

X-RAY EXAMINATIONS IN HEALTH CARE

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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 Guide lays down the essential radiation safety requirements for X-ray examinations performed in health care. The Guide applies to X-ray examinations and fluoroscopy guided procedures performed on patients (hereinafter referred to as X-ray examinations), to the X-ray appliances used for them (hereinafter referred to as X-ray equipment) and the related X-ray practices as a whole. The Guide also lays down the requirements for the quality assurance of X-ray practices in health care.

The Guide also governs X-ray examinations performed on persons participating in scientific research. The requirements for dental X-ray and mammography examinations are laid down in separate Guides ST 3.1 and ST 3.8, and this Guide supplements the above Guides where applicable.

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

The basic provisions governing the medical use of radiation are set out in Chapter 10 of the Radiation Act (592/1991). Section 41 of the Radiation Act is the authorising provision for 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). The Decree contains the provisions governing the grounds for medical procedures causing exposure to radiation and the procedures to be followed when implementing such measures.

2 A safety licence is required for X-ray practices

A safety licence is required for the use of X-ray equipment used in health care, unless the practice has been granted exemption by the Radiation and Nuclear Safety Authority (STUK). If the X-ray equipment is to be used for procedures other than conventional patient diagnostics examinations or radiological procedures, such as screening, this purpose of use shall be clearly presented in the application for a safety licence.

The party running a radiation practice (hereinafter the responsible party) shall ensure that the use of radiation remains safe and

compliant even as the practices change. The responsible party shall apply for a modification of the safety licence in good time before engaging in the practice in at least the following cases:

- the expansion of the practices mentioned in the safety licence or the starting of a new practice (see Appendix B for the categories of practice types)
- a structural modification of the X-ray equipment's location or the relocation of the equipment
- the commissioning of the X-ray equipment.

When the modification does not require a new safety assessment, it shall be reported to STUK no later than two weeks after the modification has been performed. The following shall be reported, for example, when:

- X-ray equipment is decommissioned
- the radiation safety officer is changed
- any essential change takes place in the user's organization
- the use of radiation is discontinued in whole or in part.

A safety licence is required for the installation, repair and servicing of X-ray equipment used for medical purposes. Radiation equipment may be installed, repaired and serviced only by persons with the necessary skills and expertise.

Section 16 of the Radiation Act contains provisions concerning the safety licence; further information concerning the safety licence is provided in Guide ST 1.1. Sections 16 and 18 of the Radiation Act contain provisions for the radiation user's organization and the organization description. More detailed instructions concerning the radiation user's organization and the organization description are provided in Guide ST 1.4. Guide ST 1.10 sets the requirements concerning the rooms in which X-ray equipment is used. The requirements for the installation, repair and servicing of radiation appliances are provided in Section 25 of the Radiation Act and specified in Guide ST 5.8.

3 Safety must be ensured

A good safety culture has a major impact on the safety of patients and workers. Maintaining a high level of safety and correcting any

shortcomings discovered at the workplace shall be prioritized. Safety culture can be promoted by ensuring effective communications and encouraging a questioning and learning attitude instead of settling for the status quo. Risk assessment and the documentation, reporting and analysis of deviations shall be promoted in a manner that allows for learning from mistakes and taking corrective action.

Safety culture is discussed on a general level in Guide ST 1.1. Guide ST 1.11 "Security arrangements for radiation sources" discusses the safe storage of mobile X-ray equipment, for example.

3.1 Prerequisites for safe practices

The responsible party shall ensure that it has sufficient expertise and personnel available for radiation safety issues, while taking into account the nature and scope of its practices. It is the responsible party's obligation to ensure that the qualification requirements for the physician responsible for the procedure involving exposure to radiation and the performer of the said procedure are met as required by the nature of the practice. Furthermore, the responsible party shall arrange for training and instruction for the workers, taking into account the nature of the practice and conditions at the workplace. User training for the workers and sufficient introduction for new personnel shall be provided during the commissioning of new equipment.

Section 36 of the Radiation Act contains provisions on the training and instruction of workers. Chapter 5 of the MSAH Decree contains provisions on the training and qualification requirements of physicians participating in the medical use of radiation and referring patients to examinations involving the medical use of radiation. Guides ST 1.7 and ST 1.8 contain more detailed provisions on the training and qualification of persons participating in the use of radiation.

3.2 Radiation safety of the patient

3.2.1 Principles of justification

In the medical use of radiation, the principle of justification is applied at three levels:

Level 1: The medical use of radiation is commonly accepted.

Level 2: A specific procedure shall be justified for a specific purpose. National or international referral recommendations and information concerning the typical radiation doses caused by examinations are recommended references when considering the justification of a specific examination. The responsible party is responsible for the referral practices and the implementation of the justification assessment.

Furthermore, an entirely new examination method or a new method of use of X-ray equipment that causes exposure to ionizing radiation shall be justified before it is taken into general use.

Level 3: The need for an X-ray examination shall be considered individually for each patient, and the expected benefits shall outweigh the harm to the patient in accordance with the principle of justification.

3.2.2 Patient-specific analysis of justification

An X-ray examination performed on a patient shall be based on a referral from a physician, and the referring physician shall consider the justification of the examination while preparing the referral. The analysis of justification and the preparation of the referral shall take into account the necessary information concerning earlier examinations and treatments. In addition to the referring physician, the physician responsible for the procedure involving exposure to radiation shall, for their part, ensure the justification of the examination. The need for an X-ray examination performed on a child (see item 3.2.5) or a pregnant woman (see item 3.2.4) shall be considered especially scrupulously, and alternative examination methods shall be considered.

No separate justification analysis or referral is required for patients who are invited for an examination in accordance with the decree on screening. A person meeting the screening criteria is invited for a screening examination.

Special attention shall be paid to the justification of a medico-legal procedure. The physician or dentist responsible for the procedure is also responsible for the justification analysis. As regards a person suspected of a crime, the legal prerequisites are assessed and defined by a competent authority (such as the police).

Chapter 10 of the Radiation Act and Chapter 2 of the MSAH Decree contain provisions for the justification and optimization of the medical use of radiation. Chapter 7 of the MSAH Decree contains provisions for the radiation protection of the foetus. The Government Decree on screening (339/2011) contains provisions for arranging screenings, and Section 39 of the MSAH Decree contains provisions on the justification of a screening that causes radiation exposure. The qualifications of a physician responsible for a procedure involving exposure to radiation are defined in Section 24 of the MSAH Decree. X-ray examinations may also be performed, when necessary, on the basis of Chapter 8 of the Coercive Measures Act (806/2011), Chapter 3 of the Communicable Diseases Act (583/1986) or Section 6 of the Aliens Act (301/2004).

3.2.3 Optimization

The referral shall clearly specify the examination indication and other details necessary to ensure that the X-ray examination can be performed in an optimal manner. An X-ray examination must be optimized to achieve the objective set for the examination while minimising exposure of the examinee to radiation. Radiation exposure shall be kept as low as is reasonably achievable also during examinations that are not medical in nature. The optimization requires the following, among other matters:

- the staff participating in the use of radiation meet the qualification requirements, and their supplementary training and equipment use training have been taken care of
- the equipment used for the examination is suitable for the purpose and in good condition
- the examination technique has been optimized, with special attention paid to child patients (see item 3.2.5)
 - optimization should take place in multiprofessional cooperation
- the image quality is high enough for reliable diagnosis or the performance of the procedure
 - when repeating an examination that causes a high radiation dose after a short time, it shall be considered whether the examination be further optimized such that an image containing more noise would be enough for the examination.

Comprehensive quality assurance supports the implementation of optimization (see chapter 5).

In order to minimize the patient's radiation exposure, it is important to carefully limit the radiation beam as required by the situation. The use of radiation shields shall be considered if they can be used to significantly reduce the patient's radiation exposure. In order to ensure the patient's safety and the success of the examination, it shall be possible to monitor the patient during the examination.

Chapter 10 of the Radiation Act and Chapter 2 of the MSAH Decree contain provisions for the justification and optimization of the medical use of radiation.

3.2.4 Pregnancy, and justification and optimization of the examinations

If the patient is a woman of childbearing age and the examination could expose the foetus to radiation, the possibility of pregnancy shall be investigated before starting the examination. In cases where a woman is pregnant or pregnancy is suspected, X-ray examinations of the her stomach and pelvic region shall be avoided if no weighty clinical reason for them exists. If the examination is justified, it shall be optimized in order to minimize the radiation dose to the foetus. In X-ray examinations of areas other than the stomach or pelvic region, the exposure of the foetus is usually low when the examination is performed in an optimized manner. If the foetus is subjected to the radiation beam during an examination that causes a high level of exposure (such as during a CT examination or a fluoroscopy guided procedure), an expert shall assess the exposure of the foetus and the information shall be recorded in the patient's documents.

Chapter 7 of the MSAH Decree contains provisions for the radiation protection of the foetus.

3.2.5 Justification and optimization of examinations on children

Children are of special importance in terms of radiation protection, since radiation exposure received as a child causes a higher risk than the same exposure to an adult. For this reason, special attention shall be paid to the justification analysis and optimization of examinations performed on children. Whenever possible,

examination methods that do not cause radiation exposure shall be used.

A medical X-ray examination performed on a child shall always be individually planned, and only the examinations that are essential in terms of clinical research shall be performed, while imaging only those series that are essential. Routine examinations that are performed without a situational analysis shall be avoided. X-ray examinations for children shall always be planned while taking into account their small size and the other special characteristics related to the examinations. The imaging programmes designed for adults are not usually suitable for children as such; they need to be separately designed for children. This must also be taken into consideration when commissioning new equipment.

The criteria for a good X-ray examination for children include the following:

- examination procedures are modified on a case-by-case basis
- the size of the imaging area is minimized on the basis of the indication and the preliminary information received
- the quality of imaging has been analysed and approved by the specialist responsible for the examination, and the objective has been to keep the patient's radiation exposure as low as reasonably achievable.

X-ray examinations for children are discussed in the following publications by STUK: Lasten röntgentutkimusohjeisto (X-ray examination guidelines for children) [13], Lasten röntgentutkimuskriteerit (Criteria for paediatric X-ray examinations) [12] and Lasten TT-tutkimusohjeisto (CT examination guidelines for children) [14].

3.2.6 Reference levels and determining patient dose

The responsible party must ensure that the radiation exposure of patients is determined for the most common types of X-ray examinations at least once every three years, and whenever the examination procedures or imaging values are modified in a manner that essentially affects the dose received by the patient. Radiation exposure is determined as the average of at least ten normal-sized patients, either by means of measurements or on the basis of a calculated

estimate. During those years when the patient dose determination is not performed, radiation exposure shall be monitored during quality control, for example (see item 5.2).

The average patient dose determined for a specific imaging procedure shall be compared to the set reference level if one has been provided. The reference levels for the most common types of examinations are provided by STUK, and they are revised when necessary. If children are regularly examined, their radiation exposures shall be compared to the reference levels or reference curves provided by STUK. Reference levels other than those provided by STUK can also be used, but they must not be higher than the reference levels provided by STUK. If the patient's average radiation dose determined as described above exceeds the reference level, the cause of the excess shall be analysed and, when necessary, action shall be taken in order to reduce the radiation exposure of patients. Even if the reference levels are not exceeded, it shall be ensured that the radiation exposure is not unnecessarily high. On the other hand, it shall always be ensured that the quality of the imaging is sufficient (see item 5.3.1 for discussion on the assessment of clinical image quality). The information on the imaging programme and imaging values used during the determination of the patient dose (tube voltage, filtration materials and thicknesses, and current-time product, if applicable) and the patient doses themselves shall be recorded.

The reference levels for a patient's radiation exposure and related instructions are provided in decisions published by STUK. Sections 16 and 17 of the MSAH Decree contain provisions on the use of patient radiation exposure reference levels in X-ray examinations. STUK's publication Röntgentutkimuksesta potilaalle aiheutuvan säteilyaltistuksen määrittäminen (Determining the patients exposure to radiation in X-ray examinations) [16] discusses the determination of a patient's radiation exposure due to X-ray examination.

3.2.7 Instructions, and recording and reporting examination information

Instructions on the performance of conventional X-ray examinations and on the operation of

X-ray appliances shall be available in premises when X-ray equipment is used. Instructions for examinations shall also be required because the radiation exposure of a patient may be assessed in retrospect where necessary. To ensure that the dose administered to an individual patient from an examination can be assessed at a later date, the examination instructions must be archived in a manner that enables the verification of the examination practices. The same procedure shall be applied to the storage of the examination instructions as to the storage of other diagnostic examination results and records.

The examination instructions shall describe the following issues:

- the X-ray equipment and essential accessories used for the examination
- the imaging distance and the imaging projections included in the examination
- the settings related to the imaging and fluoroscopy activities of the equipment
- the radiation shielding of the patient
- the radiation shielding of the person performing the examination and her or his assistant
- the data recorded concerning the examination on each patient
- any other noteworthy issues concerning the use of the X-ray equipment.

The X-ray examination shall be recorded in the patient's documents by using the classification of radiological examinations and procedures published by the Association of Finnish Local and Regional Authorities. If the performance of the examination deviates from the procedure recorded in the examination instructions, such as due to special instructions from the physician, and this will significantly affect the patient's radiation exposure, the deviating method of performance shall be recorded in the documents.

If the dose to the patient caused by the examination or procedure cannot be assessed to a sufficient level of precision by using the examination instructions (such as during a CT examination), the dose reading indicating the radiation exposure or other information required for the definition of the patient's radiation exposure shall be recorded in the documents or files concerning the patient or the examination

(such as an electronic patient data system). The reading from the dose display of the X-ray equipment may be part of this information, for example. The radiation exposure caused by a fluoroscopy examination or a fluoroscopy guided procedure (the DAP reading, for example) shall be recorded in the documents whenever the equipment features a display or device indicating radiation exposure. If such a display or equipment does not exist, the information or parameters that can be used, to estimate the patient's radiation exposure shall be recorded, if necessary.

During fluoroscopy examinations and fluoroscopy guided procedures where the local radiation exposure may exceed the threshold value for radiation damage, it is a good practice to employ investigation levels related to the possible occurrence of adverse radiation effects. For example, the investigation level may be a DAP reading, the exceeding of which gives cause to suspect that the local dose on the skin exceeds 3 Gy [8]. Procedures shall be defined for cases where the investigation level is exceeded, for the purpose of informing the patient and monitoring for any adverse effects caused by radiation, for example. This is also a recommended practice for patients for whom the investigation level referred to above may be exceeded during several fluoroscopy examinations or procedures performed on the same area of the body within a relatively short period of time.

Upon request, the responsible party shall submit to STUK, in accordance with the instructions provided, the information on the number of examinations, the radiation doses and the number of non-medical examinations, such as scientific examinations and medico-legal examinations. STUK will use the information to compile and publish national statistics.

Sections 14 and 43 of the MSAH Decree contain provisions on the recording of the instructions and information related to the performance of the procedures. Section 43 of the MSAH Decree contains provisions on the responsible party's obligation to compile summaries of the number of examinations and radiation doses, and their submission to STUK. The Decree of the Ministry of Social Affairs and Health on patient documents (298/2009) contains provisions

on the material related to the patient's care and the storage thereof.

3.3 Radiation safety of workers

The maximum values of radiation exposure defined in the Radiation Decree apply to all workers. The radiation exposure of workers shall be kept as low as reasonably achievable. In addition to the patient, only persons whose presence is essential for the examination or for the safety of the patient may be present in the examination room during an X-ray examination. The said persons shall be appropriately protected using suitable radiation shielding, and no part of them may be exposed to primary radiation.

Unnecessary presence in the vicinity of the patient and of the X-ray tube shall be avoided during an X-ray examination. Radiation shielding part of the equipment or portable radiation shielding shall be used when working in the immediate vicinity of the radiation beam in the course of procedures causing high levels of exposure to radiation. Use of safety goggles and a thyroid shield and overhead suspension shield for the head and upper body are also recommended.

When a woman engaged in radiation work has announced her pregnancy, her work shall be arranged so that the equivalent dose of the foetus is kept as low as reasonably achievable, and that it will not exceed 1 mSv for the remainder of the pregnancy.

During radiation protection training, attention shall also be paid to information on the health hazards of radiation and on safety-enhancing work procedures in order to prevent unnecessary exposure to radiation and events leading to exceptional exposure thereto. The operation and maintenance personnel shall have clear instructions available for failures, hazardous situations and abnormal events (see chapter 6). Workers shall for their part comply with the instructions issued, and they shall also otherwise attend to their own radiation safety and to that of others.

The inspection protocols for the inspections performed by STUK shall be made known and available to all workers operating the equipment.

Chapter 2 of the Radiation Decree contains provisions for the maximum levels of radiation exposure to radiation workers and the general public. Guide ST 1.6 provides more detailed instructions on the radiation safety arrangements at the workplace. Guides ST 1.7 and ST 1.8 lay down the requirements for the radiation protection training and supplementary training of workers participating in health care examinations that cause exposure to radiation. Guide ST 7.1 contains more detailed instructions on the monitoring of the workers' radiation exposure, and Guide ST 7.5 discusses their medical surveillance. Section 5 of the Radiation Decree (1512/1991) contains provisions on pregnant women working in tasks that cause exposure to radiation.

3.4 Radiation safety of the patient assistant

An assistant for a patient may be needed in the course of an X-ray examination (for example, when examining a child or an elderly person). The assistant must be at least 18 years of age. The assistant must not be a pregnant woman. A person who assists a patient must be directed in the said function, and it must be ensured that the said person is appropriately protected. The person must be advised of the radiation exposure related to the function and of the significance of this exposure. The primary choice of assistant should be a volunteer, for example a relative of the patient. If workers need to be used as assistants, the task must be divided among several workers whenever possible. Dose monitoring for the workers shall be set up when necessary. The radiation exposure of the patient's assistant shall be kept as low as is reasonably achievable.

Section 10 of the MSAH Decree contains provisions on limiting the radiation exposure of the voluntary assistant.

4 The X-ray equipment shall operate appropriately

The X-ray equipment shall be suitable for X-ray examinations in terms of its technical characteristics, and it shall operate in the

manner intended. It shall be possible to use the appliance to produce images that are of sufficient technical quality, or to produce a fluoroscopy image that is of sufficient quality. With the exception of equipment designed for bone mineral density measurement, any new X-ray equipment commissioned shall be equipped with a display that indicates the radiation exposure of the patient.

4.1 Acceptability requirements

X-ray equipment and accessories and instruments that are associated with its use must satisfy the acceptability requirements during use that are issued in decisions by STUK. The acceptability requirements are minimum requirements imposed on the performance capacity of the equipment, not limit values for optimal performance. The meeting of the acceptability requirements shall be verified at least once a year (see Appendix C). If the acceptability requirements are not met, one of the following measures must be taken:

- The equipment must be repaired in a manner that makes its level of performance acceptable.
- The use of the equipment must be limited in a manner that allows it to operate acceptably within this limited range of operation.
- The equipment must be decommissioned.

The meeting of the equipment's acceptability requirements can usually be confirmed during the periodic maintenance of the equipment, for example. The responsible party must ensure that a report is delivered to the place of use indicating the issues inspected, the most important measurement results and their acceptable limit values.

The limit values provided in international equipment standards and other guidelines should be used as requirements when procuring equipment and performing acceptance tests and quality control, as these are often stricter than the acceptability requirements.

Equipment introduced to the market after 13 June 1998 must bear the CE marking in accordance with the Finnish Medical Devices Decree.

The acceptability requirements for X-ray equipment used in health care are provided in decisions issued by STUK.

The acceptability requirements also contain more detailed requirements for the display that indicates the radiation exposure of the patient. According to Sections 30 and 31 of the MSAH Decree, STUK will confirm the function-specific requirements and acceptability requirements of the equipment that shall be considered in terms of radiation safety. The Finnish Medical Devices Act (629/2010) applies.

5 Arranging quality assurance is a key part of X-ray practices

The responsible party must arrange quality assurance for the practices that cause radiation exposure. In order to implement quality assurance, a quality assurance programme must be drawn up that defines the necessary quality assurance activities and their performance intervals. The quality assurance practices must be reviewed regularly and updated whenever necessary. The activities and evaluations related to quality assurance shall be appropriately documented.

The functionality and technical condition of the X-ray equipment and its accessories (e.g. image receptor and display monitor) must be monitored by using quality assurance measures and continuously during the operation. The quality of images must also be evaluated by using the clinical patient images. Practices must be improved where necessary. The evaluation of the radiology unit's practices (methods and results, for example) is an integral part of the unit's practices and the development thereof. Self-assessments and clinical audits are some of the tools used in the evaluation of the practices.

*Section 40 of the Radiation Act and Section 18 of the MSAH Decree contain provisions on the responsible party's obligation to arrange quality assurance and quality assurance programme. The publication *Terveydenhuollon röntgenlaitteiden**

laadunvalvontaopas (Quality control guide for health care X-ray appliances) [17] in the "Advice from STUK" series discusses the technical quality assurance methods.

5.1 X-ray equipment acceptance test

The responsible party must ensure that an acceptance test has been performed on any equipment that is taken into use before it is used for examining patients. The acceptance test ensures that after installation, the equipment functions in an appropriate manner and safely, so that the statutory requirements and the principal performance characteristics and safety features notified by the manufacturer are satisfied. At the time of the acceptance test it is also expedient to determine the performance capacity reference values that will be required over the course of supervising the operating condition and performance characteristics of the equipment (item 5.2).

The party who performs the acceptance test may be a representative of the operating organization (the purchaser), a representative of the supplier, or a third party. The responsible party shall ensure that the acceptance test is performed appropriately and documented.

*Section 32 of the MSAH Decree contains provisions on the acceptance tests of the equipment. Acceptance tests are also discussed in the publication *Terveysturvallisuuden laadunhallinta. Radiologisen laitteen vastaanottotarkastus (Quality management in health care. Acceptance test of radiological equipment) [11] by National Agency for Medicines.**

5.2 Supervision of the operating condition and performance characteristics of equipment

In addition to the acceptance test, equipment operation must be inspected at regular intervals according to the equipment-specific instructions, after any major repair, servicing or software update, and whenever there is cause to suspect any malfunction or alteration in the operation of the equipment. The quality assurance programme must lay down the principal tasks related to the supervision of the operating condition and performance characteristics of radiological equipment.

The equipment-specific quality assurance instructions shall present the following:

- performance instructions
- performance intervals
- responsible individuals
- action levels and measures taken when the levels are exceeded.

Appendix C presents the minimum contents of equipment quality assurance and the minimum performance intervals for the tests.

The responsible party defines the action levels described above. However, the action levels may not be less strict than the equipment acceptability requirements issued in decision of STUK. The measures stipulated in the quality assurance programme must be taken if inspection results and measurement results exceed the action levels.

In addition to the determination of the radiation exposures caused by X-ray examinations that is performed once every three years, it must be verified at least once a year that the radiation exposure has not changed. The verification shall be done at each examination stand and at least with one imaging projection of one examination type that is performed with the examination stand in question. For example, comparing the imaging values to previous values and using the results from technical quality assurance constitutes sufficient verification. If the radiation exposure has clearly changed after the previous measurement, the causes for the change must be investigated and the equipment must be repaired if necessary.

A record must be kept of any faults, malfunctions or other incidents that have occurred during the use of the equipment that disrupt the said use or endanger safety. All key documents must be archived for at least the entire period of use of the equipment. If the equipment is sold or handed over, the key documents concerning the equipment's operational history (service and measurement reports, appliance log) should also be handed over to the new owner. The procedure set out in chapter 6 must also be followed if any abnormal events resulting from the operation of the equipment are detected that are significant for radiation safety.

Section 32 of the MSAH Decree contains provisions on the supervision of the operating condition and performance characteristics of the equipment. Section 15 of the Radiation Act contains provisions on the obligation to notify of a change of ownership of a radiation source. The publication Terveysturvallisuuden röntgenlaitteiden laadunvalvontaopas (Quality control guide for health care X-ray appliances) [17] in the "Advice from STUK" series presents recommendations, advice and instructions for the quality assurance activities.

5.3 Self-assessment

The goal of any self-assessment, as well as that of a clinical audit (see item 5.4), is to ensure that the imaging performed by the unit is of a high technical quality (see item 5.3.1) and the practices meet the overall quality requirements set for them.

A self-assessment of X-ray practices must be performed annually. Self-assessment shall be commensurate with the demands and scope of the X-ray practices, and it shall focus on a selected area of the practices. Self-assessment should cover all the different types of X-ray practices (such as screening practices and operating theatre activities using C-arms), while taking into account their scope. At its best, self-assessment evaluates the different areas of X-ray practices from referral practices to patient care. Primarily, the topics of self-assessment should be selected locally in order to allow them to serve the practices at the place of radiation use in the best possible manner. Self-assessment should include the issues that are reviewed during the clinical audit.

Good self-assessment focal areas include the following, for example:

- realization of the justification assessment procedure
- assessment of the examination and referral practices
- assessment of the quality of the X-ray examination statements and comparison with the referrals
- determining and analyzing the patient doses (see item 3.2.6) and assessing the quality of the clinical patient images (see item 5.3.1)
- the adequacy of radiation protection training for referring physicians

- monitoring of repeated examinations or projections due to failure and an analysis of the contributing factors
- analysis of the causes of abnormal events (see chapter 6).

Section 19 of the MSAH Decree contains provisions on the responsible party's obligation to arrange self-assessment of the medical use of radiation.

5.3.1 Assessment of clinical image quality

Together with determining the patient dose (see item 3.2.6), the assessment of image quality is very important for optimization of examinations. The assessment of image quality refers to a regular assessment of diagnostic patient images where the patient images taken over a specified interval (from a specific examination type, for example) are reviewed in a documented manner and compared to the generally accepted criteria for a good image. A specialist in radiology or another specialist responsible for the procedure is responsible for the assessment. The aim of the assessment is to ensure that the quality of the images is sufficient for the examination. A representative sample of different examinations should be assessed. The assessment must be carried out according to the local clinical practice in terms of the methods and conditions of viewing the images. It must also be ensured that the archival or transfer of the images does not essentially reduce the quality of visual information.

The image quality assessment must be performed regularly and its performance must be documented at least once per year. If the image quality deteriorates in a manner that has an adverse effect on the diagnosis, the source of the error must be located by reviewing the entire imaging sequence, if necessary. In this case, constancy tests may be required and the test images may need to be compared to the reference images taken during the acceptance test. If necessary, the equipment shall be serviced or repaired.

The quality of the patient images and the fluoroscopy image shall also be continuously visually monitored.

5.4 Clinical audit

The responsible party shall arrange a clinical audit of the medical use of radiation. Clinical audits shall be arranged in a manner where they supplement the self-assessment of the practices in an appropriate manner. The objective must be to perform an audit of all the essential practices at least once every five years. The responsible party shall ensure that the clinical audit focuses on the issues essential for each place of radiation use and the areas of radiation use, and that the audit team includes sufficient expertise from each area.

Section 39 c of the Radiation Act and Chapter 4 of the MSAH Decree contain provisions on the responsible party's obligation to arrange a clinical audit of the medical use of radiation. Section 21 of the MSAH Decree presents issues to be included in the clinical audit. The Finnish Advisory Committee for Clinical Audit appointed by the National Institute for Health and Welfare (THL) has prepared several recommendations for clinical audits (including the composition of the audit group and a recommendation concerning self-directed audits of the medical use of radiation), see <http://www.clinicalaudit.net>.

6 Abnormal events in X-ray practices shall be prepared for

The responsible party shall chart any potential abnormal events in its practices and make preparations for them in advance. It must be ensured that the information concerning the abnormal event is relayed within the organization, allowing it to reach the responsible party and the responsible individuals. Whenever abnormal events causing radiation exposure occur, the causes of the event must be analyzed and the radiation dose caused to the patient or other party must be estimated. The causes of the event must also be analyzed in case of near misses. A record shall be maintained of all cases and their processing in accordance with the internal quality management system.

The necessary actions and instruction revisions must also be performed in order to prevent the occurrence of similar events. Any significant abnormal events must be reported to STUK (see item 6.1 and Appendix D).

The responsible party must ensure that all necessary persons (such as the patient and the referring physician) are informed of an abnormal event concerning the party.

6.1 Reporting of abnormal events

STUK must be immediately notified of an abnormal event related to radiation use that significantly endangers safety at the place of radiation use or in its vicinity, and of any other abnormal observations and information that is significant in terms of the radiation safety of workers, patients or the environment.

STUK must be immediately notified of abnormal events related to X-ray examinations or procedures (including X-ray practices related to nuclear medicine imaging) at least in the following cases:

- unintended exposure of an external person
- imaging of the wrong patient in category III practices (see Appendix B)
- exceptional exposure of a worker during an abnormal event
- significant excess exposure of a patient in an abnormal event during category III practices
- significant excess exposure of a foetus in an abnormal event during category III practices
- systematic equipment failure or system failure
- some other event that should be communicated to other responsible parties in order to prevent similar events.

Other abnormal events shall be compiled together and reported to STUK by the end of January of the following year (grouped in accordance with Appendix D). Typical cases of imaging failures leading to an extra exposure (due to a projection error, the movement of the patient or a similar reason, for example) do not need to be reported to STUK as abnormal events.

Whenever a hazardous situation requires that a report be also submitted to the National

Supervisory Authority for Welfare and Health, the notification delivered to STUK may be a copy of this report. In this case, it must be ensured that the report includes the information required by STUK.

Section 17 of the Radiation Decree contains provisions on the reporting of abnormal events that cause exposure to radiation. Guide ST 1.6 presents instructions for preparing for abnormal events and reporting thereof, as well as examples of abnormal events. The information to be reported on an abnormal event and the electronic reporting form can be found on STUK's website. The Medical Devices Act (629/2010) contains provisions on the obligation of professional users of devices and supplies to report hazardous situations to the National Supervisory Authority for Welfare and Health.

7 Scientific research causing exposure to radiation

Scientific research must adhere to the relevant legislation. Before a research project is started, an assessment of the justification of the research project must be received from an ethics committee. When selecting persons for scientific research, the following issues shall be considered:

- Participation of children and young adults in scientific research is generally not justified. If possible, healthy volunteers should be over 50 years of age. Persons under 18 years of age must not be used in research, unless the subject of the research is problems particular to this specific age group.
- The number of persons participating in the research shall be limited to the smallest possible number required to procure the desired information. The prior radiation exposure of the persons participating in the research must be investigated for the purposes of the justification assessment.
- A dose constraint must be imposed on healthy volunteers. The effective dose to healthy volunteers should be as low as possible and it must not normally exceed 10 mSv per year.

- When women of childbearing age participate in research, the possibility of pregnancy must be considered. Pregnant women may participate in scientific research only if the prerequisites listed in the legislation concerning scientific research are met.
- A person performing scientific research shall ensure that the volunteers participating in the research understand the significance of the additional risk caused by the research.

As regards the implementation of the research and the methods employed during the research, the Medical Research Act (488/1999) applies. The publication by the European Commission [2] presents the risk categories into which the research has been divided on the basis of the radiation exposure of participants. This risk classification may be applied when assessing the justification of the scientific research. The classification originates from International Commission on Radiological Protection (ICRP) Publication 62. Section 6 of the MSAH Decree contains provisions on the justification of scientific research causing exposure to radiation.

Literature

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4. European Commission. European guidelines for quality criteria for diagnostic radiographic images in paediatrics. Report EUR 16261 EN. Luxembourg: Office for official publications of the European Communities; 1996.

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16. Röntgentutkimuksesta potilaalle aiheutuvan säteilyaltistuksen määrittäminen. (Determining the patient's exposure to radiation in X-ray examinations). Advice from STUK 1/2004. Helsinki: STUK; 2004.
17. Terveysthuollon röntgenlaitteiden laadunvalvontaopas (Quality control guide for health care X-ray appliances). Advice from STUK 2/2008. Helsinki: STUK; 2008.

APPENDIX A

DEFINITIONS

Quality assurance

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

Abnormal event

An event deviating from normal radiation use, resulting in a substantial safety hazard in a place where radiation is used or in its environs. An abnormal event may also consist of an exceptional observation or fact that is of substantial significance to the radiation safety of workers, the environment or patients.

(Technical) quality control

Quality assurance procedures designed to show that the equipment and their performances conform to the set criteria.

Safety culture

The way in which individuals and the organization work to ensure safety.

Additional information: Safety culture includes a systematic way of working that promotes safety as well as leadership and management, values and attitudes that support such a culture.

Worker

For the purposes of this Guide, a worker shall refer to both workers engaged in radiation work and other workers who may be exposed to X-radiation during their work and who are subject to the dose limits set for the members of the public.

APPENDIX B

CATEGORIES FOR X-RAY PRACTICES IN HEALTH CARE, AND TYPES OF PRACTICE

Category I

- Small-scale X-ray practices involving
 - bone mineral density measurement devices
 - conventional dental X-ray equipment (equipment by which images are created on intraoral imaging receptors, panoramic tomography equipment and cephalostats).

Category II

- X-ray practices involving
 - conventional X-ray equipment
 - mammography equipment
 - cone beam computed tomography (CBCT) equipment
- C-arm practices involving
 - mobile fluoroscopy equipment
- X-ray practices outside X-ray departments involving
 - mobile conventional X-ray equipment
- Screening in category I or II practices

Furthermore:

- Installation, repair and servicing of radiation equipment and radiation sources in category I and II practices
- Clinical trial use of radiation equipment in category I or II practices
- Research and teaching using X-ray equipment in category I or II for health care practices.

Category III

- Challenging X-ray practices and interventional radiology involving
 - computed tomography equipment
 - fixed fluoroscopy equipment
- Screening in category III practices

Furthermore:

- Installation, repair and servicing of radiation equipment and radiation sources in category III practices
- Research and teaching using X-ray equipment in category III for health care practices.

APPENDIX C

MINIMUM INTERVALS FOR QUALITY CONTROL ACTIVITIES OF X-RAY EQUIPMENT

The following presents the minimum requirements for quality control (including the acceptability requirements referred to in item 4.1) and the intervals for testing, in addition to which quality assurance activities shall be performed after major repairs or servicing, and when there is cause to suspect a malfunction or a change in the operation of the equipment. More detailed information on the testing of the features presented herein is provided in the quality control guide for health care X-ray appliances (Terveydenhuollon röntgenlaitteiden laadunvalvontaopas, STUK opastaa 2/2008). The equipment shall also undergo any other tests required by the manufacturer.

Test or feature	Test in the guide	Minimum interval	
Safety tests			
Condition, mechanical operation, and emergency switches of X-ray equipment	4.1.1	6 months	
Functioning of the warning lights	4.1.2	6 months	
Condition of radiation shielding	4.1.2	12 months	
X-ray equipment tests			
X-ray tube voltage	4.1.3	12 months	
Constancy and linearity of radiation output	4.1.6	12 months	
Accuracy of dose display	4.1.7	12 months	
Radiation beam indicators and alignment	4.1.8	12 months	
Constancy of the working of the automatic exposure control unit	4.1.11	12 months	
Image receptor tests			
Cleanliness of the image plates and condition of the cassettes	4.3.1	6 months	
Smoothness and correctness of the image	4.3.2	6 months	
Sensitivity of the image receptor (exposure index or equivalent)	4.3.3	12 months	
Image retention	4.3.5	12 months	
Sensitivity differences between the image plates	4.3.6	12 months	
Spatial resolution (using an image quality phantom, for example)	4.3.8	12 months	
Contrast and noise (using an image quality phantom, for example)	4.3.9	12 months	
Calibration of the flat panel detector	**)	12 months	
Computed tomography equipment tests			
Functionality of the equipment (according to equipment-specific instructions)	4.5.1	1 day	
Verifying the CT numbers, noise and image correctness (using an image quality phantom, for example)	4.5.2, 4.5.3	1 month	
Fluoroscopy equipment tests			
		Category II^{*)}	Category III^{*)}
Basic system settings, smoothness and correctness of the image	4.4.1	1 month	Daily before starting a procedure
Image quality (spatial resolution, contrast) (using an image quality phantom, for example)	4.4.4	12 months	1 month
Highest dose rate	4.4.3	12 months	12 months
Image monitor tests			
		Diagnostic monitors	Other monitors used for image viewing
Monitor testing by means of a test image	4.6.2, 4.6.5	1 week	1 month
Image quality and luminance of the image monitor	4.6.6	12 months	
*) see Appendix B			
**) According to manufacturer instructions			

APPENDIX D

ABNORMAL EVENTS TO BE COMPILED AND REPORTED EACH YEAR

Abnormal events related to X-ray examinations or procedures that do not need to be immediately reported to STUK (see item 6.1) may be compiled and reported together, grouped as shown in the table below (select the option that best describes the event). In practice, the abnormal events to be compiled and reported annually are the abnormal events in category I and II practices and those category III events for which an event-specific report has not been submitted to STUK.

Exposed party	Type of abnormal event	Cause or contributing factor	Number of events per year
Abnormal events related to the referral			
Wrong patient	Referral written for the wrong person	Human error	
		Human error, the high likelihood of errors in the referral system*) a contributing factor	
Patient	Incorrect examination or anatomical object in the referral	Human error	
		Human error, the high likelihood of errors in the referral system*) a contributing factor	
	Another type of error in the referral		
Abnormal events related to the performance of the examination			
Wrong patient	Wrong patient examined	The patient's identity was not verified before the examination	
Patient	An incorrect examination was performed or an incorrect anatomical object was imaged	Human error during the performance of the examination	
	Failed examination or an excess exposure related to the examination	Erroneous or deficient instructions Human error during the performance of the examination	
Extraordinary exposure, other events			
Patient	Failed examination or an excess exposure related to the examination	Isolated case of equipment failure	
		The high likelihood of errors in equipment, an auxiliary appliance or system*) as a contributing factor	
	Examination repeated unnecessarily	No information available on earlier similar examination, or results from earlier examination not available	
Patient and worker	Worker also exposed due to the abnormal event mentioned above (when the worker's exposure is not significant)		
Worker	Worker exposure (when the exposure is not significant)		
	Other event:		
Unintended exposure of the foetus			
Foetus	Pregnant person exposed	The pregnancy is at such an early stage that it cannot be verified	
		The possibility of a pregnancy was not considered before the procedure	
A near miss that caused actions to be taken at the place of radiation use			
	When a more detailed report to the authorities is not considered purposeful		
*) A high likelihood of errors refers to the poor usability of equipment or a system, allowing extraordinary radiation exposure to be caused by a human error that can occur easily.			

ST GUIDES (19.10.2015)

General guides

- ST 1.1 Safety in radiation practices, 23 May 2013
- ST 1.3 Warning signs for radiation sources, 9 December 2013 (in Finnish)
- ST 1.4 Radiation user's organization, 2 November 2011
- ST 1.5 Exemption of radiation use from safety licensing, 12 September 2013
- ST 1.6 Operational radiation safety, 10 December 2009
- ST 1.7 Radiation protection training in health care, 10 December 2012
- ST 1.8 Qualifications and radiation protection training of persons working in a radiation user's organization, 17 February 2012
- ST 1.9 Radiation practices and radiation measurements, 17 March 2008
- ST 1.10 Design of rooms for radiation sources, 14 July 2011
- ST 1.11 Security arrangements of radiation sources, 9 December 2013

Radiation therapy

- ST 2.1 Safety in radiotherapy, 18 April 2011

Diagnostic radiology

- ST 3.1 Dental X-ray examinations in health care, 13 June 2014
- ST 3.3 X-ray examinations in health care, 8 December 2014
- ST 3.8 Radiation safety in mammography examinations, 25 January 2013

Industry, research, education and commerce

- ST 5.1 Radiation safety of sealed sources and devices containing them, 7 November 2007
- ST 5.2 Use of control and analytical X-ray apparatus, 26 September 2008
- ST 5.3 Use of ionising radiation in the teaching of physics and chemistry, 4 May 2007
- ST 5.4 Trade in radiation sources, 19 December 2008.
- ST 5.6 Radiation safety in industrial radiography, 9 March 2012
- ST 5.7 Shipments of radioactive waste and spent fuel, 6 June 2011
- ST 5.8 Installation, repair and servicing of radiation appliances, 4 October 2007

Unsealed sources and radioactive wastes

- ST 6.1 Radiation safety when using unsealed sources, 17 March 2008
- ST 6.2 Radioactive wastes and discharges, 1 July 1999
- ST 6.3 Radiation safety in nuclear medicine, 14 January 2013

Radiation doses and health surveillance

- ST 7.1 Monitoring of radiation exposure, 14 August 2014
- ST 7.2 Application of maximum values for radiation exposure and principles for the calculation of radiation doses, 8 August 2014
- ST 7.3 Calculation of the dose caused by internal radiation, 13 June 2014
- ST 7.4 The dose register and data reporting, 8 December 2014
- ST 7.5 Medical surveillance of occupationally exposed workers, 13 June 2014

Veterinary medicine

- ST 8.1 Radiation safety in veterinary X-ray examinations, 20 March 2012

Non-ionizing radiation

- ST 9.1 Radiation safety requirements and regulatory control of tanning appliances, 1 July 2013 (in Finnish)
- ST 9.2 Radiation safety of pulsed radars, 2 September 2003 (in Finnish)
- ST 9.3 Radiation safety during work on masts at FM and TV stations, 2 September 2003 (in Finnish)
- ST 9.4 Radiation safety of laser displays and shows, 30 April 2015

Natural radiation

- ST 12.1 Radiation safety in practices causing exposure to natural radiation, 2 February 2011
- ST 12.2 The radioactivity of building materials and ash, 17 December 2010
- ST 12.3 Radioactivity of household water, 9 August 1993
- ST 12.4 Radiation safety in aviation, 1 November 2013