

MAMMOGRAPHY EQUIPMENT AND THEIR USE

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APPENDIX A ACCEPTABILITY CRITERIA FOR THE USE OF MAMMOGRAPHY EQUIPMENT, IMAGING CASSETTES AND THE DEVELOPMENT OF FILM

APPENDIX B QUALITY ASSURANCE MEASURES

This Guide is valid as of 1 January 2002 until further notice. It replaces Guide SS 3.2, Radiation Safety Requirements for Mammographic Equipment, issued on 17 February 1987. Requirements in chapter 4 shall be met no later than the end of 2004.

Helsinki 2003

ISSN 0789-4465

ISBN 951-712-741-3 (pdf)

ISBN 951-712-742-1 (html)

Authorization

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.

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.

Translation. Original text in Finnish.

1 Introduction

Effective diagnostics and treatment of breast cancer require a high standard of breast X-ray examination and follow-up measures. X-ray examinations involve both X-ray imaging and image interpretation.

Decree 423/2000 of the Ministry of Social Affairs and Health on the Medical Use of Radiation (hereinafter referred to as the MSAH Decree) sets out general requirements for medical procedures involving exposure to radiation. This guide provides the radiation safety requirements governing mammography equipment and their use. The requirements apply to mammography equipment used both in clinical work and in screening, where radiographic film and an intensifying screen are used in imaging. In applicable respects the requirements also concern the use of digital image receptors.

Mammography-based breast cancer screening is also discussed in Guide ST 3.7.

2 Mammography Equipment

2.1 Safety Licence

A mammography equipment is subject to a safety licence referred to in section 16 of the Radiation Act (592/1991).

An application for a safety license must be submitted to the Radiation and Nuclear Safety Authority (STUK) in writing. The safety license will stipulate the purpose of using the mammography equipment, for example for clinical mammography examinations and mammography screening.

An X-ray equipment for which a safety license has been granted for mammography operations may also be used for examining the outermost limbs and tissue samples.

2.2 Criteria for Acceptability of Equipment

The technical properties of a mammography equipment must be suitable for mammography examinations and it must be possible to take X-

ray images of a high standard using the equipment.

X-ray equipment manufactured after 13 June 1998 must bear the CE marking (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices) required by the Medical Devices Act (1505/1994). The CE marking provides an assurance that the device meets the essential requirements applicable thereto. The essential requirements applicable to health care equipment and materials, and the procedures for assessing compliance with the said requirements, are prescribed in Decision of the Ministry of Social Affairs and Health concerning Medical Devices (66/1994, amended by Decree 832/2000).

According to section 30 of the MSAH Decree, the functional requirements and acceptability criteria of equipment to be considered from the point of view of radiation safety are to be confirmed by STUK. Mammography equipment, imaging cassettes and the development of film must satisfy the criteria for acceptability at time of use set out in Appendix A hereto, or corresponding criteria that achieve the same standard of safety.

Mammography equipment for which a safety licence has been granted before the entry into force of this guide may continue to be used according to earlier requirements (Guide SS 3.2) until 1 January 2004. Thereafter these equipment must either be brought into compliance with the new requirements or decommissioned.

2.3 Checking of Equipment's Operation Condition

The party running a radiation practice (hereafter responsible party) shall ensure that the acceptance inspection referred to in section 32 of the MSAH Decree is performed with respect to a mammography equipment, complete with all ancillary equipment, accessories and instruments, before these are taken into use.

The operation and technical condition of an X-ray equipment and the associated ancillary equipment, accessories and instruments and the development of film must be monitored not only at the time of quality control measures, but also during use. Corrective measures must be taken where necessary.

To minimize image fading there must be no needless delay in developing X-ray images. If X-ray images are developed elsewhere than at the site of the X-ray equipment, then the images should be developed no later than two days after they are taken.

On days when patients are examined the operation of the mammography equipment should be checked before beginning the said examinations. This checking is performed by taking an X-ray of a test device including details enabling assessment of the optical density, contrast and spatial resolution of the X-ray image. The mAs rating or exposure time regulated by the automatic exposure control unit is also recorded at this time. The test device X-ray image and mAs rating or exposure time regulated by the automatic exposure control unit are used to ensure that there has been no change in the functioning of the equipment. If X-ray images are developed elsewhere than at the site of the X-ray equipment, then it suffices to monitor the mAs rating or exposure time regulated by the automatic exposure control unit.

The operation of the equipment must be checked during use according to the instructions for each device. Inspections must be performed at regular intervals, after each significant occasion of repair or servicing, and whenever there is cause to suspect any malfunction or change in the operation of the equipment.

3 Radiation Shielding of Place of Use

Mammography equipment must be sited in the examination rooms so that their use cause no radiation hazard to operating staff or other persons. The principles for determining the protective shielding of X-ray rooms are set out in the Guide ST 3.6. The dose constraint outside of the examination room is 0.3 mSv per year. Due to the low energy radiation involved, radiation shielding of the premises in which a mammography equipment is used may be readily arranged so that the annual dose falls considerably below the said dose constraint.

A layer of lead 0.25 mm thick in the immediate vicinity of a mammography equipment and 0.1 mm thick at a greater distance from it generally provides adequate shielding. No further shielding is generally necessary if a mammography equipment is housed in a room with walls made of concrete or brick.

The exposure of X-ray images should be executed in a radiation shielded control room in visual contact with the person undergoing examination. If this cannot be arranged, then there must be a protective shield for the operator with a lead equivalent thickness no less than 0.25 mm.

Instructions for classifying working premises and staff engaged in radiation work are set out in Guide ST 1.6. If more than 4000 examinations are performed annually using a mammography equipment, then the immediate surroundings of the said equipment are to be designated as a supervised area. No such classification need be made if fewer than this number of exposures occur annually.

4 Training and Qualification Requirements

Physicians, staff performing X-ray examinations and those interpreting X-ray images, who are involved in activities involving radiation exposure, must possess the knowledge required for their duties regarding the health effects of ionizing radiation and of radiation exposure in X-ray examinations.

4.1 Mammography Radiographers

A person performing mammography imaging shall be a physician or a radiographer.

A person performing imaging for screening purposes shall also have experience of clinical mammography imaging and shall receive the necessary special training in imaging for screening purposes.

Staff performing imaging shall participate in appropriate supplementary training.

4.2 Image Interpreters

A **mammography image interpreter** shall be a specialist in radiology.

Interpretation of mammography images taken for screening purposes shall be performed by two specialists in radiology with experience in mammography operations and image interpreting. At least one of these specialists shall possess special competence in mammography screening. The said specialist shall have completed the mammography screening course of the Radiological Society of Finland (certificate of competence issued by the Finnish Medical Association) or a corresponding course in Finland or abroad.

Staff interpreting mammography images shall participate in appropriate supplementary training.

5 Instructions for Performing Examinations

The premises in which an X-ray equipment is used shall be furnished with written instructions for performing X-ray examinations pursuant to section 14 of the MSAH Decree. These instructions shall state the examination practices to be followed and shall include at least the following information:

- the imaging views included in an examination
- imaging values, focus selection, primary radiation filtration, grid use
- the sensitivity selections of the automatic exposure control unit
- details of the image recording method (type of intensifying screen and film, or parameters affecting radiation exposure in digital imaging)
- practices for radiation protection of the patient and any necessary instructions for optimizing radiation doses and image quality.

6 Radiation Exposure Reference Level

Mammography examinations shall be performed in a manner achieving the objectives of the examination while minimizing exposure to radiation.

The radiation exposure reference levels required by section 16 of the MSAH Decree shall be used. STUK shall issue instructions for using the said reference levels.

7 Recording and Reporting of Examination Data

An entry shall be made in the patient's medical records for an X-ray examination using the classification of radiological examinations and procedures published by the Association of Finnish Local and Regional Authorities. If the examination practice in an individual case differs essentially from customary practice (see chapter 5), then an entry to this effect is to be made in the medical records of the patient concerned. Such an entry shall be required, for example, in the case of repetition of an examination, extraordinary imaging projections involved in an examination, and other deviations from customary practice with significant impact on radiation exposure.

The written instructions referred to at chapter 5 for performing X-ray examinations shall be retained for the period during which the X-ray equipment is in use, in order to enable subsequent evaluation of the dose administered to a patient if necessary. It must be possible from these instructions and the patient's medical records to determine at a later date the examination practice that was used. Retention of patient medical records is governed by the provisions of Decree (99/2001) of the Ministry of Social Affairs and Health concerning the preparation of patient records and the retention thereof and of other materials pertaining to treatment.

Section 43 of the MSAH Decree (423/2000) imposes an obligation on the responsible party to compile summaries of the number of examinations performed and of the radiation doses administered. For the purpose of preparing national evaluations STUK requests the said information in particular years, at which time it also issues the necessary instructions.

8 Quality Assurance

The obligation of the responsible party to arrange quality assurance is prescribed in section 40 of the Radiation Act (592/1991, amendment 1142/1998). The responsible party must compile a quality assurance programme according to section 18 of the MSAH Decree. This programme must set out the measures pertaining to a mammography equipment in respect of its acceptance inspection, testing of operating condition and performance characteristics, determination of basic values and monitoring of constancy. The programme also provides instructions for performing these measures, states the thresholds for corrective action, and specifies the responsibilities and practical instructions for supervision.

Appendix B sets out the minimum range of measures that must be included in technical quality assurance. The responsible party is free to specify the action thresholds for quality assurance. These thresholds may not be looser than the criteria for acceptability at time of use set out in Appendix A. Measurements and observations shall be documented so that the quality of operations may be monitored. All essential documents shall be retained for the entire period of use of the equipment. Quality assurance practices shall be evaluated at regular intervals and amended whenever justified.

A quality assurance programme shall include an annual evaluation of patient doses and a comparison of results with reference levels in the manner set out at chapter 9. Data on doses

administered shall be supplied to STUK when separately requested.

Besides technical quality control, a quality assurance programme shall also include medical quality assurance. The obligation of the responsible party to arrange self-assessment of the medical use of radiation is prescribed in section 19 and the obligation to arrange clinical auditing is prescribed in chapter 4 of the MSAH Decree.

The procedures and responsibilities pertaining to the handling of hazardous situations to be included in the quality assurance programme and reporting of abnormal events are governed by the Medical Devices Act (1505/1994).

9 Determination of Radiation Exposure to the Patient

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

The determination shall be performed by calculation based on patient images or images of a test device: Radiation exposure is evaluated based on X-ray images of ten people. These people shall be selected so that the thickness of their compressed breasts is 40–60 mm and the average thickness is about 50 mm. The mAs ratings regulated by the automatic exposure control unit shall be recorded for the patient images, and this shall be used to calculate the ESD^{*)} and average value thereof using the radiation output measurements for the X-ray tube. The average value so obtained shall be compared to the reference level. The entrance surface dose may also be determined by imaging a 45 mm thick acrylic test device a few times in the same way, by recording the mAs ratings and

^{*)} The Entrance Surface Dose, ESD, is the dose absorbed in air at the surface of the patient within the radiation beam.

calculating the entrance surface doses and the average value thereof.

Radiation exposure may be determined by measuring in the course of imaging a test device. A thermoluminescence dosimeter or other suitable radiation measurement probe is mounted on the surface of a test device in the radiation beam. Imaging is repeated in the same way twice, for example, the mAs ratings are recorded, and an average is calculated for the measuring results.

Radiation exposure data must be recorded and compared to the reference level. If the reference level is exceeded, then the reason for this must be investigated and any measures necessary to reduce radiation exposure must be taken. Even when the reference levels are not exceeded it must be ensured that image quality is adequate for a reliable diagnosis and that radiation exposure is not unnecessarily large.

10 Notification of Abnormal Events

Notification of abnormal events pertaining to the use of radiation is governed by section 17 of the Radiation Decree (1512/1991). STUK must be notified without delay of any abnormal event or other abnormal observation or data that are of essential significance from the point of view of radiation safety.

Persons using medical devices professionally must notify the National Agency for Medicines of all seriously hazardous situations that are encountered or suspected in the course of using medical devices. The National Agency for Medicines must also be notified of any inadequate or inaccurate markings or operating instructions that might cause such a hazardous situation to arise. This notification must be made in the manner prescribed in the Medical Devices Act (1505/1994).

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APPENDIX A

ACCEPTABILITY CRITERIA FOR THE USE OF MAMMOGRAPHY EQUIPMENT, IMAGING CASSETTES AND THE DEVELOPMENT OF FILM**A.1 Dose Rate**

The dose rate in the primary beam of an X-ray tube at the distance of the film from the focus must be at least $7.5 \text{ mGy}\cdot\text{s}^{-1}$. The tube voltage will then be 28 kV or more.

A.2 Setting Values

The mAs rating indicating the product of tube current and exposure time of a mammography equipment may deviate from the true value by no more than ± 20 per cent. The same concerns the exposure time (ms or s).

The tube voltage may deviate from its nominal value by no more than ± 5 per cent. When imaging is repeated no fewer than five times consecutively, deviating between set values, the coefficient of voltage variation^{*)} of the imaging shall be less than 5 per cent.

When imaging a 45 mm thick acrylic test device the imaging time must be less than 2.0 seconds using typical imaging values.

A.3 Operation of the Automatic Exposure Control Unit

When imaging a 45 mm thick acrylic test device the basic film density of the X-ray image (the combined baseline density of the X-ray film and the fog density arising from the developing process) should be at a reference point^{**)} between 1.2 OD and 1.8 OD using typical imaging values.

When imaging is repeated five times consecutively, deviating between set values, the automatic exposure control unit must repeat the irradiation sufficiently well that the deviation in measuring results from the mean value of them is less than ± 5 per cent. The film density of the X-ray images must not deviate from the basic film density by more than ± 0.2 OD. This requirement must also be met in the long term.

When imaging a 45 mm thick acrylic test device using an automatic exposure control unit and various imaging voltages in the range from 25 kV to 30 kV the deviation in film density of the X-ray images from the basic film density as measured from the reference point may not exceed ± 0.30 OD. The automatic exposure control unit density control setting normally used when imaging a breast of average thickness are used in the tests.

When imaging acrylic test devices of thickness 20, 45 and 60 mm using an automatic exposure control unit the film density of the X-ray images must not deviate from the basic film density by more than ± 0.3 OD. The imaging voltage and automatic exposure control unit density control setting normally used when imaging a breast of average thickness is used in the tests.

The change arising from each step of the automatic exposure control unit density control setting should be between 0.1 OD and 0.3 OD on the film.

A.4 Collimation of the Radiation Beam to the Image Receptor

The radiation field on the thoracic side must cover the entire X-ray film but may not exceed the film by more than 5 mm from the edge of the film. The radiation field may not exceed the film in the lateral direction.

^{*)} The coefficient of variation (relative standard deviation) is the standard deviation divided by mean value of the measurement results.

The standard deviation is the positive square root of the arithmetic mean of the squares of differences of the measurement results and their mean value.

^{**)} The reference point is located at a distance of 6 cm from the edge on the side of the thorax and laterally in the middle of the film.

APPENDIX A

A.5 Breast Compression

The maximum compression force regulated automatically by the equipment shall be between 130 N and 200 N. When regulated manually the compression force must not exceed 300 N.

A.6 Grid

When the grid is used the gridlines must not be visible on the X-ray image in a manner that impedes diagnosis. The dose may be increased no more than threefold on account of use of the grid (a grid coefficient not exceeding 3).

A.7 Image Quality

Spatial resolution in contact imaging should be no less than 12 line pairs per millimetre. To determine resolution the spatial resolution test plate (0.025 mm of lead) is mounted on the front surface of the irradiated side of a 45 mm thick acrylic test device in a direction lateral to the central axis of the radiation field and at a distance of 6 cm from the edge of the film on the thoracic side.

When a contact and magnification image is taken of a test device including details mimicking microcalcifications and tissue changes, the image quality should meet the criteria for a good image imposed by a radiologist interpreting mammography images.

A.8 Imaging Cassettes

Imaging cassettes must be intended for use in mammography. The condition of cassettes is tested by imaging a homogeneous test device using an automatic exposure control unit. The imaging values are kept constant and the imaging cassettes are changed. When using various cassettes the difference in film densities measured for the same point of the image may not exceed 0.2 OD. The maximum deviation in mAs rating regulated by the automatic exposure control unit from the average mAs rating may not exceed ± 5 per cent.

A.9 Development of Film

Before developing patient images the functioning of the development process is to be checked using a sensitometer and densitometer within about one hour of starting the developing machine.

The sum of the baseline density of the X-ray film and the fog density arising on the film due to the development process may not exceed 0.2 OD.

The sensitometric speed index may deviate from the basic value by no more than ± 10 per cent.

The sensitometric contrast index (MGrad^{*)} must be no less than 2.6 and should be at least 3.0.

Changes in film density caused by light leakages of darkroom and other illumination may not exceed 0.1 OD on the film compared to the film density of film that has not been exposed to stray light or other illumination.

^{*)} For a definition see page 7 of chapter 11, reference 2.

APPENDIX B

QUALITY ASSURANCE MEASURES

Measurements and verification pertaining to monitoring of constancy are made at regular intervals during use, when circumstances change and when faults are suspected.

Object of inspection	Quantity/property to be monitored	Necessary instruments
Daily or weekly		
development process	fog density, speed index, contrast index	X-ray film, sensitometer, densitometer
functioning of X-ray equipment	reproducibility of radiation output (mAs rating or exposure time regulated by automatic exposure control unit)	acrylic block of thickness 45 mm
image quality	contrast, fine detail, film density	image quality phantom, X-ray film, densitometer
cassettes	cleanliness of intensifying screen	visual inspection
stereotactic accessories	collimation	manufacturer's recommended test phantom and X-ray film
Monthly or semi-annually		
automatic exposure control unit	film density, mAs rating, exposure time	acrylic blocks of thickness 20, 45 and 60 mm, X-ray film, densitometer
breast compression plate	compression force	suitable scales ^{*)}
^{*)} Conversion coefficient: A scale display of 10 kg corresponds to a compression force of about 100 N.		

APPENDIX B (CONTINUED)

Object of inspection	Quantity/property to be monitored	Necessary instruments
Annually		
X-ray equipment	tube voltage	voltmeter
	exposure time	exposure time meter
	radiation output	radiation meter
	spatial resolution	acrylic block of thickness 45 mm, spatial resolution test plate, X-ray film, magnifying glass
cassettes	field size limitation	X-ray film, adjustment marks
	contact between intensifying screen and film	metal mesh or riddle and X-ray film
	locking	visual inspection
	light-proofing	X-ray film
light board	even quality (relative speed)	X-ray film, densitometer
	luminance and illuminance	visual inspection or luminance and illuminance meter
darkroom and film store	uniformity of light field	visual inspection, luminance or illuminance meter
	temperature and humidity film storage period light-proofing	thermometer and hygrometer
dose	dose on the surface of a test device (ESD)	acrylic blocks of thickness 20, 45 and 60 mm, radiation meter

ST GUIDES (12 May 2004)

General Guides

- ST 1.1 Radiation Practices and Regulatory Control, 20 June 1996
- ST 1.3 Warning Signs for Radiation Sources, 10 November 1999
- ST 1.4 Radiation User's Organization, 16 April 2004
- ST 1.5 Exemption of the Use of Radiation from the Safety Licence and Reporting Obligation, 1 July 1999
- ST 1.6 Operational Radiation Protection, 29 December 1999
- ST 1.7 Radiation Protection Training in Health Care, 17 February 2003
- ST 1.8 Qualifications and Radiation Protection Training of persons working in the Radiation User's Organization, 16 April 2004

Radiation Therapy

- ST 2.1 Quality Assurance for Radiotherapy, 22 May 2003 (in Finnish)
- ST 2.2 Radiation Safety of Radiotherapy Equipment and Treatment Rooms, 2 February 2001.

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- ST 3.2 Mammography Equipment and their Use, 13 August 2001
- ST 3.3 Diagnostic X-ray Equipment and Its Use, 27 August 1992
- ST 3.4 Quality Control of Image Intensifier - Television Chains, 24 October 1991
- ST 3.5 Quality Control of Diagnostic X-ray Equipment and Film Processing, 3 December 1991
- ST 3.6 Radiation safety in X-ray facilities, 24 September 2001.
- ST 3.7 Breast Cancer Screening Based on Mammography, 28 March 2001

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- ST 5.3 Use of Ionizing Radiation in the Teaching of Physics and Chemistry, 17 February 1999
- ST 5.4 Trade in Radiation Sources, 2 October 2000
- ST 5.6 Radiation Safety in Industrial Radiography, 17 February 1999

- ST 5.8 Installation, Repair and Servicing of Radiation Appliances, 17 February 1999

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- ST 6.1 Radiation Safety Requirements for Radionuclide Laboratories, 1 July 1999
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- ST 7.2 Application of Maximum Values for Radiation Exposure and Principles for the Calculation of Radiation Dose, 1 July 1999
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- ST 9.1 Radiation Safety Requirements and Regulatory Control of Tanning Appliances 1.12.2003 (in Finnish)
- ST 9.2 Radiation Safety of Pulsed Radars, 2 September 2003 (in Finnish)
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- ST 9.4 Radiation Safety of High Power Display Lasers, 8 October 1993 (in Finnish)

Natural Radiation

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- ST 12.2 Radioactivity of Construction Materials and Ash, 8 October 2003 (in Finnish)
- ST 12.3 Radioactivity of Household Water, 9 August 1993