STUK

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RADIATION SAFETY IN NUCLEAR MEDICINE

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

1 General

This ST Guide presents the essential radiation safety requirements for nuclear medicine. These requirements shall also apply to procedures performed on healthy persons participating in scientific research and to procedures performed on patients. These requirements shall also apply to the radiation exposure of persons who voluntarily and otherwise than due to their occupations assist persons subjected to procedures involving exposure to radiation.

The basic provisions concerning medical uses of radiation are laid down in chapter 10 of the Radiation Act (592/1991). The Decree of the Ministry of Social Affairs and Health on the medical use of radiation (423/2000, hereinafter referred to as the MSAH Decree) lays down the provisions concerning the grounds of procedures which cause exposure to radiation. Guides ST 1.1 and ST 1.6 present general safety principles, radiation safety measures, and general principles concerning security arrangements.

Guide ST 6.1 presents the radiation safety requirements for laboratories and patient facilities as well as general instructions on working with unsealed sources. Guide ST 1.10 gives instructions concerning the radiation shielding of places of use of radiation sources. Instructions concerning the handling and discharges of radioactive wastes into the environment are set forth in Guide ST 6.2.

Guide ST 5.1 presents the radiation safety requirements for sealed sources and devices containing sealed sources as well as for the use and installation of them. Instructions on the use of sealed sources in radiotherapy are set forth in Guide ST 2.1.

Provisions concerning the classification of facilities into controlled and supervised areas as well as the protection of workers and their medical surveillance are laid down in sections 32 and 33 of the Radiation Act. Guide ST 1.6 gives instructions concerning the classification of working areas and workers. Guide ST 7.1 gives more detailed instructions on the monitoring of radiation exposures of workers, and Guide ST 7.5 gives more detailed instructions on the medical surveillance of occupationally exposed workers.

Provisions are laid down in section 14 a of the Radiation Act concerning the responsible party's duty to arrange training for individuals engaged in the use of radiation. Provisions on the training and instruction of workers are laid down in section 36 of the Radiation Act. Also Guide ST 1.6 gives instructions concerning the training and instruction of workers. The requirements for the training and qualifications of health care professionals are prescribed in chapter 5 of the MSAH Decree. The requirements for the professional supplementary training for persons engaged in medical use of radiation are prescribed in section 27 of the MSAH Decree. Guide ST 1.7 prescribes the requirements concerning the radiation protection training of workers participating in procedures involving exposure to radiation in health care.

2 Definitions

In this Guide,

quality control refers to the measurements, tests, inspections and assessments used for determining and monitoring the operating conditions and performance capabilities of appliances used in radiation practices

quality assurance refers to all the planned, systematic measures taken in order to ensure that all methods, appliances and their use fulfil the specified quality requirements

quality assurance programme refers to the document referred to in section 18 of the MSAH Decree, specifying in writing the quality assurance activities in the medical use of radiation

management system refers to the system comprising the organizational structures, procedures, processes and resources required for managing and developing the operation. A management system can also be called a quality system.

3 Use of radiation and the safety licence

3.1 The responsible party shall be responsible for safety

The party running a radiation practice (hereafter the responsible party) shall be responsible for ensuring that all operations are arranged so that their practices fulfil all requirements and regulations under the Radiation Act and any statutes under it, and that the danger of events leading to any abnormal exposure to

radiation is prevented with sufficient efficiency. The responsible parties shall be liable for the implementation of such measures to improve radiation safety that can be considered reasonable with respect to their nature and extent.

In matters concerning the safety of operations, the responsible parties shall ascertain that they possess the expertise required with respect to the nature and extent of the operations.

The general obligations of a responsible party are laid down in chapter 4 of the Radiation Act. The training and qualification requirements for operating personnel are laid down in the Radiation Act and in chapter 5 of the MSAH Decree.

3.2 The use of radiation requires a safety licence

Safety licences are granted by STUK upon application. STUK shall grant the safety licence if the intended use of radiation fulfils the general provisions laid down in the law and if the application demonstrates in a sufficiently reliable manner that, for example:

- the purpose and the place of use of radiation, the radiation sources, and the equipment related to the use of radiation
- radiation user's organization, and
- the arrangements for handling the radioactive waste possibly produced by the operations

are such that radiation can be used safely.

The safety licence application shall have an organization description appended that specifies the responsibilities relating to the use of radiation.

The provisions concerning the general principles of radiation safety are laid down in section 2 of the Radiation Act. The provisions concerning the safety licence and granting the safety licence are laid down in section 16 of the Radiation Act, and the provisions concerning organization description are laid down in section 18 of the Radiation Act. More details are set out in Guide ST 1.1. Guides ST 1.4 and ST 1.8 give more precise requirements concerning radiation users' organizations.

4 Performance of procedures

4.1 Procedures shall be justified and optimized

Responsible parties shall ensure that good practices are applied in nuclear medicine examinations and radionuclide therapies.

The referring physicians shall consider the justification of the nuclear medicine examinations and radionuclide therapies when writing the referrals. In addition, the nuclear medicine specialists in charge of these procedures shall ascertain the justification of each procedure. A referral shall clearly state the indication of the examination or treatment and other necessary information so that the procedure can be performed in an optimal manner.

Nuclear medicine examinations shall be optimized to fulfil the purpose of the procedure while minimising the radiation exposure to the subject. This requires e.g. that

- all staff participating in the use of radiation have been trained and fulfil the respective qualification requirements
- the appliances in use are suitable for the intended examinations and in proper working order
- the examination procedures are optimized
- the image quality is sufficient for reliable diagnoses.

Radiation doses in radionuclide therapy shall be planned individually for each patient so that the radiation dose to the target tissue or organ is sufficient to bring about the desired effect. At the same time, the radiation exposure of non-target tissues shall be as low as reasonably achievable.

Provisions concerning justification and optimization are laid down in section 38 of the Radiation Act and chapter 2 of the MSAH Decree.

4.2 Radiation protection of patients

Before performing a procedure, the respective unit shall ensure that the patient holds a proper referral for the examination, that radiation

protection and safety have been ascertained, and that the patient has been appropriately informed about the intended procedure.

Before a radiopharmaceutical is administered to a patient, its activity shall be measured with an activity meter.

If alternative radiopharmaceuticals are possible for an examination, the radiopharmaceutical selected shall, when possible, be the radiopharmaceutical that minimizes the radiation dose to the patient. If the activity administered to the patient depends on the device used for the examination, then the device selected shall be the one that minimizes the activity that is necessarily delivered to the patient in the examination.

All available measures must be made use of in order to reduce the radiation exposures of patients caused by nuclear medicine examinations and radionuclide therapies. These measures include e.g. preventing radioactive substances from accumulating in organs that are not being examined and accelerating the excretion of the radioactive substances.

The management system documentation must describe the measures applied in ensuring that the right patient receives the right amount of the right radiopharmaceutical. These documents must also describe the measures to be taken to reduce the patient's radiation exposure in the case of a dosage error.

4.3 Reference levels for nuclear medicine examinations and their use

The dose limits set forth in the Radiation Decree do not apply to patients' radiation exposures. However, the principle of optimization requires that the radiation exposure of any subject of an examination or a therapeutic procedure be limited to the amount that is necessary for the gaining of the intended outcome to the procedure. Reference levels form an optimization tool for nuclear medicine examinations. Reference level refers to predetermined activity levels administered to patients in nuclear medicine examinations that are not presumed to be exceeded in procedures performed according to the standards of good practice upon patients of normal size.

Reference levels are determined for groups of patients on the basis of activity administered in a certain examination. They should not be applied to examinations of individual patients.

Responsible parties are required to introduce reference levels to nuclear medicine examinations. The reference levels for the most common examinations are issued by STUK, and they are revised as necessary.

Dose limits are given in chapter 2 of the Radiation Decree (1512/1991). The requirements concerning the use of reference levels are laid down in sections 16 and 17 of the MSAH Decree.

4.3.1 How to determine the mean activity to be administered to patients?

The mean activity of radiopharmaceuticals administered to patients in nuclear medicine examinations shall be compared to the reference levels. Quality assurance programmes shall include instructions concerning the assessment of the activity administered to patients in different types of examinations. The mean activity shall be determined for a group of no fewer than ten patients of normal size for each type of examination at intervals of at least three years. If the activity administered to a patient depends on the weight of the patient, patients shall be selected so that their weights fall in the range 60–80 kilograms. If the activity administered to a patient depends on the device used for the examination, the mean activity shall be determined per device. If the examination practice or equipment changes in a manner that affects the activity administered to patients, then the mean activity shall be determined again at the earliest opportunity.

4.3.2 Actions in the case that the mean activity differs from the reference level

If the mean activity administered to patients in an examination clearly exceeds the reference level, the reasons for this shall be investigated, any potential deficiencies corrected, and, if necessary, the examination must be optimized. If the mean activity administered to patients falls substantially below the reference level, it must be ensured that the acquired information is sufficient for diagnosis.

4.3.3 Recording of results

The mean activity values and all information concerning corrective measures must be recorded and kept for at least five years. In addition, the information itemized in Appendix must be recorded and kept.

4.4 Radiation protection shall be ensured for patients' family members and other individuals

4.4.1 Dose constraints

Patients who have had radioactive substances administered to them may be treated as outpatients when radiation exposures caused to family members and other persons by the residual activity in these patients remain insignificant. The following dose constraints shall be applied:

Family members of the patient	
Children (including unborn children)	1 mSv/treatment
Adults (under 60 years of age)	3 mSv/treatment
Adults (60 years of age and older)	15 mSv/treatment
Other persons (members of the public)*)	0.3 mSv/year

If it is possible that the dose constraints of family members or any other individuals might be exceeded, (e.g. because of a long journey, or if there are small children at home) the patient must remain in hospital until the residual activity in this patient has fallen sufficiently.

Patients who have received radionuclide therapy shall be accommodated in the hospital facilities in a manner that minimizes the radiation exposure of workers, other patients and visitors. The doors leading to patient rooms (isolation rooms) shall carry signs calling attention to a radiation hazard.

After ^{131}I treatment the patient may be released from hospital after receiving the relevant radiation protection instructions when the residual ^{131}I activity in patient no longer exceeds 800 MBq. Appropriate measurements shall be made in order to ascertain the residual activity. Patients should be able to use public transportation for journeys of no longer than two hours.

Patients with incontinence should not be released to their own home or to nursing home immediately after treatment.

When using beta-emitting radionuclides, such as ^{32}P, ^{89}Sr and ^{90}Y, no radiation protection measures are necessary after the residual activity in patients no longer exceeds 200 MBq.

Autopsies may be performed without radiation protection measures after the residual ^{131}I activity in the patients no longer exceeds 600 MBq.

Provisions are laid down in section 10 of the MSAH Decree concerning the use of dose constraints for limiting the radiation exposure of voluntary assistants. Instructions for the release of patients after ^{131}I treatment are available in the EU Commission publication "Radiation protection 97, Radiation Protection following Iodine-131 therapy (exposures due to out-patients or discharged in-patients)".

4.4.2 Radiation protection instructions shall be provided both orally and in writing

If there is any reason to suspect that the dose constraints presented in item 4.4.1 may be exceeded, and before releasing patients who have had radionuclide therapies, the unit responsible for the procedures shall provide these patients or their caretakers with instructions concerning the limiting of the radiation exposure of individuals who come into contact with these patients. These instructions shall take into account the individual circumstances of the patients, such as their living and working conditions. The instructions must be provided both orally and in writing, and in a form that the patients understand. The importance of following the instructions shall be emphasized to the patients. The fact that instructions were given shall be entered into the patients' medical records. The instructions should include at least the following information:

- the name and identity number of the patient
- the name, address and telephone number of the hospital

*) The exposure of other persons is subject to the dose limit for the members of the public, which is 1 mSv per year. As doses may be caused also by other radiation sources, the dose constraint for exposure due to a single radiation source is 0.3 mSv.

- the person to contact if problems arise
- the radiopharmaceutical administered to the patient and its activity
- the date on which the pharmaceutical was administered
- practical instructions for limiting the radiation exposure of persons coming into contact with the patient
- the period during which the instructions must be followed.

Practical instructions for steps for limiting the radiation exposure of persons coming into contact with the patients shall be issued also when patients are transferred between units at a hospital or to other hospitals.

The period during which the instructions must be followed depends on the residual activity in the patient and on the dose rate that this causes.

If a patient plans to travel abroad immediately after radionuclide therapy, the patient must be given a certificate of treatment, preferably in English, because radiation measurements are likely at national borders.

The activity of radiopharmaceuticals administered to patients in nuclear medicine examinations is generally so small that no precautions or restrictions on the behaviour of the patient are necessary. After nuclear medicine examinations, no practical instructions are usually necessary in order to limit the radiation exposures of persons coming into contact with these patients. Exceptions to this are nuclear medicine examinations in which the patient is administered 30 MBq or more of ^{131}I, and the cases in which reasons exist to suspect that any of the dose constraints referred to in item 4.4.1 might be exceeded.

Section 11 of the MSAH Decree lays down the provisions concerning protection instructions to the patient or a person attending to the patient. The publication "Radiation protection 97, Radiation Protection following Iodine-131 therapy (exposures due to out-patients or discharged in-patients)" includes an example of the instructions to be provided to a patient following ^{131}I therapy.

5 Written instructions shall be available for examinations and treatments

Written instructions shall be available for performing nuclear medicine examinations and radionuclide therapies. These written instructions shall cover all stages of examinations and therapeutic procedures for the most common examinations and therapies, and they shall also include the preparation and processing of radiopharmaceuticals and dealing with radioactive wastes. The written instructions are also required to issue the relevant instructions and safety directions concerning the radiation protection of both workers and patients.

The requirements concerning written instructions for the performance of procedures are laid down in section 14 of the MSAH Decree.

6 Equipment shall comply with the set requirements

6.1 General requirements

The statutes on medical devices also apply to devices used in nuclear medicine. Procedures involving exposure to radiation shall be performed using equipment that is suited for the intended purpose. All devices must have a CE marking to indicate their compliance with regulations.

General requirements and limitations concerning equipment and their uses are given in section 30 of the MSAH Decree. Provisions concerning the CE marking are laid down in section 9 of the Medical Devices Act (629/2010).

6.2 Acceptability criteria during the use of equipment

Nuclear medicine equipment and the related auxiliaries and devices shall comply with all acceptability criteria during the use of equipment

given in STUK's decisions. Acceptability criteria refer to the minimum requirements for the performance capacity of equipment. If the acceptability criteria are not met, then one of the following measures must be taken:

- Repairs must be implemented to restore the performance capacity of the device to an acceptable level.
- The use of the device must be restricted so that the characteristic exceeding the tolerance limit does not affect any examination or treatment.
- The device must be decommissioned.

Acceptability criteria are not tolerance limits for the optimal performance of the apparatus. When procuring new equipment, at acceptance tests and in the course of monitoring performance during the use of equipment, responsible parties should apply stricter requirements, which may be based, for example, on the device specifications or the performance tolerance limit proposed in equipment standards.

Requirements and criteria of acceptability are laid down in section 30 of the MSAH Decree.

7 Responsible parties shall be liable for quality assurance for their operations

The best way to implement the requirements imposed on responsible parties by radiation legislation is to use a management system covering all operations. The management system shall be documented, and the respective documents shall be arranged to form a unified, continuously updated entity (the procedures manual, the quality manual or similar).

7.1 Quality assurance programme

Responsible parties shall be liable for quality assurance for their operations. Quality assurance functions shall be specified in writing in a quality assurance programme. The quality assurance programme shall include the principles for the prevention of errors and mishaps which may cause unintended radiation exposure. Quality assurance practices shall be assessed regularly and, when appropriate, changed.

Provisions are laid down in section 40 of the Radiation Act concerning the responsible party's duty to implement quality assurance measures. The requirements concerning the drafting of the quality assurance programme are laid down in section 18 of the MSAH Decree.

7.2 Quality control of devices

7.2.1 Acceptance testing

The responsible party shall ensure that any device about to be commissioned has an acceptance test conducted before the device is used for examining or treating patients. The purpose of the acceptance test is to verify that the device functions appropriately and safely after transportation, installation and connection of all parts. All equipment shall comply with the requirements imposed by legislation, with the key performance values and safety characteristics given by the manufacturers, and with the acceptability criteria during the use of equipment given in the respective STUK decisions (see item 6.2). During the acceptance test, it is expedient to define the reference values for the performance parameters needed for monitoring the operating condition of the equipment.

Acceptance tests may be carried out by a representative of the user organization (purchaser), a representative of the supplier, or a third party. If acceptance tests are carried out by a party other than the user organization's representative, the tests shall be appropriately supervised and a person shall be assigned to take charge of supervision.

Requirements for acceptance test are laid down in section 32 of the MSAH Decree.

7.2.2 Quality control during the use of equipment

In addition to acceptance testing, the operation of all equipment shall be inspected according to device- specific instructions

- at regular intervals
- following significant repairs or servicing

- at any time when there is cause to suspect a malfunction or a change in the operation of the equipment.

The quality control programme for a device shall set out the principal tasks involved in monitoring the operating condition and performance characteristics of the equipment. The instructions and responsibilities pertaining to the monitoring of equipment shall be specified per appliance. A quality control programme for a device shall specify

- the inspections and measurements to be performed as well as their purposes
- the inspection and measurement methods
- the devices and instruments to be used in inspections and measurements
- the intervals at which inspections and measurements must be performed
- the approval criteria (action levels) for inspection and measurement results
- the measures to be taken when the approval criteria are exceeded.

If inspection and measurement results exceed the set action levels, the measures given in the quality control programme must be performed. The responsible party may set the action levels. However, action levels set to require repair shall not be higher than the acceptance criteria set by STUK.

The persons performing inspections and measurements and the persons in charge of them (professional groups) must be specified.

Instructions concerning the inspection and measurement methods must be issued in writing in sufficient detail so that all inspections and measurements can be repeated on the basis of these instructions as intended by the person who prepared the instructions.

Requirement for quality assurance programme is laid down in section 32 of the MSAH Decree.

7.3 Quality assurance for radiopharmaceuticals

The handling and preparation of radiopharmaceuticals shall conform to good radiopharmaceutical practice. This includes both radiation safety and purity requirements. The quality assurance functions for radiopharmaceuticals shall be specified in the quality assurance programme.

Section 9.2 of regulation 6/2012 "Sairaala-apteekin ja lääkekeskuksen toiminta" ("Operation of hospital dispensaries and central dispensaries") by the Finnish Medicines Agency (Fimea) sets forth statutes concerning radiopharmaceuticals.

7.4 Records for quality assurance

Records must be kept of all inspections and measurements performed for the purpose of quality assurance, detailing which inspections and measurements have been made, by whom, the results thereof, and the measures taken on account of those results.

Records must also be kept of any equipment faults, malfunctions and other incidents that occur during the use of the equipment and that disrupt its normal use or endanger safety. All essential documents shall be kept through the service-life of the equipment.

In addition, if any abnormal events are observed that are significant for radiation safety, the measures should be taken that are presented in chapter 12.

8 Clinical audit and self-assessment

The objective is for operations to be audited in all essential respects at least once per five years. Clinical audits must be arranged so that they complement the self-assessment of activities in an expedient manner. An expedient audit respects the recommendations by the Finnish Advisory Committee for Clinical Audit, set by the National Institute for Health and Welfare (THL) (www.clinicalaudit.net).

The obligation of the responsible party to arrange clinical auditing for the medical use of radiation is laid down in section 39 c of the Radiation Act and in chapter 4 of the MSAH Decree. The duty of the responsible party to set up self-assessment procedures for the medical use of radiation is prescribed in section 19 of the MSAH Decree.

9 Grounds shall be given for the justification of radiation exposure due to scientific research

The research plan for a scientific investigation shall assess the radiation exposure to which the participants of the investigation may be subjected, and it shall also explain the grounds that justify the exposure.

The publication "Radiation protection 99" by the EU Commission presents a risk categorization for scientific research projects on the basis of the radiation doses to the participants. This risk categorization, based on ICRP publication No. 62, can be applied to the assessment of the justification of scientific research that involves radiation exposure.

Special care shall be taken when subjects are selected for scientific research in which participants are administered radioactive substances. The principles presented in "Radiation protection 99" shall be followed in the selection of subjects.

Dose constraints shall be presented for healthy volunteers. Effective doses to healthy volunteers should not normally exceed 10 mSv per year.

The requirements for scientific research involving exposure to radiation are laid down in section 6 of the MSAH Decree. Provisions concerning medical research are laid down in the Medical Research Act (488/1999). The EU Commission publication "Radiation protection 99, Guidance on medical exposures in medical and biomedical research" provides instructions concerning the risk categorization and selection of subjects applicable to scientific research.

10 Special protection during pregnancy and breastfeeding

10.1 Assessing the possibility of pregnancy

If the patient is a woman of childbearing age, the possibility of pregnancy shall be ascertained and the radiation protection of the foetus shall be implemented as prescribed in chapter 7 of the MSAH Decree.

Before radionuclide therapy or any examination that might expose a foetus to an excessive dose, the possibility of pregnancy shall be ruled out through a sensitive, specific pregnancy test.

Assessing the possibility of pregnancy is prescribed in section 34 of the MSAH Decree.

10.2 Protection of the foetus

If it is seen that performing a procedure involving exposure to radiation on a pregnant woman is absolutely necessary, the optimising of the procedure shall receive particular attention. The starting point is that the dose to the foetus should not exceed 1 mSv. If the procedure is performed, the exposure of the foetus to radiation shall be kept as low as possible. The estimated radiation dose to the foetus and all data concerning the procedure that are significant in view of radiation exposure shall be entered in the patient's records.

The protection of the foetus is prescribed in section 35 of the MSAH Decree.

10.3 Avoiding pregnancy after nuclear medicine examinations or radionuclide therapies

There is no need to avoid pregnancy after most nuclear medicine examinations. Some nuclear medicine examinations may, however, cause radiation doses exceeding 1 mSv to an unborn child. In such cases the patients should be urged to avoid pregnancy for a certain period of time.

Female patients shall be urged to avoid pregnancy after radionuclide therapy. This ensures that the dose to the unborn child does not exceed 1 mSv. The duration of the period in which pregnancy should be avoided depends on the applied radionuclide therapy. Spermatozoa may also be damaged through radionuclide therapy; for this reason, male patients shall be advised not to father children for a certain period after radionuclide therapy. When thyroid cancer is treated with ^{131}I, both female and male patients shall be instructed to use effective birth control and to avoid pregnancy for at least six months after the therapy.

Instructions on special protection during pregnancy and breastfeeding are available in the EU Commission publication "Radiation protection 100. Guidance for protection of unborn children and infants irradiated due to parental medical exposure."

10.4 Protection of the child during breastfeeding

When nuclear medicine examinations or radionuclide therapies are considered, attention shall be paid to radiation protection during breastfeeding. Before prescribing an examination or treatment, it must be ascertained whether a woman is breastfeeding. Before any procedure is performed, breastfeeding women shall be advised of interruption that will be necessary in breastfeeding or, even, of the cessation of breastfeeding. Children should not be breastfed after nuclear medicine examinations until the dose to them can be estimated to be below 1 mSv.

The recommended lengths of interruption in breastfeeding following various nuclear medicine examinations are set out in ICRP publication 106, in European Commission publication "Radiation protection 100" and in the specifications of radiopharmaceuticals. If it is not possible otherwise ascertain, that the dose to the child remains below 1 mSv, the length of the interruption shall be determined on the bases of activity concentration measured in breast milk and biological half life.

Breastfeeding must be ceased altogether after radionuclide therapy.

Protection during breastfeeding is prescribed in section 36 of the MSAH Decree.

11 How to record and report information on nuclear medicine examinations and radionuclide therapies?

All procedures must be entered into the patients' medical records. If a procedure was performed in a substantially different manner than usual, this must also be entered into that patient's medical records.

Patient data shall include the following items concerning radiopharmaceuticals administered during examinations and treatments

- activity
- radionuclide
- chemical form or the abbreviation generally used for it.

Any CT examinations performed in connection with nuclear medicine examinations shall be recorded in the patient data in a manner that enables the determination of patients' radiation exposures even retrospectively.

All written instructions on the performance of procedures shall be archived so that the radiation doses to patients can be assessed afterwards if necessary. It shall also be possible to ascertain on the basis of the archived documents afterwards which practice was followed at the time of a particular procedure. Examination instructions shall be kept for 20 years.

Upon request and in the manner specified by STUK on a case-by-case basis, the responsible party shall submit to STUK information concerning nuclear medicine examinations and radionuclide therapies for national appraisals of radiation exposure and its development.

The recording of information concerning procedures and the obligation of STUK to collect and publish national appraisals is prescribed in section 43 of the MSAH Decree.

12 Abnormal events in the use of radiation

An abnormal event in the use of radiation refers to an event that differs from the normal activities and results in a substantial safety hazard in a place where radiation is used or near such a place. An abnormal event may also consist of an exceptional observation or information concerning an issue that is of substantial significance for the radiation safety of workers, the environment or patients.

Examples of abnormal events are presented in Guide ST 1.6.

12.1 Anticipation of abnormal events

The responsible party should identify in advance the possible abnormal events relating to the use of radiation. The responsible party shall plan and implement all operations so that the likelihood of any abnormal event is minimized. Abnormal events shall be anticipated by, for example, providing the workers with written instructions for the case that any such should occur.

The anticipation of abnormal events is treated in more detail in chapter 7 in Guide ST 1.6.

12.2 Dealing with abnormal events

When an abnormal event is noticed or suspected, steps taken shall be in accordance with the instructions provided for the workplace. The radiation doses due to the abnormal event shall be assessed. Abnormal events shall be studied by the radiation safety officer and the staff together so that these events would be learned from and similar events could be avoided in the future.

More detailed instructions concerning dealing with abnormal events are presented in Guide ST 1.6.

12.3 Reporting abnormal events

All events which result in a substantial safety hazard in a place where radiation is used or in its environs shall be reported to STUK without delay. The initial report may be submitted by telephone, but it must later be confirmed in writing. The personnel shall have clear instructions for reporting abnormal events.

A report of an abnormal event must specify

- the responsible party (holder of the safety licence) and the radiation safety officer
- the name and contact information of the person giving the report
- the time and place of the event
- a description of the event
- information about the endangered persons and the radiation exposures to which they may have been subjected
- immediate measures taken after the event
- first estimates of the reasons for the event.

All hazardous situations in the use of medical devices shall also be reported to the National Supervisory Authority for Welfare and Health (Valvira).

Provisions are laid down in section 17 of the Radiation Decree concerning the responsible party's duty to report abnormal events to STUK. The reporting of abnormal events is treated in chapter 7 in Guide ST 1.6. Guide ST 5.1 provides instructions concerning the reporting of abnormal events relating to sealed sources. Reporting of hazardous situations to Valvira (www.valvira.fi) is prescribed in the Medical Devices Act (629/2010).

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APPENDIX

Data to be recorded when determining the mean activity of radiopharmaceuticals to be administered to patients

Research Type of research

Equipment

Imaging device

- Manufacturer and type
- Collimator type
- Imaging type (planar, SPECT, etc.)
- Sensitivity (cps/MBq)

Uptake measurements

- Manufacturer and type of detector
- Sensitivity (cps/MBq)

Activity meter

- Manufacturer and type
- Accuracy (%)

Radiopharmaceutical

- Radionuclide and chemical form

Patient data

- Date of examination
- Activity of radiopharmaceutical administered to the patient (MBq)
- Weight of the patient
- Time span between administering the activity and beginning imaging
- Imaging time
- Other factors affecting the activity administered to the patient