

6.1 The responsible party shall also be responsible for protecting outside workers

Workers of an outside undertaking and temporary workers who participate in radiation work assigned by and for the responsible party are considered outside workers referred to in section 37 a of the Radiation Act. This type of work takes place under the responsible party's safety licence, and the responsible party shall also be responsible for protecting the outside workers in the same manner as the internal workers. The responsible party shall, for example, instruct the workers of an external subcontractor in safe working practices and arrange monitoring of the working conditions as well as individual monitoring and medical surveillance, if they have not been arranged otherwise.

An outside undertaking, in this context, does not refer to a safety licence holder with a safety licence intended under section 25 of the Radiation Act for installation, repair and servicing of appliances. A responsible party performing installations, repairs and service operates independently and shall be responsible for its operations under its own safety licence.

The responsible party shall arrange, or authorize an outside undertaking through a mutual agreement to arrange, the radiation protection of outside workers. When an outside worker is expected to engage in work involving exposure to radiation, the responsible party must ensure and provide documentation on the following:

- the worker, intended to work in a controlled area, has been deemed fit by the medical practitioner responsible for medical surveillance to work as a category A worker in accordance with item 4.1
- medical surveillance has been arranged for the worker
- dose limits set for workers are not exceeded allowing for the possible previous exposure to radiation and exposures caused by other radiation work; foreign category A workers' information can be checked from their radiation passbooks or similar documents,

whereas previous exposures of other persons can be checked from yearly individual monitoring summaries and up-to-date Dose Register extracts

- the worker is qualified for the intended task; he/she has received the required radiation protection training and been sufficiently introduced to the tasks
- the worker has been informed of the radiation safety regulations and instructions concerning his/her work
- the worker uses personal protective devices necessary for the work
- radiation exposure monitoring has been arranged for the worker, and he/she has, according to the nature of the work, a radiation alarm or a radiation meter with an alarm
- personal dose information is given to the Dose Register maintained by STUK, or, in the case of a foreign worker, dose information is entered in his/her radiation passbook or an equivalent document.

6.2 An outside undertaking shall be responsible for the radiation protection of its workers

As the employer, the outside undertaking shall be responsible for its employees' training and their introduction to their tasks in accordance with the relevant regulations. In addition, the outside undertaking shall be obliged to ensure that appropriate protection, radiation exposure monitoring and medical surveillance have been arranged for workers.

When a worker of an outside undertaking, under the safety licence of another responsible party (the principal responsible party), performs tasks which may lead to radiation exposure, the outside undertaking shall either arrange the worker's radiation protection for those tasks itself, or ensure and appropriately document the fact that the principal responsible party has taken care of the matter. This shall include, in particular:

- arranging for adequate training and practical instruction for radiation work
- arranging for radiation exposure monitoring and medical surveillance for workers engaged in radiation work

- caring for practical radiation safety measures (such as safe working methods, use of protective devices and dosimeters etc.)
- ensuring that a worker's radiation exposure remains as low as reasonably achievable and it does not exceed any dose limits or dose constraints set
- reporting a worker's dose information to the Dose Register maintained by STUK, or, in the case of a foreign worker, entering the information in the radiation passbook or an equivalent document.

6.3 Cooperation is required when an outside worker works for several responsible parties

When one worker performs radiation work for several responsible parties, each responsible party shall, relating to its own practice, be liable for appropriately arranging the worker's individual monitoring and medical surveillance as well as the appropriate monitoring of the working conditions. When a worker's individual monitoring and medical surveillance needs are being assessed, all tasks with a risk of radiation exposure which he/she performs for different responsible parties as well as the nature of these tasks and his/her total working hours shall be taken into account.

When a worker is expected to perform radiation work for several responsible parties in different places in which radiation is used, the worker's radiation exposure shall be assessed in advance in consultation with the worker, his/her employer (outside undertaking) and, if necessary, the other responsible parties. Workers engaged in radiation work shall be classified either as category A or B workers, and individual monitoring or working condition monitoring shall be arranged for them appropriately. To the extent possible, the worker should use one personal dosimeter which he/she carries with him/her in the different places in which radiation is used. If it is, however, estimated that the worker's radiation exposure occurs mainly in one place in which radiation is used, it is allowed that one dosimeter be assigned for the worker at that

post, and he/she use a different dosimeter in all the other locations.

The outside undertaking, as the employer, shall monitor the doses received by its workers. The same is true pertaining to other responsible parties for which the worker performs radiation work. Investigation levels shall be set for the worker's individual monitoring (see Guide ST 7.1, chapter 7). If the worker's personal dosimeter shows readings above the investigation level, the reasons for exposure shall be found and the necessary actions taken to decrease exposure.

When individual monitoring is arranged by and the required personal dosimeter is ordered by the worker's employer (the outside undertaking), it shall:

- record each worker's workloads per workplace and per individual monitoring period
- ensure that the individual monitoring results are delivered, in agreement with the worker, to all those responsible parties for which the worker performed radiation work.

In connection with agreeing upon the work, the outside undertaking and the other responsible parties (holders of safety licences) for which the worker intends to perform radiation work, shall agree in writing:

- procedures relating to individual monitoring, medical surveillance, working condition monitoring and communications
- investigation levels concerning individual monitoring results, the follow-up of the results, and the procedures to be undertaken in case the investigation levels are exceeded.

6.4 The worker shall observe regulations and instructions on radiation protection

A worker exposed to radiation is, for his/her part, obliged to attend to his/her radiation protection and that of others, to use the necessary personal radiation protection devices and dosimeters, to take part in medical surveillance and to observe regulations and instructions on radiation protection.

7 Abnormal events in the use of radiation

7.1 Abnormal events shall be anticipated

Abnormal events identifiable in advance and abnormalities in the use of radiation with significance from the viewpoint of safety may include:

- disappearance, theft or unlawful removal of a radiation source from the possession of the licence holder
- a fire or similar incident at a facility which contains radioactive materials
- significant contamination of working places in connection with handling unsealed sources
- unplanned discharge of radioactive materials into the environment in connection with using unsealed sources
- access of unauthorized persons to a controlled area
- occurrences in the medical use of radiation
 - accidental exposure of an external person (such as a patient's attendant or the wrong patient) or worker
 - a significant overdose or underdose received by a patient (due to, for example, faulty dose planning, unnecessarily high exposure during interventional radiology, or an incorrect radioactive material)
 - a significant, unplanned exposure of the abdomen of a pregnant patient.
- a safety-threatening fault in a radiation appliance or safety device
- a user mistake endangering safety or almost endangering safety
- another safety-threatening event relating to the use of radiation or to the possession, import, export, transport, handling or decommissioning of radioactive materials
- information acquired or a rumor heard concerning radioactive materials having entered the environment or food products.

When procedures are planned to prepare for abnormal events and abnormalities which have significance from the viewpoint of safety, the planning shall take into account the likelihood of a particular abnormal event, the consequences of a possible event, and the prevention of similar

events in the future.

Solutions as to working places, radiation sources to be used, shielding structures, warning and alarm systems, working methods and work equipment shall be such that abnormal events can be prevented as effectively as possible. The operation of radiation sources and appliances, the sufficiency and condition of structural shielding and protective devices, as well as the operation of warning and alarm devices and systems, shall be checked at defined intervals according to the management system.

In a practice in which there is the possibility for a significant abnormal event, workers shall have available workplace-specific instructions in writing concerning the actions to be taken in the case of such events. The instructions shall, where applicable, include at least the following issues:

1. Identified significant abnormal events.
2. Immediate measures to be taken to limit exposure to radiation:
 - Radiation exposure must immediately be reduced to the minimum.
 - The area with a radiation hazard must be identified and cordoned.
 - Access of unauthorized persons to the area must be prevented.
 - Respiration protectors must be used if there is a suspicion of radioactive materials having entered breathing air and it is not possible to exit the area.
 - The spread of contamination must be prevented (prevent access to the contaminated area, no handling of contaminated goods, use protective gloves and protective clothes etc.).
 - The radiation safety officer must be informed.
3. Recording the flow of events as soon as possible (before details are forgotten):
 - the flow of events, the actions taken and the time they were taken
 - names and contact information of persons exposed or otherwise involved
 - detailed information concerning exposure (duration of stay at different distances from the source, use of respiration protectors etc.).
4. Informing other required parties of the event (such as STUK, National Agency for Medicines, the police etc, including the necessary contact information).
5. Actions to determine the magnitude of the

radiation exposure.

6. In the case of high exposure, urgent actions to assess the workers' health status and to conduct chromosomal analyses (see item 7.2).

7. If the abnormal event relates to a patient, instructions as to informing the patient and the physician in charge of the patient.

The responsible party shall maintain its operative preparedness to anticipate identified abnormal events in the following manner, for example:

- The identification of possible abnormal events as well as risk assessments and updates of applicable instructions shall be repeated at regular intervals or every time a change is implemented in the practice.
- A suitable expert (such as a radiation safety officer, a medical physics expert or a qualified expert) shall be available for assessing the significance of any abnormal events.
- Equipment required to immediately contain the radiation exposure shall be available at all times and its operational condition shall be ensured.
- Workers shall be sufficiently trained and instructed for the case of abnormal events.
- Procedures shall be drilled regularly for the case of abnormal events which might lead to discharges into the adjacent premises or outside the building.
- Procedures shall be created for taking lessons from abnormal events and avoiding similar events in the future.

7.2 In the case of an abnormal event, one shall proceed as instructed for the particular workplace

If a fire, traffic accident or some other accident takes place in connection with an abnormal event in the use of radiation, or if people are in danger otherwise, the first actions shall be the same as those always required in that type of accident: according to the situation, take care of the immediate emergency measures and call the emergency response center.

If a public authority (such as the rescue authority in the case of a fire) takes charge of actions required to gain control of the situation, the radiation safety officer or another representative of the responsible party at the

site shall give the necessary information to the authority in charge concerning the radioactive materials and other matters required for the assessment of the radiation protection needs.

When an abnormal event is noticed or suspected, the steps taken shall be in accordance with the instructions provided for the workplace. Corrective actions at one's own initiative, such as transferring a misplaced sealed source back inside from outside the shielding, shall not be attempted without sufficient expertise. The spread of radioactive materials shall be prevented by cordoning them off and cleaning the area according to the site-specific instructions and the radiation safety officer's instructions. The cleaning of a contaminated area shall not be attempted without sufficient expertise.

If the individuals exposed to radiation used dosimeters, the dosimeters shall be sent to a dosimetry service for reading without delay. Any relevant additional information concerning the exposure situation shall be enclosed with the dosimeters. Individual monitoring results of exposure caused by measures taken during an abnormal event or accident shall immediately be sent by the responsible party to STUK, the worker concerned, and the medical practitioner in charge of the medical surveillance or the occupational health service.

The doses due to the event and their distribution in the body shall be assessed. If necessary, consultations shall be conducted with STUK concerning the methods to be used in the assessment.

If it is suspected that so extensive an amount of radioactive material has entered the body that the worker's annual dose could be exceeded, it may be necessary to determine the person's internal dose by a whole body counting or some other method. Whole body countings are performed at the Laboratory of Environmental Research at STUK (see Appendix D).

If it is suspected that the worker has received an effective dose exceeding 50 mSv or if the quantity of the dose is not known, it may be necessary to have a chromosomal analysis done. The Laboratory of Radiation Biology at STUK will provide more detailed instructions on blood sampling for chromosomal analysis (see Appendix D).

The radiation safety officer shall inform STUK as soon as possible of an abnormal event (see item 7.3). In an urgent case, some other person involved in the use of radiation at the site may inform STUK. STUK is usually first notified of a significant event over the telephone. Outside office hours, STUK can be contacted by telephone via the emergency number of the emergency response center of Helsinki (see Appendix D).

When an abnormal event takes place that was identified in advance or an event takes place that could not be anticipated, changes must be implemented in practical procedures and the applicable instructions. Such events shall be studied by the radiation safety officer and the staff together so that abnormal events are learned from and similar events are avoided in the future.

7.3 STUK shall be notified of all significant abnormal events

According to the Radiation Decree, STUK shall be notified immediately of the following:

- any abnormal event pertaining to the use of radiation that is substantially detrimental to safety at the place where the radiation is used or in its environs
- any disappearance, theft or other loss of a radiation source such that it ceases to be in the possession of the licensee
- any other abnormal observation or information of essential significance for the radiation safety of workers or the environment.

In addition, STUK shall be notified of any abnormalities significant for safety (see item 7.1). Similarly, the responsible party shall notify STUK of a radiation dose close to or exceeding the dose limit, measured in the course of individual monitoring (see Guide ST 7.1).

When first notifying STUK of an abnormal event or an observation significant for safety, usually by telephone, the following matters shall be stated:

- the responsible party (holder of the safety licence) and the radiation safety officer
- the name and contact information of the person giving the notification
- time and place of the event
- radiation source

- description of the event
- information of the endangered persons and the radiation exposure to which they may have been subjected
- immediate measures
- first estimates of the reasons for the event.

The first notification shall be confirmed in writing as soon as possible.

The responsible party shall report in writing any abnormal event or observation significant for safety, detailing the event or observation, and in addition to the information listed above, include more precise reasons for the event and the consequences of the event, such as spread of radioactive materials, the names of exposed workers (if possible), doses received by them and measures taken. In addition, the report shall present measures for the prevention of similar events in the future. The report must be sent to STUK without delay.

Provisions concerning notifications of abnormal events are given in sections 13 and 17 of the Radiation Decree.

7.4 Radiation exposure due to an accident shall be anticipated

In accident situations relating to the use of radiation, persons in radiation hazard may need to be helped, radiation exposure of other people may need to be prevented, and valuable establishments or goods may need to be saved. If in these measures necessary to be taken immediately the persons involved may receive doses greater than the annual dose limit for workers, then the responsible party shall prepare in advance for radiation exposure resulting from an accident. In those cases, workers engaged in radiation work or other persons shall be nominated in advance to perform these measures. Individual monitoring shall be arranged for these persons, or their individual doses shall be determined by some other method during the accident situation or after it. Only volunteers who have been informed in advance of the risks pertaining to accident situations shall be assigned to perform these measures.

The workers' dose limits shall apply to protection work and to other measures taken

to mitigate the consequences of the accident. The protection of workers participating in these measures, the monitoring of their radiation exposure, and their medical surveillance shall be arranged as decreed on radiation work.

No duties which might cause exposure to radiation shall be assigned to a pregnant woman either during or after an accident situation.

The individual monitoring results concerning measures taken in accident situations shall be sent without delay to STUK, to the workers

concerned, and to the medical practitioner responsible for the medical surveillance or the occupational health service.

Provisions concerning dose limits applicable to volunteers involved in measures necessary to be taken immediately in accident situations and participating in protective work to mitigate the consequences of the accident, or involved in other measures, are given in sections 8 and 8 a of the Radiation Decree.

APPENDIX A

Definitions and concepts

Dose constraint

In planning radiation shieldings, the radiation source-specific limit on an individual dose used for the protection of the individuals most exposed to the source. Dose constraints are also used as the maximum limits when optimizing protection against radiation emitted by certain sources.

High-activity sealed source

A sealed source containing a radionuclide of activity that was equal to or exceeded the activity level set per nuclide when the source was manufactured or, if the activity at this time is not known, at the time when the source was first placed on the market.

NOTE! Activity levels for different radionuclides are presented in Guide ST 5.1, Appendix A.

Abnormal event

Disappearance or theft of a radiation source or an incident in the use of radiation that differs from normal activities and results in a substantial safety hazard at the place where the radiation is used or in its environs. An abnormal event may also consist of an exceptional observation or information that is of essential significance for the radiation safety of workers, patients or other persons.

Potential exposure

A possible exposure that cannot, however, be anticipated with certainty. An exposure may be the result of an accident, an event or a series of events which may happen incidentally. Such events include equipment faults and human errors.

Risk

A concept that connects the probability of a certain event and the seriousness of the detriment caused by the event.

Investigation level

An operation-specific limiting value imposed by the responsible party for a dose, activity or some other regularly monitored radiation quantity. When a limiting value is exceeded, the responsible party takes predetermined actions to investigate the reason for exceeding and to prevent the value from being exceeded again. Most often, an investigation level is set for an individual measurement result.

Note! An investigation level is a limiting value smaller than a dose limit or a dose constraint.

Use of radiation

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

Radiation safety measures

Procedures to prevent or decrease radiation doses and detrimental effects of radiation to humans and which ensure the safety of the responsible party's own workers, students and apprentices as well as the safety of any members of the public and outside workers working for the responsible party. These procedures also include the measures aimed at preventing accidents and mitigating their results.

Radiation practices

Radiation practices refers to the use of radiation and other practices causing exposure to radiation.

Other radiation practices

Other radiation practices are operations or circumstances in which the exposure of human

beings to natural radiation causes or may cause a health hazard. STUK decides, when necessary, whether a particular operation constitutes a radiation practice.

Radiation work

Work in which the radiation exposure of a worker might exceed any of the dose limits for members of the public prescribed in section 6 of the Radiation Decree.

Supervised area

A working area subject to appropriate monitoring of working conditions for the purpose of protection against radiation.

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 something other than a physical person (such as 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.

Management system

The steering and control system of an organization, consisting of the rules and operation modes in common and shared in the organization. The management system contains, for example, the organization's business idea, its visions, values, strategy, operating processes, performance measurement principles, human resource policy principles and a description of how the operation is developed. The management system is manifested in various documents (guides, models, forms).

Note! A management system is also called a quality system.

Security arrangements

Measures to detect and prevent the theft, sabotage or unlawful transfer of a radiation source, unlawful entry to an institution or facilities which contain these sources, or a similar malicious act. These measures also include the counter-measures after the malicious act.

Outside worker

A worker, student, apprentice or self-employed person who takes part in the radiation work assigned by the responsible party but is not employed by the responsible party.

Outside undertaking

The employer of outside workers or a self-employed person.

Sealed source

A radiation source in which the radioactive material has been encapsulated or covered so that this material cannot be touched and will not spread into the surroundings under the operating conditions for which the radiation source was designed.

Controlled area

A working area subject to special rules for the purpose of protection against radiation and preventing the spread of radioactive contamination, and to which access is controlled.

Radiation safety officer

A responsible person nominated by the responsible party to handle the practical activities to ensure the safe use of radiation, to maintain safety and to repair any defects.

APPENDIX B

Classification of workplaces and other areas – examples

1. X-ray practices in health care

1.1 X-ray diagnostics

Fixed x-ray equipment

The controlled area in a room in which fixed x-ray equipment is used shall consist of that area next to the patient which, during irradiation, is exposed to primary radiation or radiation scattered directly from the patient. The rest of the use area may be classified as supervised, and the control room may be unclassified. If the control room is only partly shielded or open at the top or sides, it may be classified as supervised.

Fixed fluoroscopy equipment

A room in which fluoroscopy equipment is used shall be classified as a controlled area during irradiation. In interventional radiography, for example, the control room shall also be classified as a controlled area if the control devices are located in a partly shielded space or in a space which is open at the top or sides.

Transportable x-ray equipment and transportable fluoroscopy equipment

The controlled area shall, during irradiation, consist of that area next to the patient which is exposed to primary radiation or radiation scattered directly from the patient.

1.2 Dental x-ray practices

The controlled area shall, during irradiation, consist of that area next to the patient which is exposed to primary radiation or radiation scattered directly from the patient.

2. Radiotherapy

In radiotherapy, controlled areas shall consist of the room used for radiotherapy and those adjacent utility rooms the occupancy in which

requires special protection. The control room for radiotherapy equipment shall be classified as a supervised area.

3. Radionuclide therapy

Rooms used for the isolation of patients who have been subject to radionuclide therapy (in particular treatment with ¹³¹I) shall, in general, be classified as controlled areas.

4. Veterinary x-ray practices

The controlled area shall, during irradiation, consist of that area next to the animal which is exposed to primary radiation or radiation scattered directly from the animal.

5. Industrial radiography

Enclosures used for industrial radiography shall be classified as controlled areas.

When an open installation is used, the area around the X-ray or gamma exposer device shall be enclosed with ropes or barriers and classified as a controlled area within the range exposed to primary or scattered radiation (see Guide ST 5.6).

6. Use of accelerators and irradiation equipment

Irradiation and accelerator rooms shall be classified as controlled areas. Adjacent, shielded control rooms shall be classified as supervised areas.

7. Radionuclide laboratories

Laboratories of types A and B as well as storages of radionuclides and radioactive wastes shall be classified as controlled areas. In type C laboratories, those laboratory rooms should be classified as controlled areas in which the risk of contamination is great or the activity handled at one time exceeds the activity limits presented

in “Use of Unsealed Sources” in Appendix C. Other type C laboratories shall be classified as supervised areas.

8. Other places where radiation is used

Laboratory rooms in which x-ray analyzers or equipment containing sealed sources are used shall usually be classified as supervised areas. If the primary beam of the x-ray equipment can be directed outside of the appliance, the area next to the beam shall be classified as a controlled area.

Classification guidelines for spaces around radiometric measuring devices used in industrial and other manufacturing plants are given in

Guide ST 5.1.

During service, the area around radiation sources shall be classified as controlled or supervised, as appropriate, if shieldings have to be dismantled or radiation sources changed, or if work has to be performed immediately next to sources with the shutter open.

Storage rooms for sealed sources or for equipment containing sealed sources shall be classified as controlled or supervised areas according to the number and type of the sources. Radiation sources shall be in their shieldings and the storage room shall be locked.

APPENDIX C

Classification of workers into category A in different practices – examples

Workers classified as category A workers are usually the individuals listed in this Appendix. The list is not comprehensive. The classification into categories shall take into account the local working conditions and the total exposure a worker is subjected to considering all work exposing the worker to radiation.

1. X-ray practices in health care

1.1 X-ray diagnostics

- individuals who regularly or repeatedly work in controlled areas during irradiation. Such persons include, for example, those regularly participating in fluoroscopy or examinations or in interventional radiology at X-ray wards, operating rooms, emergency units and patient wards, or assisting patients often.

1.2 Dental x-ray practices

- individuals who regularly work in controlled areas during irradiation

3. Radiotherapy

- individuals who perform quality control measurements on radiotherapy equipment
- individuals who handle radiation sources or give intracavitary or interstitial radiotherapy

4. Radionuclide therapy

- individuals who regularly give radionuclide therapy or who, next to the patient, handle patients who have received such treatment

5. Veterinary x-ray practices

- individuals who regularly work in controlled areas during irradiation

6. Industrial radiography

- individuals who participate in radiography in which open installation is used

7. Use of accelerators and irradiation equipment

- individuals who repeatedly visit irradiation rooms or accelerator rooms

8. Use of unsealed sources

- individuals who continuously handle radioactive materials in their work so that the activity handled at one time exceeds the following activity limits:

Gamma emitters	100 MBq
Beta emitters (maximum energy exceeding 0.3 MeV)	10 MBq
Beta emitters (maximum energy 0.1–0.3 MeV)	100 MBq.

9. Installations, repairs and service

- individuals who carry out installations, repairs or service of radiation appliances and may thus be exposed to radiation
- individuals who carry out installations, repairs or service on other equipment connected to radiation sources and doing this are obliged to carry out trial runs of radiation appliances or handle radiation sources and may thus be exposed to radiation.

APPENDIX D

Contact information

Postal address:

Radiation and Nuclear Safety Authority
P.O.Box 14
00881 HELSINKI, FINLAND

Street address:

Laippatie 4
00880 HELSINKI, FINLAND

Telephone: + 358 9 759 881

Abnormal events in the use of radiation and Dose Register for workers:

Department of Radiation Practices Regulation

Chromosomal analysis:

Department of Research and Environmental Surveillance

- Laboratory of Radiation Biology

Measurements of internal exposure:

Department of Research and Environmental Surveillance

- Laboratory of Environmental Research

Urgent contacts to STUK outside office hours via emergency response centers:

Phone **112** (the emergency response center in your own area)

Ask the emergency response center to request STUK's on-duty expert to phone you.

All emergency response centers have STUK's on-duty contact information.