STUK

GUIDE **ST 3.8** / 25 JANUARY 2013

RADIATION SAFETY IN MAMMOGRAPHY EXAMINATIONS

This Guide is valid as of 1 April 2013 until further notice. It replaces Guide ST 3.2, Mammography equipment and their use, issued on 13 August 2001 and ST 3.7, Breast cancer screening based on mammography, issued on 28 March 2001.

In film-based systems the acceptability criteria and quality assurance methods presented in Guide ST 3.2 may still be applied.

Helsinki 2013
ISSN 0789-4465
ISBN 978-952-478-770-3 (pdf)
ISBN 978-952-478-771-0 (html)

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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 radiation safety requirements for the clinical practice in mammography, breast cancer screening with mammography, and the use of mammography equipment. This Guide also presents the requirements for organizers of screenings.

Mammography is used for examining tumours and changes in breast tissue. Mammography involves both x-ray imaging and image interpretation. The party running a radiation practice (hereafter the responsible party) shall make sure that mammography examinations are not undertaken without ensuring the radiation safety of the patients and all other individuals in the vicinity of the equipment. Effective diagnostics and treatment of breast cancer require a high standard of both the breast x-ray examination and the eventual follow-up measures. Thus, quality assurance procedures of the responsible party play a key role.

The purpose of breast cancer screening with mammography (mammography screening) is to reduce the breast cancer death rate among the women screened, as well as to detect breast cancer as early as possible. In order to be successful, such operations require x-ray images of sufficiently high technical and clinical quality and competent interpretation of the images so that even early-stage cancerous growths are detected. In mammography screening, symptom-free women are exposed to x-rays and, therefore, the radiation doses caused by these examinations should be kept as low as reasonably achievable without endangering image quality.

The requirements concerning medical procedures causing exposure to radiation are laid down in the Decree of the Ministry of Social Affairs and Health on the medical use of radiation 423/2000 (hereafter referred to as the MSAH Decree). Provisions concerning the quality and safety of screening examinations involving exposure to radiation are laid down in chapter 8 of the MSAH Decree. The decree issues provisions concerning e.g. the justification of screening as well as the requirements for the contents of screening programmes. The Government Decree on Screenings (339/2011) lays down the provisions concerning the arranging of screenings.

2 Definitions

In this Guide

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

(technical) quality control refers to quality assurance procedures designed to show that the equipment and their performances conform to the set criteria

screening organizer (the party carrying out the screening programme) refers to a municipality, federation of municipalities or other official body responsible for arranging screenings

party executing the screening refers to a specialist unit or group of professionals specialized in breast cancer screening with mammography that carries out screening examinations according to an approved screening programme either in the service of the screening organizer or on the basis of a commission agreement made with the screening organizer.

3 A safety licence is required for mammography

The use of mammography equipment requires a safety licence.

An application for a safety licence shall explain clearly the intended use of the mammography equipment.

If the equipment is intended for breast cancer screening, this must be separately specified in the safety licence application.

If the mammography equipment is intended for scientific studies that expose individuals to radiation, this intended use must be clearly presented in the safety licence application. Scientific studies shall follow the current legislation on scientific research. Before a scientific study is begun, the ethical committee shall assess

the justification of the particular study.

The responsible party shall ensure the safety of the use of radiation and its compliance with requirements at all times, including times in which the practice undergoes changes. All significant changes to the practice shall be reported to STUK before their implementation. The responsible party shall obtain permission from STUK before implementing any changes at least in the following cases:

- an extension or change of a practice itemized in the safety licence
- a change to the space in which a radiation appliance is used (a new place of use or changes to existing structures)
- an introduction of a new radiation appliance or a replacement unit.

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

Section 16 of the Radiation Act stipulates that the use of radiation shall require a licence, and lays down the provisions concerning applications for safety licences. Section 18 of the Radiation Act lays down the provisions concerning radiation user's organizations and the organization descriptions. The requirements concerning medical physics expertise are laid down in section 15 of the MSAH Decree. More details concerning these issues are available in Guides ST 1.1 and ST 1.4. The principles presented in Guide ST 1.10 shall be applied when planning and implementing structural radiation shieldings of places of use.

The Government Decree on Screenings (339/2011) lays down the provisions concerning the arranging of screenings. Provisions concerning the obligation to notify the National Supervisory Authority for Welfare and Health (Valvira) concerning clinical tests with medical devices are laid down in the Medical Devices Act (629/2010).

4 The screening organizer is required to prepare a breast cancer screening programme

In order to implement screenings, screening organizers (see definitions) are required to prepare screening programmes. Screening programmes are detailed plans presenting, in a comprehensive manner, the key issues relevant to the medical quality and radiation safety of screenings and also presenting the method of their implementation. Screening programmes shall be submitted to STUK for inspection before screenings are begun. If a screening is not based directly on the Government Decree on Screenings, a statement of the justification of the screening by the National Institute for Health and Welfare (THL) must be appended to the screening programme. An evaluation of the justification for screening by THL is required if, for example, other than the conventional projection imaging is used in screening mammography .

A screening programme shall present:

- the screened age groups and screening intervals
- the party executing the screening
- the qualifications of persons who carry out x-ray imaging or interpret mammographic images (see item 5.2)
- a list of the X-ray equipment used in the screening including any related auxiliaries and tools
- the intended routine for arranging verification examinations.

If a screening programme is changed, which may take place for justifiable reasons, the entire programme must be presented for re-inspection by STUK. To conduct screening mammography, the party executing the screening is required to hold a valid safety licence (chapter 3).

The provisions concerning the information and explanations to be included in a screening programme are laid down in section 40 of the MSAH Decree.

5 The quality of mammography examinations shall be attended to

5.1 Justification and optimization of mammography examinations

The need for a clinical mammography examination must always be considered on a patient-specific basis and, under the principle of justification, the examination must be of more benefit than harm to the patient. The referring physician shall consider the justification of the mammography examination when writing the referral. In addition, the physician responsible for the procedure involving exposure to radiation shall ascertain the justification of the examination. Any clinical mammography examination of a patient shall be performed on the basis of a physician's referral only. The referral shall clearly state the indication for examination and other necessary information so that the mammography examination can be performed in the optimal manner.

When a screening mammography examination is based on the Government Decree on Screenings, the justification of the screening need not be separately evaluated by a physician. Physicians' referrals are not possible for screening mammography examinations but instead, the party executing the screening will invite the persons to be screened by personal letters.

Clinical mammography examinations and screening mammography examinations shall be optimized to fulfil the purpose of the examinations while minimising the radiation exposure to the examinees. This requires e.g. that

- all staff participating in the use of radiation fulfil the respective qualification requirements and supplementary training for the staff has been established
- the appliances are suitable for the intended examinations and are in proper working order
- the technology has been optimized (imaging views, patients' exposure to radiation, imaging voltage, anode and filter materials) and it is systematically and regularly assessed
- the image quality is sufficient for reliable diagnoses
- images are interpreted by qualified physicians (see item 5.2).

Justification and optimization of medical uses of radiation are dealt with in chapter 10 of the Radiation Act. The Government Decree on Screenings (339/2011) lays down the provisions concerning the arranging of screenings.

5.2 Staff training and qualification requirements

All staff using radiation shall have the required qualifications and competences, sufficient radiation protection training, familiarity with mammography examinations, and sufficient user training for the relevant appliances. The responsible party shall ensure that the expertise of the staff operating X-ray equipment is properly maintained. All staff taking mammographic images as well as interpreting mammographic images shall participate in supplementary training. The operating staff shall be provided with appliance-specific, up-to-date user instructions as well as instructions for cases of malfunction and hazard.

Physicians responsible for procedures in clinical mammography examinations and screening mammography examinations shall be specialists in radiology.

Screening radiographers shall be experienced in clinical mammography, and they are required to receive supplementary training in screening mammography. It is good practice that screening radiographers pass the course in mammography offered by SORF, the Society of Radiographers in Finland (becoming holders of respective diplomas granted by SORF), or a corresponding course held either in Finland or abroad.

Physicians who interpret mammographic images shall be specialists in radiology.

Interpretation of screening mammographic

images shall be performed by two specialists in radiology with experience in mammography and interpreting of mammography images. At least one of these specialists shall hold a special qualification in screening mammography.

Specialists in radiology can prove their special qualifications to the organizers of screenings by presenting appropriate certificates from the Finnish Medical Association or from the Special Qualification Advisory Committee of the Radiological Society of Finland. To obtain a certificate of special qualification in screening mammography, a physician first needs to hold relevant certificates of practical training, theoretical education and passed exams.

The training and qualification requirements for staff engaged in the use of radiation are laid down in section 18 of the Radiation Act and in chapter 5 of the MSAH Decree. Sections 24 and 25 of the MSAH Decree lay down the provisions concerning the competence of the physician responsible for a procedure involving exposure to radiation and the competence of a person participating in the performance of a procedure involving exposure to radiation. More detailed information on competences and radiation protection training is available in Guides ST 1.4, ST 1.7 and ST 1.8.

5.3 Instructions necessary for performing examinations shall be made available in places of use

Written instructions and the criteria of good radiographic images shall be available for performers of mammography examinations in places of use of all X-ray devices. These examination instructions shall be detailed enough to enable retrospective assessment of patients' radiation exposures. The quality of patient images shall always be checked visually. Radiographers shall check image quality at the time of imaging in order to ascertain that physicians receive images of high standard for interpretation, all fulfilling the criteria of good radiographic images (the THKR meter).

Examination instructions shall include at least the following items:

- X-ray equipment and any auxiliary equipment to be used in examinations
- imaging views to be used in examinations
- imaging settings of the equipment (imaging values, focus selection, filtration, grid use, settings on the automatic exposure control unit)
- radiation protection of the person using the equipment and that of the person assisting in the use
- patient-specific data to be recorded for examinations
- any other essential items that need to be observed when using the X-ray equipment.

An examination may be performed in a manner that differs from the respective instructions, if the special needs explained on the referral so require or if the physician responsible for the procedure has given special instructions for the particular examination (such as radiation shielding for the patient). Any deviations from examination instructions shall be recorded in the respective patients' medical records (see item 5.4).

The provisions concerning instructions for conventional X-ray examinations are laid down in section 14 of the MSAH Decree. Instructions on clinical mammography and further examinations after screening mammography are available in Current Care Guidelines on the diagnostics of breast cancer, published by the Finnish Medical Society Duodecim and Suomen Rintasyöpä ry (Finnish Breast Cancer Association). Mammografian kuvausopas (Guide to Mammographic Imaging), published by the Society of Radiographers in Finland and the Radiological Society of Finland, gives national quality criteria for mammographic imaging (the THKR meter).

5.4 Recording and reporting of examination data

Entries in patients' medical records concerning mammography examinations shall apply the classification of radiological examinations and procedures published by the Association of Finnish Local and Regional Authorities. If an examination procedure in an individual case differs essentially from customary practice (see item 5.3), this shall be recorded in the patient's medical records. Such entries are required, for example, for repeated examinations, any extra imaging views in an examination, and other

deviations from the customary practice that may have a significant impact on radiation exposure.

The responsible party shall provide STUK, according to separately issued instructions, with information on radiation doses and the number of examinations; this information will form the basis for the collation and publication of national reports by STUK.

Summaries shall be compiled of screening data as instructed by the Mass Screening Registry so that the effectiveness of screening can be evaluated. The screening organizer shall ensure that the relevant screening data is submitted to the Mass Screening Registry.

Section 43 of the MSAH Decree imposes an obligation on the responsible party to compile summaries of the number of examinations performed and of the radiation doses administered, and to submit the data concerning the number of examinations to STUK. The requirements concerning the presentation of summary information are laid down in section 42 of the MSAH Decree.

The provisions concerning the Mass Screening Registry, operating in connection with the Cancer Registry of the National Institute for Health and Welfare (THL), are laid down in section 7 of the Decree on National Personal Records Kept under the Health Care System (774/1989, amendment 1135/1992). More detailed information by THL concerning the submitting of summary information is available at http://www.cancer.fi/syoparekisteri/joukkotarkastusrekisteri/seulojille/ohjeita_seulonnasta/.

6 Mammography equipment shall comply with the set requirements

6.1 General requirements for mammography equipment

The statutes on medical devices also apply to mammography equipment. Equipment launched on the market after 13 June 1998 must bear a CE marking in compliance with the decree mentioned below. The CE marking is the manufacturer's warranty that the apparatus meets the essential equipment safety requirements imposed by European Community Directives.

The requirements of this Guide shall be observed in the use of these appliances.

Medical devices are covered by a law (629/2010) and a decree (1506/1994).

6.2 Acceptability criteria during the use of mammography equipment

The technical properties of mammography equipment and the associated auxiliaries (such as imaging plates and scanners, if any) as well as the imaging software must be suitable for mammography examinations.

The equipment and all associated auxiliaries and tools shall comply with the acceptability criteria during the use of equipment given in the relevant decision by STUK. Acceptability criteria refers to the minimum requirements for the performance of equipment. If the acceptability criteria are not met, one of the following measures must be taken:

- The appliance must be repaired and its performance restored to an acceptable level.
- The use of the appliance must be restricted so that it functions on a level acceptable for the intended use.
- The appliance must be decommissioned.

Acceptability requirements are not limiting values for the optimal performance of appliances. When procuring new appliances, in acceptance testing and in quality control, the applied requirements should be based on e.g. the tolerances given in international apparatus standards, as these are often stricter than the acceptability criteria.

The provisions concerning STUK's authority to confirm appliances' acceptability criteria and any functionality-specific requirements that must be considered for radiation safety are laid down in section 30 of the MSAH Decree. More information on acceptability criteria is available in Guide ST 3.3.

7 Quality assurance provides radiation safety

The responsible party shall establish quality assurance for practices involving exposure to radiation. Therefore, a quality assurance programme is required. This programme shall define the necessary quality assurance procedures, and it shall also include the principles for preventing errors and mishaps from which radiation doses may arise unintentionally. Quality assurance practices shall be assessed regularly and, when appropriate, changed. Quality assurance can be categorized as assurance of the technical quality and assurance of the quality of practices. The appendix presents the minimum requirements for the contents of quality assurance activities as well as the time limits for the required tests.

The obligation of the responsible party to establish quality assurance for procedures involving exposure to radiation in the medical use of radiation is laid down in section 40 of the Radiation Act; section 18 of the MSAH Decree (423/2000) sets forth the provisions concerning quality assurance programmes. Quality management is discussed in more detail in Guide ST 3.3.

7.1 Technical quality assurance ensures the operating condition of appliances

Technical quality assurance consists of acceptance testing and quality control during the use of equipment. The purpose of technical quality assurance is to ascertain the appropriate operating condition of the equipment and the associated auxiliaries and tools, as well as the sufficiency of all performance characteristics. The responsible party shall ensure that any appliance about to be commissioned is acceptance-tested before it is used for patient examinations. The party that supervises the placing on the market of medical devices is Valvira, and the party supervising the use of radiation is STUK.

Quality control tests are carried out at prescribed intervals (see Appendix). In addition, tests are conducted as applicable after significant repairs or servicing, and when there is cause to suspect a malfunction or a change in the operation of the equipment. Conformance to acceptability criteria during the use of equipment shall be checked at least annually with appropriate technical tests. In addition, users shall at specified intervals perform the tests defined by the equipment suppliers. In addition to the proper operation of the X-ray equipment, factors important for the reaching of correct diagnoses include the appropriate operating condition of the devices intended for image formation and viewing. Therefore, testing procedures shall be established for imaging plates and image receptors, and quality assurance shall be established for work stations and monitors. In addition, quality assurance shall be separately established for magnification imaging, tomosynthesis devices and biopsy functionalities, if any of these are used.

Records shall be kept of any equipment faults, functional errors and other incidents disturbing the use of equipment or endangering safety. All essential records shall be kept at least through the service-life of the equipment. Should any equipment be re-sold, it is good practice to deliver documentation concerning the equipment's history (service reports, fault logs) with the appliance.

The duty of the responsible party to arrange acceptance testing is laid down in section 32 of the MSAH Decree. Acceptance testing and quality control are discussed in more detail in Guide ST 3.3. Information on acceptance testing is available in "Lääkelaitoksen julkaisu 2/2001, Terveydenhuollon laadunhallinta. Radiologisen laitteen vastaanottotarkastus" (Publication of the National Agency for Medicinen 2/2001, Quality management in health care. Acceptance testing of a radiological device.). Recommendations, instructions and guidelines concerning quality assurance procedures are available in "Terveydenhuollon röntgenlaitteiden laadunvalvontaopas, STUK tiedottaa 2/2008" (Quality control guide for health service X-ray appliances, Advice from STUK 2/2008).

7.2 Assurance of the quality of practices covers all areas of mammography

The assurance of the quality of practices shall include:

- the determination of patient doses and their comparisons to reference levels

- clinical image quality assessments
- self-assessments
- clinical audits.

Written instructions shall be given to assure the quality of practices. These instructions shall include procedural instructions to cover and prevent abnormal events (chapter 8).

7.2.1 Determination of patient doses and the use of reference levels

The responsible party shall ensure that the average radiation exposure from mammography is annually determined in at least one imaging view either by calculation or by measurement.

The radiation dose from an examination is measured with a dosemeter suitable for radiation measurements in mammography. If a device has a reliable patient dose display, the device may be used for determining doses. The reliability of the dose display shall be annually checked with measurements in connection with e.g. the technical quality assurance procedures.

The average dose from a certain imaging procedure, determined in a place of use, shall be compared to the reference level. Reference levels are issued by STUK in specific decisions, and they are changed as necessary. Other reference levels in addition to those issued by STUK may be used, but their values shall not exceed the reference values set by STUK.

If the average dose determined in a certain place of use exceeds the reference value even after verification, the reason for this shall be investigated and all necessary measures be taken to reduce the doses. Even when reference levels are not exceeded, it must be ensured that the image quality suffices for reliable diagnoses and that the radiation exposure is not unnecessarily large. All information shall be stored concerning the imaging programme used for dose determination, the imaging values (tube voltage, tube current, exposure time, or quantity of electricity and anode/filter materials) and the patient doses.

Instructions for dose determination are provided in the Radiation and Nuclear Safety Authority report "Potilaan säteilyaltistuksen määrittäminen mammografiassa. STUK-TR 11" (Determination of the radiation exposure of a patient in mammography. STUK-TR 11).

7.2.2 Evaluation of mammographic image quality

In optimising an X-ray examination, the aim is to reach the goals set for the examination while minimising the radiation exposure to the examinee. In addition to determining patient doses (see item 7.2.1), optimising therefore always includes the evaluation of image quality.

Evaluation of image quality refers to regular, documented patient image assessments in which patient images produced during a certain period are investigated and compared to generally accepted criteria of good radiographic images (e.g. the THKR meter). Physicians in charge of such evaluations shall be specialists in radiology. The purpose of evaluation is to ensure that image quality suffices for examinations regardless of the storage and transfer method of the images. The images to be evaluated should include a comprehensive set taken of different types of breasts. A systematic and appropriately documented mammographic image quality evaluation may form a part of self-assessment activities as well (see item 7.2.3.

Evaluations shall be conducted under conditions that correspond to the local clinical practices and conditions of image viewing. It is important to make sure that all examination object -specific software solutions in X-ray appliances function appropriately and all examination procedures have been optimized.

Appropriately documented image quality evaluations shall be performed regularly at least once a year. If image quality deteriorates enough to disturb diagnosing, the source of the error shall be located by a step-by-step analysis of the entire imaging chain. It may be necessary, for example, to conduct constancy measurements and compare test images to the reference images taken during acceptance testing. If needed, the equipment shall be serviced or repaired.

7.2.3 Clinical audits and self-assessment

Parties undertaking to conduct mammography are required to conduct systematic, regular self-assessments. It is good practice to conduct annual self-assessments. In addition, mammography practices are required to undergo clinical audits

at least once every five years. The purpose of both the self-assessment and the clinical audit is to ensure that the unit produces images of high diagnostic standard and all practices fulfil the set quality criteria. Observations made during self-assessments and clinical audits can be made use of so that practices are made more effective and unified, facilitating the reaching of the given objectives.

All parties executing screenings must continually evaluate and improve the quality of their screening practices by analysing and monitoring their operation and their results. It is good practice for a party executing screenings to report on clinical audits and their results to the organizer of the screenings.

Properly conducted, self-assessments and clinical audits investigate the whole X-ray practice from the writing of referrals to the treatment of the patients. Good topics for self-assessment include e.g. assessments of the quality of radiological reports and comparing them to the referrals, the determination and analysis of patient doses, the monitoring of clinical patient image quality (the THKR meter), and the monitoring of re-imaging and the analysis of the reasons for re-imaging.

The duty of the responsible party to establish self-assessment procedures in the medical use of radiation is set forth in section 19 of the MSAH Decree, and the obligation to clinical audit is set forth in chapter 4 of the MSAH Decree. Section 21 of the MSAH Decree presents issues to be included in clinical audits. The Finnish Advisory Committee for Clinical Audit gives recommendations on in-house assessments of the medical use of radiation: http://www.clinicalaudit.net/suositus_no7.pdf.

8 Abnormal events in mammography examinations

Should an abnormal event causing exposure to radiation or a nearmiss incident take place, the reasons for this shall be investigated. In addition, the radiation dose shall be determined that a patient or another individual received due to the abnormal event. An abnormal event in mammography consists of e.g. mammography performed on a wrong person, or a re-imaging due to equipment fault. STUK shall be notified of all significant abnormal events. All abnormal events caused by faulty operation of equipment shall also be reported to the National Supervisory Authority for Welfare and Health (Valvira). In addition, all appropriate measures shall be taken and the respective guidelines shall be updated in order to prevent similar events in the future.

Sections 13 a and 17 of the Radiation Decree lay down the provisions concerning abnormal events causing exposure to radiation and notifications of observations significant for safety. Examples of abnormal events are presented in Guide ST 1.6, and instructions concerning notifications of abnormal events are available in Guide ST 3.3. The Medical Devices Act (629/2010) issues the provisions concerning the obligation of professional users of medical devices to report all incidents involving a hazard to the National Supervisory Authority for Welfare and Health (Valvira).

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APPENDIX

Minimum standards and test intervals for technical quality control of mammography equipment

The following presents the minimum standards and test intervals for quality control, in addition to which quality control measures are also required following significant repairs or servicing, and when there is cause to suspect a malfunction or a change in the operation of the appliance. In addition to the tests presented here, the devices' compliance with the acceptability criteria during the use of equipment shall be checked annually (see item 6.2), and the tests defined by the device suppliers shall be performed.

More information concerning the testing of the characteristics presented here and the performing of these tests will be given in a guide in the Advice from STUK series, available soon.

Tests	Maximum interval
Safety tests	
Mechanical functions and the operating condition of the X-ray equipment	6 months
Operation of warning lights	6 months
Condition of radiation protection devices	12 months
Functional tests	
Constancy of operation of the automatic exposure control unit	1 day
Image uniformity and freedom of defects	1 day
Constancy of image quality	1 week
Alignment of radiation beam and light-field	12 months
Operation of the compression plate	12 months
Operation of the selected filtration	12 months
Constancy and linearity of radiation output	12 months
Correctness of the dose display	12 months
Operation and thickness compensation of the automatic exposure control unit	12 months
Image receptor tests	
Cleanness of imaging plates and condition of cassettes	6 months
Sensitivity of image receptor	12 months
Sensitivity differences of imaging plates	12 months
Image retention	12 months
Spatial resolution	12 months
Contrast and noise	12 months
Errors of scale and distortions of geometry	12 months
Image monitor tests	
Operation of the image monitor, viewing conditions with test images in use	1 week
Image quality and luminance of the image monitor	12 months
Gray scale calibration	12 months