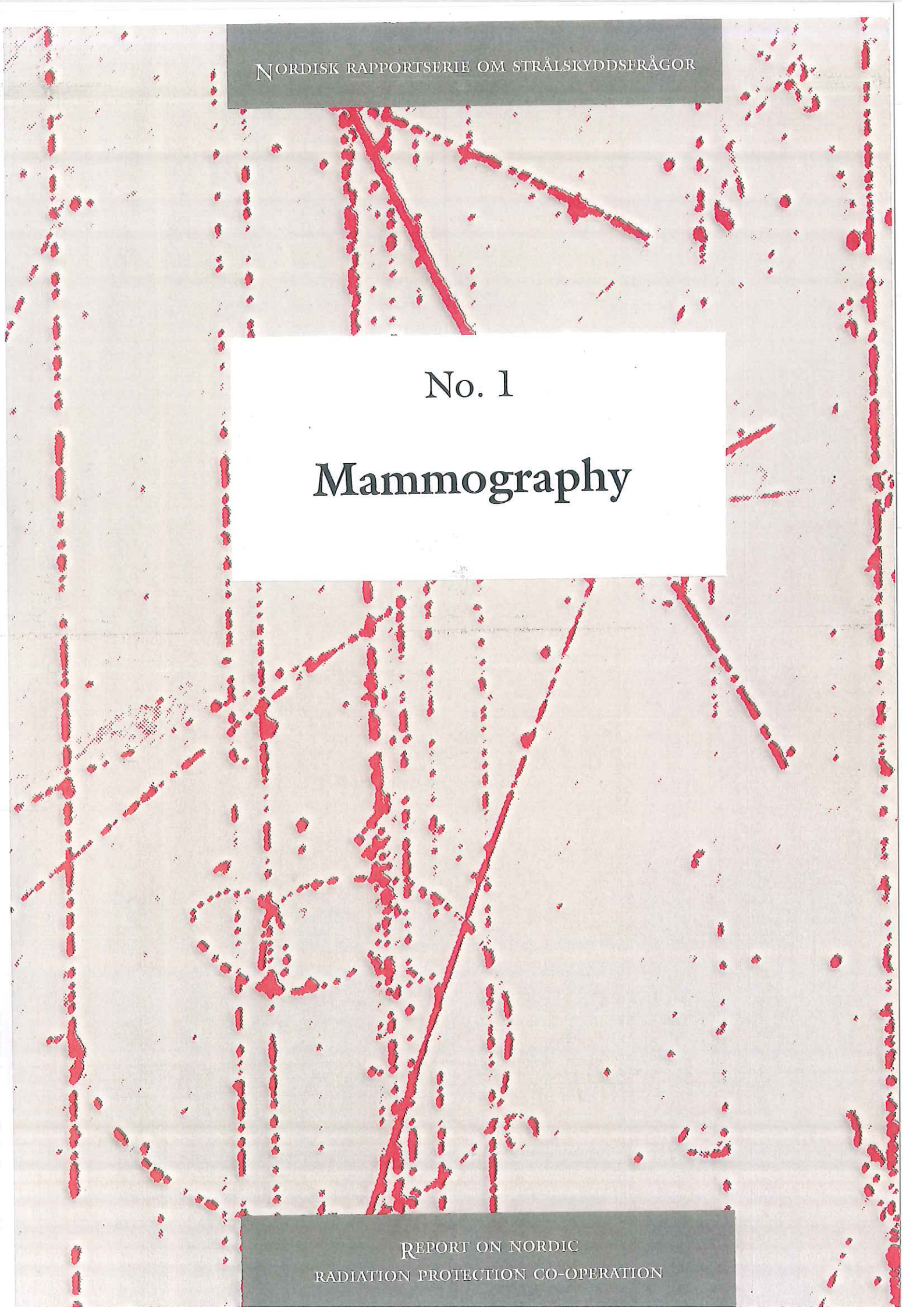


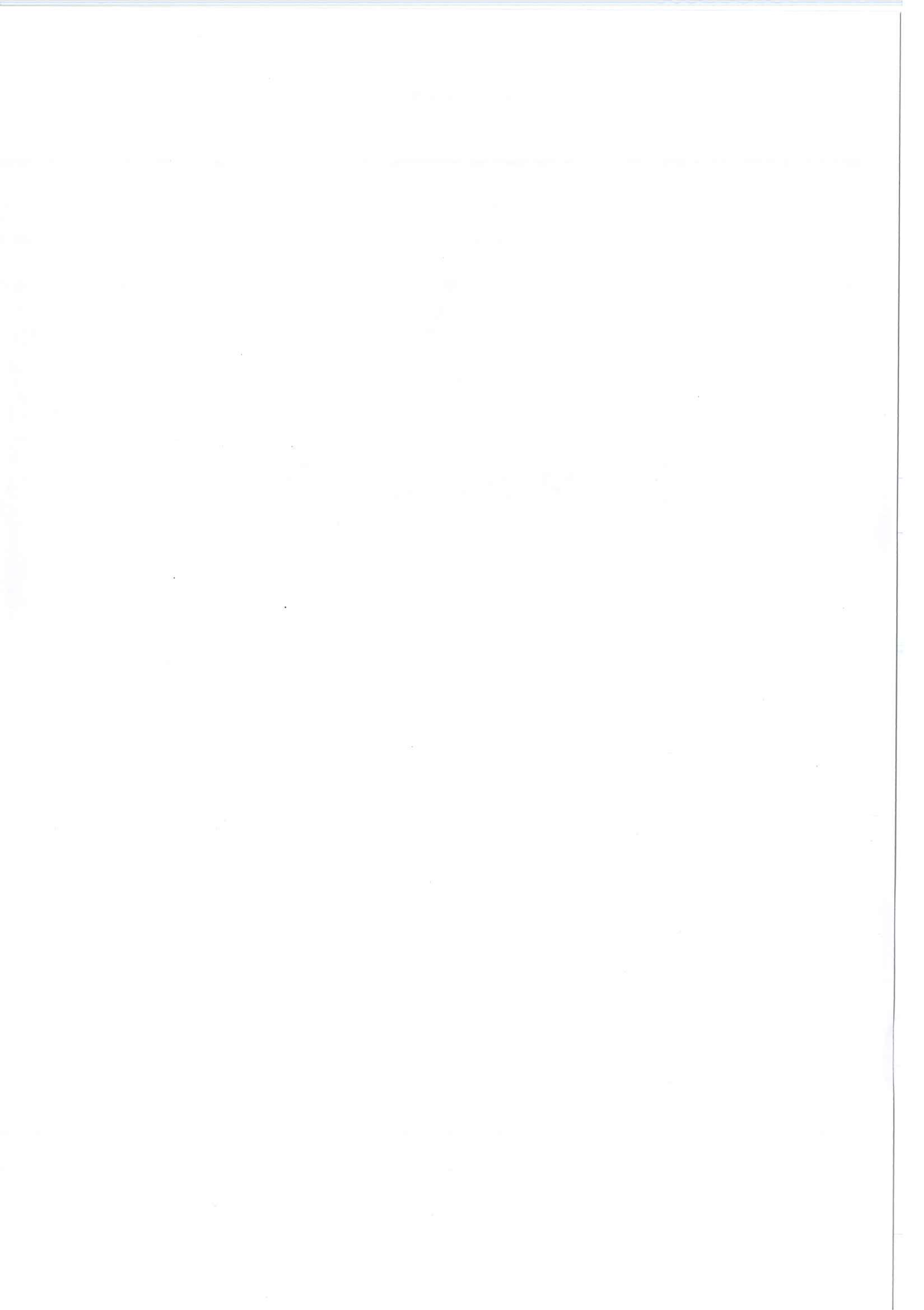


NORDISK RAPPORTSERIE OM STRÅLSKYDDSFÖRÅGÖR

No. 1

Mammography

REPORT ON NORDIC
RADIATION PROTECTION CO-OPERATION



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Mammography

The radiation protection and nuclear safety authorities in
Denmark, Finland, Iceland, Norway and Sweden

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Summary : This publication describes the Code of Practice for quality control in Mammography, and sets a standard of performance of mammography equipment. The intention is to achieve optimum image quality within certain dose constraints and common routines in Nordic health institutions.

Key words : Mammography, quality assurance, quality control, performance, acceptance tests, status tests, periodic tests

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QUALITY ASSURANCE IN MAMMOGRAPHY - QUALITY CONTROL OF PERFORMANCE AND CONSTANCY

Recommendations by the Nordic Radiation Protection Authorities

1. Introduction

Mammography has undergone a technical revolution between the early 70s and the present time. There have been continuous improvements in image quality, which has presented increased diagnostic opportunities, and at the same time the patient dose has been reduced significantly. Mammography is the only reliable method for the early discovery of breast cancer. A number of scientifically based studies have revealed that regular screening by mammography leads to reduced mortality from breast cancer.

Health screening by mammography has started in several Nordic countries in recent years: it is available in the whole country in Finland and Iceland, and in just over two-thirds of the country in Sweden (1989). The question is still unresolved in Norway and Denmark, although mammography screening is also likely to be introduced there. The wide geographical distribution of the mammography service and the requirement for the highest possible quality to be achieved in order to obtain the desired benefit make it appropriate to formulate basic regulations which must be adhered to. These recommendations describe the major assumptions for an optimized mammography system from a technical viewpoint and give advice on how the optimization may best be achieved.

Mammography differs in a number of respects from other conventional forms of radiography. Extremely low-energy radiation must be used in order to show up small structures with minimal differences in density and chemical composition, and the detection of microcalcifications places high demands on the resolution of the system. These demands are accentuated in a screening context, where the examination takes place without prior assumptions, in the absence of clinical notes, and with a limited number of projections. An optimized mammographic system is required in order to create the most favourable conditions for perception and to permit a selection process which gives high sensitivity and specificity - the conditions on which a screening programme will stand or fall.

The Nordic Radiation Protection Institutes have compiled this programme of quality control for mammography in order to assist and support those involved in providing the mammography service. The programme has been developed essentially for the equipment on which screening is performed, although it can also be applied to so-called clinical equipment. Additions have been made to cover magnification techniques and other special techniques.

The aim of the programme is to provide guidance in respect of the quality control related to radiation hygiene by describing methods which have been tried and tested in practice. Account has been taken of both Nordic and international standards. The programme is aimed at both suppliers and users in the area of health care who may be affected by quality controls - hospital physicists, engineers, technicians and, not least, radiologists and radiographers.

The programme broadly contains the following:

- methods for testing the technical performance of the X-ray equipment;
- advice on how image quality can be defined and measured in an objective manner;
- determination of the radiation dose;
- optimization of the film processing;
- checking radiation shielding devices for staff;
- test methods for ensuring the quality in both the short and the long term.

The programme and, in particular, the indicated tolerances were arrived at by the application of currently available technology. They may not be static, but must be evaluated continuously and adapted to any new findings uncovered by ongoing developments. It is most appropriate for this reason that all those who work in the field should have the opportunity to express their views and criticisms to the Nordic Radiation Protection Institutes, which can then disseminate their experiences for the benefit of everyone.

2. Equipment performance and testing

Certain minimum requirements must be met in order to be able to achieve acceptable image quality and safety. Such requirements, which are based on national recommendations and regulations, mainly in Finland and Sweden, and on international standards (IEC), are

based on national recommendations and regulations, mainly in Finland and Sweden, and on international standards (IEC), are described in Appendix I. The requirements are directed primarily at equipment intended for screening, but can also be applied to equipment intended for clinical use.

A high level of consistent quality can only be maintained by regular testing of the mammography system. The quality assurance programme includes the organization of acceptance tests, status tests and regular constancy tests. The latter are intended to ensure that the image quality and the patient doses are maintained at a previously acceptable level.

3. Acceptance testing

The following procedures should be carried out on newly installed equipment:

- checking that everything has been supplied in accordance with the order and has been installed in a safe fashion;
- testing that the performance and functions meet the specified requirements;
- checking that the radiation shielding devices etc. provided for the staff is to a satisfactory design;
- the selection of technique factors to give optimum results in clinical application.

3.1 Delivery inspection

Once it has been delivered and installed, the equipment is compared with the order. Is everything there, and do the model number and type designation agree with the order details? Operating instructions (in the language of the country) and technical documentation must be supplied. These shall be comprehensive, and the operating instructions (directions for use) kept with the equipment shall only include details of the functions which are available in the equipment itself.

Electrical and mechanical safety shall be subject to testing. Earthing, stable mounting of the X-ray equipment, good balance in conjunction with movements of equipment parts, and efficient stops are some of the important points to be checked.

Subsequent deliveries of accessories, such as film and cassettes, must also be examined. New cassettes must be compared with the reference cassette (see Appendix IV, page 33) in respect of attenuation and relative sensitivity. Films with different batch numbers may exhibit, not insignificant, variations in their sensitometri-

cal characteristics. New supplies of film (i.e. from a different production run with a different batch number) should be compared with existing stocks of film. A sensitometry test in accordance with Appendix 4, page 34, is performed on both the new and the old film. Depending on the result, the new film may be rejected or accepted. In the latter case, the reference values for the sensitometry test may require adjustment.

3.2. Testing of performance and functioning

Determine the accuracy and reproducibility of technical parameters such as tube voltage, tube current, exposure time, absorbed dose per set mAs, automatic exposure control, limitation of field size, focal spot size, compression force, radiation shielding, and grid movement, etc. The results are compared with the specified requirements. The test methods are presented in Appendix IV.

A further test concerns the radiation shielding provided as protection for the staff. The location at which the exposure is released shall be protected against secondary radiation by means of a radiation protection shield or wall. The shield shall be of sufficient width and height to afford protection to those persons present whilst exposure takes place. An area of the shield with dimensions of at least 40 x 40 cm² at eye level shall be transparent, so as to permit the operator to observe the patient.

3.3. Adjustment and optimization

X-ray equipment and its accessories shall not simply be appropriate for their intended purpose, but shall also be used in an appropriate fashion. The technical factors shall be selected so as to ensure an optimum radiological examination. The image quality parameters, their diagnostic significance, and the manner in which they are affected by the technical factors are covered in Appendix II. The main factors when speaking of the X-ray equipment are the radiation quality (tube voltage), the film focus distance, and the adjustment of the automatic exposure control system. For a given film and developer chemistry, the processing is determined essentially by the developer temperature, the development period and the replenishment rate.

The recommendations impose high requirements on the equipment and its

optimization. Studies in Sweden and Finland have shown that only a small number of systems are able to meet all the requirements which are set. On the other hand, this serves to indicate that the requirements can be met, but that both time and new investment may be needed in certain cases before the aims can be satisfied in full.

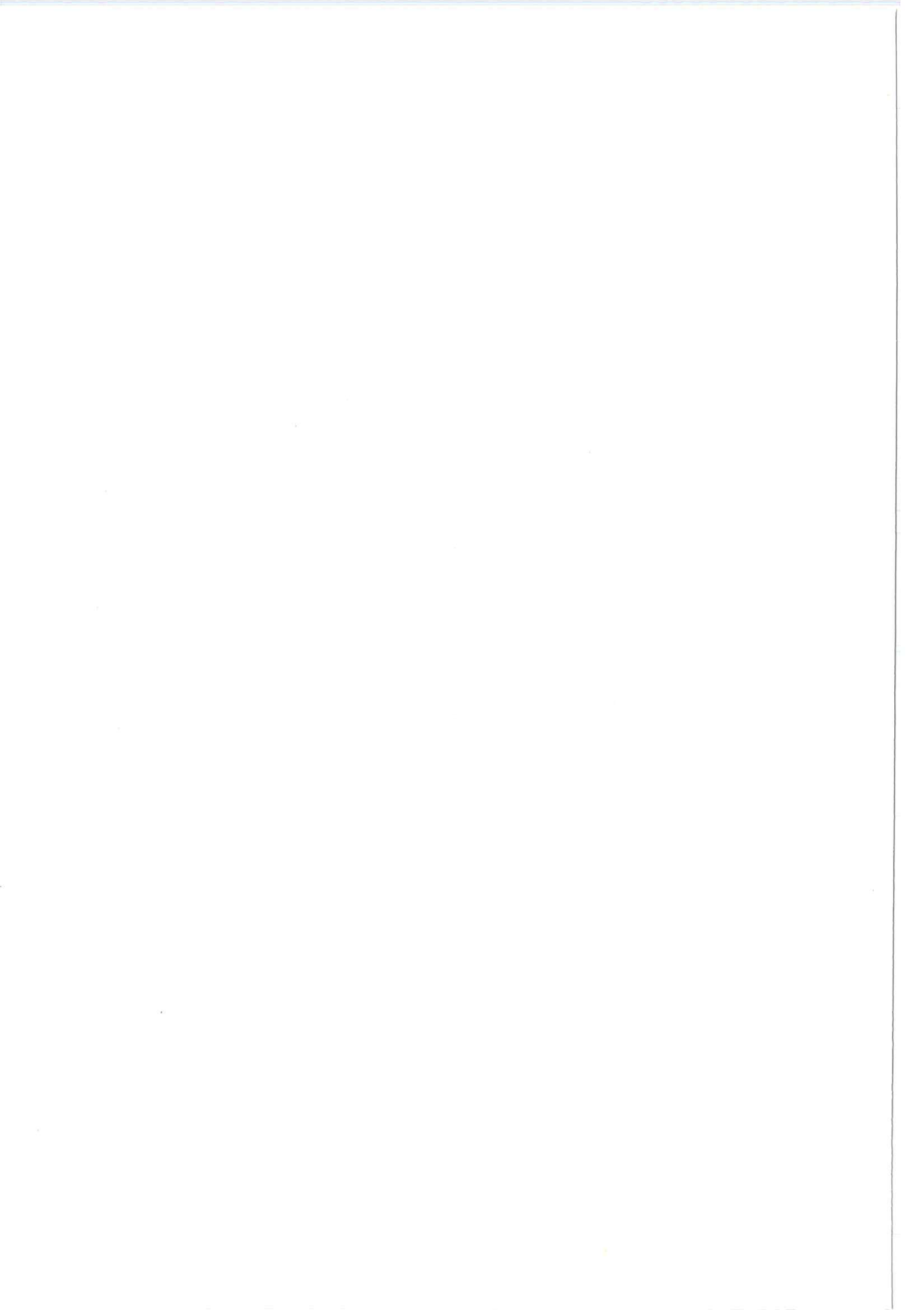
3.3.1. Choice of tube voltage

The radiographical contrast increases as the tube voltage is reduced. However, reduced tube voltage involves a higher radiation dose and a longer exposure time. The lengthening of the exposure time can in itself lead to a further increase in the radiation dose, due to the reciprocity failure effect. Briefly, the reciprocity failure effect means that the sensitivity of the film is reduced when the exposure rate is decreased i.e. with an increased exposure time. Clinical experiences have shown that 25 kV is to all intents and purposes the optimum value for mammography equipment with a Mo anode; this value should be respected in non-grid methods. The tube voltage can be increased by one or two kV, if necessary, when using the grid technique. These recommendations are for breasts of normal size. An increase in the tube voltage may be justified when examining thick, dense breasts - this may even be absolutely necessary in order to obtain a properly exposed image.

In order to achieve equivalent radiation quality when using equipment with a W anode, it is necessary to select other values for the tube voltage. In the case of conventional filtration in particular, the radiation quality is affected to a very considerable degree by small changes in the tube voltage, and it is for this reason that strict requirements must be imposed on both the accuracy and the reproducibility of the tube voltage.

3.3.2. Adjustment of the automatic exposure control system

A properly functioning automatic exposure control will give the same predetermined density on the X-ray image, irrespective of the thickness and density of the breasts, the radiation quality (tube voltage), or the choice of



technique (grid / non-grid). This film density normally lies within the range between 1.0 and 1.5 above base plus fog. The automatic system should make it possible to vary this density at defined, suitably large intervals through appropriate correction steps.

The detector for the automatic exposure is always situated beneath the cassette. This, in combination with the low radiation energy, means that, for the same signal received by the automatic exposure detector, the radiation dose absorbed in the intensifying screen, and thus the density of the film, will vary with the radiation quality (tube voltage), with the thickness of the object, and with the choice of technique (grid/non- grid). Compensation for these differences is made electronically in modern equipment, for example by measuring the radiation quality or the dose rate and correcting the interruption level of the automatic system so as to obtain the correct film density. The automatic system in older equipment may be difficult to adjust to a satisfactory level. Replacement of the apparatus may then be the only alternative.

There should be at least 4 correction steps to either side of the normal position. Two adjacent correction steps should provide a difference in film density of between 0.1 and 0.2. The difference in exposure then corresponds to a half mAs step, i.e. a factor of approximately 1.1. Compared with other conventional X-ray equipment, the difference in exposure is smaller for the same change in film density, due to the steep path of the density curve.

3.3.3. Use of grid technique

The grid technique reduces the proportion of scattered radiation in the film plane from approximately 40 per cent to approximately 10 per cent, thereby achieving an improvement in the contrast in the image of between 20 and 50% (Alm Carlsson G et al., 1989). However, this results in a higher radiation dose. In practice, both stationary and moving grids are used. In fixed raster grids aluminium is used as a general rule as the intermediate layer, for technical design reasons, whereas low-absorption organic materials are

used in moving grids. This means a higher dose and poorer contrast when using a stationary grid compared with a moving grid. The radiation dose increases by a factor of approximately 3.5 for stationary grids and 2.5 for moving grids, relative to the non-grid technique (with an unchanged radiation quality of 25 kV). If the tube voltage is increased to 28 kV when using the grid technique, the relative dose increase is reduced to a factor of under 3 and 2 respectively.

Stationary grids should not be used for screening, since the radiation dose is higher and the improvement in contrast is lower.

3.3.4. Film processing

Optimally adjusted processing is perhaps the most important and the most critical technical parameter. The choice of development conditions affects both the radiation dose and the image quality to the highest degree, although oddly enough in this case a reduction in the radiation dose goes hand in hand with an improvement in image quality, within certain limits. Mammographic film, at least that which is commercially available today, requires different development conditions compared to other X-ray film, and should accordingly be processed in a separate processor.

The long process time (3 to 4 minutes, development time 45-60 s) and the high development temperature (34-37°C) are necessary for optimum processing of mammography film. Optimization should proceed in such a way that sensitometrical tests are performed at successive increments in development temperature and/or process time. The base plus fog, contrast and sensitivity are evaluated, and the processor is adjusted to the values which provide maximum contrast and no increase in fog. Processing can be pushed even further when using grid technique - the loss of contrast at the start of the characteristic curve (toe) is offset by the gain in contrast due to the reduction in the scattered radiation. In this way, the increase in dose produced by the use of a grid can be reduced slightly.

In order to ensure constant processing, the replenishment rate must be correctly adjusted. It is not possible, as a general rule, to use exactly the same values as for the processing of ordinary X-ray film. The appropriate values must be found by trial and error, since mammography film is special in this respect, too.

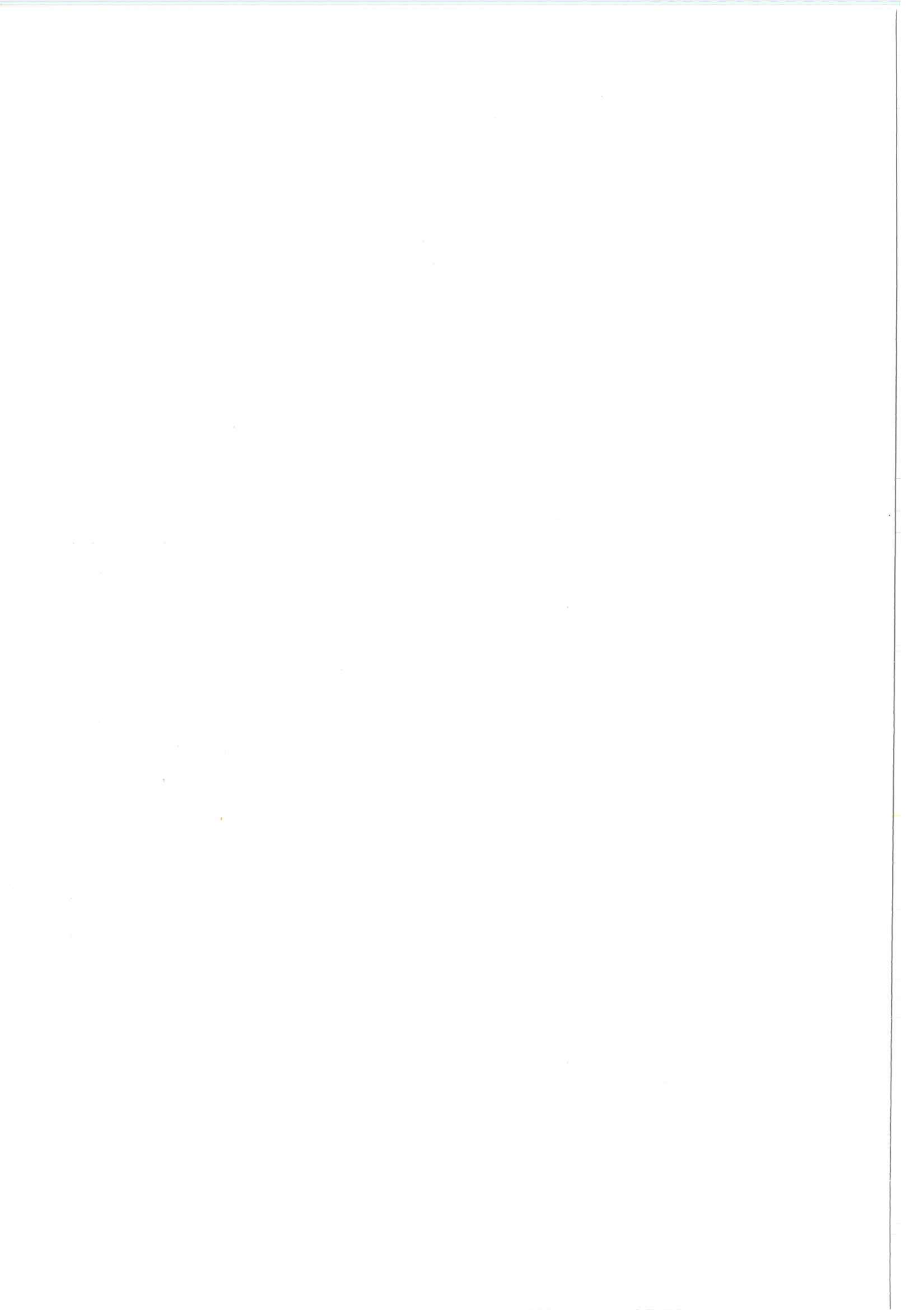
3.3.8. Absorbed dose

An optimized mammography system using a non-grid technique gives a mean absorbed dose of around 0.6 mGy per projection to the mammary gland tissues for a breast of average thickness and composition. This normal breast is simulated with a 45 mm thick plexiglass phantom. Measurement and calculation of the absorbed dose are performed using the method of Rosenstein et al., 1985 (see Appendix III). Under otherwise identical conditions, the average absorbed dose is approximately 1.5 mGy for the grid technique (with a moving grid).

Both dose values may be regarded as standard values which can be achieved by current techniques with an optimized system. A certain distribution of the values must be accepted, however, due to variations in the operating conditions encountered in different clinics. It is not acceptable for the radiation dose to exceed 0.8 mGy (with non-grid technique) or 2.0 mGy (with grid technique), standardized to a net film density of 1.0.

4. Status tests

Once the mammography system has been optimized and is producing good clinical results, the performance of the system in various respects should be mapped out, evaluated and documented. The same methods of measurement can be employed which are used for the testing of performance and function (Chapter 3.2; see also Appendix IV). The initial status is documented, so that faults or other changes can be identified more easily and the appropriate remedies taken. The aim of this procedure is to have control of the radiation dose and to prevent the image quality from deteriorating. New reference values are also established following servicing or any other action which may have affected its performance.



8. Periodic tests

High image quality optimized with regard to the radiation dose must not only be achieved, but must also be maintained. Regular tests are one method of achieving this. The frequency of the different tests will vary: some should be carried out daily, others perhaps only once a year. One feature common to all the tests is the importance of maintaining detailed documentation and follow up. The tolerances and frequencies recommended below for the various tests should be regarded as guidelines. Depending on local conditions and the results of the evaluation of the tests, it may be necessary to increase or reduce these values.

Those inspections which are repeated at frequent intervals, ranging from daily to monthly, should be performed by personnel who work with the equipment every day. The six-monthly to twelve-monthly tests include advanced physical and technical measurements with a need for higher competence. Hospital physicists or X-ray engineers should preferably take responsibility for this part. They should also be involved in the organization and evaluation of the more frequent inspections.

8.1. Daily tests

8.1.1. Film processing

The constancy of the processing is verified with the help of a sensitometer test. A film is exposed in two areas with a sensitometer, say on the two long sides, and is processed immediately. Feeding into the automatic processor should be in the same position (for example by the right-hand edge) and with the same orientation (for example with the short side first) as in the reference case. Quality control should be carried out at the same time each day, preferably one hour after the development process is switched on in the morning. Films from mammography screening are sometimes held for a whole day for later processing in a central unit. It is particularly important in this case to carry out a sensitometer test just before these films are processed, to verify that the processing conditions are satisfactory.

The evaluation is made by comparing the sensitometer image with that recorded in the reference case, when the processing was optimized. The daily tests can be limited to:

- measurement of the density of the background (base plus fog). An increase of more than 0.03 relative to the value recorded in the reference case should not be accepted.
- measurement of the density at the sensitivity step. This is the step in the sensitometer scale which lay closest to net density of 1.0 in the reference case. This test is related to the sensitivity of the film processing system. The difference relative to the value recorded in the reference case should not exceed ± 0.15 .
- measurement of the density at the step on the sensitometer scale lying immediately above net density of 2.0 in the reference case (contrast step). The difference between this density and the density at the sensitivity stage is related to the contrast. The difference should lie within ± 0.1 relative to the value recorded in the reference case.

Note:

The performance of the processing can be monitored easily if the quality control values are represented graphically. Trends can then be identified and, it is hoped, interrupted before they lead to a noticeable deterioration in image quality.

5.1.2. Exposure

A 45 mm thick, homogeneous phantom is exposed at the same setting of the automatic exposure control as in the reference case and using the same cassette. The recorded mAs value should lie within 10% compared with the reference case. The film is then developed, and the density is determined at the centre line of the film at a point 3 cm from the edge along the wall of the chest. The density should not differ by more than ± 0.2 from that obtained in the reference case.

If the density lies outside the tolerance, the first step should be to test the processing once more using a sensitometer test. If this indicates correct processing, and similarly if the mAs value lies outside the tolerances, then the test should be repeated with manual adjustment of the exposure parameters in order to localize the fault. In this case, too, the density is

compared with that obtained in the reference case with the same setting. If the density when using automatic exposure is correct, but if the mAs value is high or low, then the tube voltage has probably changed. This may probably also be taken to indicate that film density when using the manual technique will be respectively reduced and increased. If density is found to be correct using a manual setting, but incorrect with automatic exposure, the cause is probably a fault in the automatic exposure system.

It is particularly important to test the automatic exposure control when the films are not developed immediately, but are sent for processing at a central location. A fault in the X-ray equipment can lead to abnormal mAs values when using the automatic exposure control, and in this way can be discovered in good time before too many women have undergone an incorrect X-ray examination, which must then be repeated subsequently.

8.2. Weekly tests

8.2.1. Film processing

The whole sensitometer curve is evaluated (see Appendix IV, Paragraph 2.2). Base plus fog, sensitivity expressed in step numbers which give net density of 1.0, and contrast values in the different parts of the curve are measured and quantified (see Appendix IV, 2.2). Suitable levels at which measurements need to be taken may be: ≤ 0.03 for the increase in the base plus fog, $\pm 10\%$ for the sensitivity (corresponds to ± 0.3 step for sensitometers with a step spacing of 0.15 log exposure), and $\pm 3\%$ for the different contrast values.

8.2.2. Cassettes

The intensifying screens are quality checked visually in respect of dust, dirt or marks and are cleaned as appropriate.

8.3. Monthly tests

8.3.1. Cassettes

The intensification screens are cleaned with a cleaning fluid intended for

that purpose. The date of cleaning should be noted in a register.

8.3.2. Image quality

The image test phantom is exposed using the same exposure data and the same cassette as in the reference case. The different structures in the mammogram, such as the spacial resolution, contrast, low contrast detectability and anatomical details, are compared with the reference image. In order to be able to make a reliable comparison with the reference image, it is desirable for the densities to be identical within ± 0.1 . More often than not, such small changes in exposure as may be required here cannot be achieved directly with the X-ray equipment. They can be achieved as a rule, however, by adopting the following procedure: when using the automatic exposure control system, movement of the sensor for this system will produce a change in the exposure, and the choice of position is often continuous. In other cases it is possible partially to screen off the sensor, in so doing allowing continuous control of the exposure.

Testing of the image quality is performed for all clinically relevant techniques. The spacial resolution is especially critical in relation to the magnification technique. The small focal spots are often achieved through electronic focusing, and the risk of changes in the focal spot are not non-existent. It is important that the degree of magnification should be the same when comparing the resolution capacity on different measurement occasions.

8.3.3. Automatic exposure control systems

The test described under 5.1.2 is repeated for a thinner homogeneous phantom (20 mm thick) and for a thicker phantom (60 mm thick). The film density and the mAs values are compared with the reference values. Any deviation of the density from the reference value should not exceed ± 0.2 , and the deviation in the mAs values should not exceed $\pm 10\%$. The X-ray films are examined visually for evidence of the grid lines. An incorrect pattern of movement of the grid often leads to the grid structure appearing

on the film. Such a fault should be corrected immediately, as clinically significant structures may be concealed.

The exposure times are often relatively long for the magnification technique, sometimes as much as several seconds. The reciprocity failure effect can influence the density in exposures of this kind, and any deviations from the reference value may have been caused as a result of the new film stock exhibiting a different reciprocity dependency from the previous stock (see page 4, checking the quality of new films).

8.3.4. Stereotactic attachments

Stereotactic attachments are used in conjunction with sampling and localisation. The requirements for accuracy are considerable, being of the order of magnitude of one millimetre for the small tumours which are revealed by mammography screening. In addition to the daily clinical test with the help of verification images after localisation/application of the needles, a specific test should be performed on a suitable phantom. The position of the tip of a needle, for example, estimated with the help of the stereotactical images should not deviate by more than 2 mm from the intended position.

8.3.5. Compression

The compression force is measured, for example with a set of bathroom scales. The reading is compared with the value indicated on the X-ray equipment, if this is available. Where the maximum force is capable of being varied, and where there is no measuring instrument on the equipment to indicate the value, if possible a fixed scale should be applied to the adjusting wheel and calibrated against the measurements taken with the scales.

8.4. 6- to 12-monthly tests

All the tests described under tests of Performance and Functioning (Appendix IV) should be repeated at least once annually. Additional tests must be performed after

servicing, if these can influence the performance. The whole measurement programme shall be carried out, for example after an X-ray tube is replaced.

Checking the cassettes with regard to attenuation, film-screen contact and relative sensitivity should be carried out if it is suspected that a change has taken place. The annual test may possibly be restricted to a random sample.

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Appendix I: Performance requirements for mammography systems

Optimization leads to the following performance requirements on the X-ray equipment, film-screen-processing and viewing conditions. These requirements are applicable both to screening and to clinical mammography.

X-ray equipment:

The X-ray equipment shall satisfy the general requirements stipulated in IEC safety standards IEC 601-1 (Medical electrical equipment) and IEC 601-2-7 (Particular requirements in respect of X-ray generators) and in IEC radiation protection standard (at present Draft 62B(Sec)131). The following additional performance requirements can be deduced from requirements imposed on the image quality which shall be capable of being achieved with reasonably short exposure times:

Anode material:

For screening, molybdenum. A tube with a tungsten electrode and appropriate K-edge filtration may offer certain advantages in clinical mammography in certain cases.

Tube voltage:

Should be capable of being set to between 25 kV and 30 kV (between 22 kV and 30 kV for equipment with a tungsten anode), in steps of 1 kV. Agreement between the indicated and actual tube voltage should be within $\pm 5\%$.

Tube current:

This should be sufficiently high to permit the exposure time to be kept reasonably short - it should not be significantly greater than 1 s for a breast of normal size in the case of contact mammography. Where the grid technique is used, this means that the tube current should be at least 80 mA.

Focal spot:

≤ 0.4 for contact mammography and ≤ 0.1 for the magnification technique (according to IEC 336).

Note: The spacial resolution for the whole mammography system should be at least 15 line-pairs per millimetre for structures in the middle of a 45 mm thick phantom.

Filtration:

film plane of $\leq 70 \mu\text{Gy}$. This is applicable to a tube voltage of 25 kV and a 45 mm thick plexiglass phantom.

Limiting resolution:

≥ 20 pairs of lines per millimetre. Applicable to the film-screen system in itself, without the influence of the focal spot (i.e. with infinitely small focus).

Processing:

This shall be optimized with regard to contrast, fog and sensitivity. The values for the developer temperature, development time and replenishment rate shall be selected so that the highest contrast and sensitivity are achieved without any increase in fog density. The characteristic curve should then satisfy the following criteria:

Base plus Fog	≤ 0.20
Contrast in the toe (between net density 0.25 and 0.5)	≥ 1.6
Contrast in the straight part (between net density 0.5 and 1.5)	≥ 3.0
Average contrast (between net density 0.25 and 2.0)	≥ 2.8

It should be noted that it is not possible with all films and development chemicals to meet the requirements for the appearance of the characteristic curve, and at the same time to achieve high sensitivity.

Centralized development often involves a long time between the exposure and development of the film, even up to 24 hours. This can lead to a loss of sensitivity due to fading, resulting in an increased dose. The extent of this effect should be investigated, and the procedures should be adapted wherever possible in such a way as to minimize any negative consequences.

Absolute sensitometry is difficult to perform, especially under field conditions. The appearance of the characteristic curve may vary for the different sensitometers, not simply with regard to its position (sensitivity step), but also with regard to its form, which is influenced by, amongst other things, the uniformity of the distances between the steps on

the sensitometer scale and by the exposure time. Also, films of the same type can vary between different emulsions, and the development processes exhibit unavoidable variations. Account must be taken of these potential sources of error when evaluating and assessing sensometrical results.

Examination conditions:

A facility for turning down the background lighting should be provided in the viewing room. The viewing box should have even lighting over the whole of its illuminated surface and should be free from disturbing reflections from windows, lamps, etc. Any light to the side of the X-ray films should be capable of being screened off so as to eliminate distracting dazzle when evaluating the film. A magnifying glass (Mattsson's glass) and an extra-strong viewing lamp should be provided for examining dark areas of the mammogram.

Appendix II: Image quality parameters

The following parameters in the final mammographic image are of primary interest for high image quality.

Contrast:

Both the radiographical contrast and the film contrast must be high in order for small differences in density or atomic composition to be capable of being identified. The radiographic contrast is influenced by the radiation quality (tube voltage, ripple, filtration, anode material) and by the proportion of scattered and extrafocal radiation. The film contrast is determined by the characteristic curve (gradient) of the film.

Spacial resolution:

A high spacial resolution is important for the ability not only to detect small structures (microcalcification), but also to visualize their form. The capacity is affected primarily by the size of the focal spot and by the degree of magnification. In the case of an object at the middle of a breast of normal thickness, the objective should be to achieve a capacity of 15 lines per millimetre (at magnification of 1.05). It may, however, be acceptable to use a somewhat poorer resolution if the radiation intensity can be increased sufficiently due to the higher loading capacity of an X-ray tube with a larger focus. The shorter exposure times reduce the risk of unsharpness due to movement and produce a potential reduction in the dose due to the reciprocity failure effect.

Noise:

Noise from a variety of sources is present in the X-ray image: screen noise (related to the crystal structure in the intensifying screen), film noise (related to the grain size) and quantum noise due to the statistical fluctuation in the number of photons which make up the X-ray image.

There is also a series of other, less easily definable characteristics which have an effect on the image quality, and thus on diagnostic accuracy. For example, the appearance of the characteristic curve as a whole, and not simply that of the straight part where the

mean contrast and sensitivity are defined, is of great significance: the shape of the curve at the toe and at the shoulder, and the value of base plus fog and the maximum density have a critical influence on the appearance of details in the light and dark areas. The ambient lighting, the colour temperature and intensity of the viewing box, and the colour of the film base affect the visual impression to a high degree, which is also perceived differently from one individual to the next.

In spite of the existence of a number of areas of uncertainty and individual variations, it is still possible to stipulate certain physical and technical minimum requirements. These must be met in order for the diagnostic output to be on the whole satisfactory.

Appendix III: Dose calculation

The calculation of the dose is performed in accordance with the method set out in M. Rosenstein et al, "Handbook of Glandular Tissue Doses in Mammography" (Rosenstein, 1985). On the basis of the radiation quality (HVL - half-value layer) and with the air kerma free in air at the plane of the skin, values are given here for the absorbed dose in the tissue of the mammary gland, i.e. the part of the breast which is considered to be responsible for the predominant proportion of the radiation risk. The "standard breast" is assumed to be composed of 50% of fatty tissues and 50% of glandular tissues. It can be simulated closely using PMMA, polymethyl methacrylate, the commercial names for which include plexiglass, perspex and lucite, of identical thickness. The reference thickness used when comparing different techniques is 45 mm.

Table I shows the conversion factors between the air kerma and the absorbed radiation dose for different radiation qualities and thicknesses. The values have been converted from the corresponding Table in Rosenstein 1985 (see literature references) from the exposure in R to the air kerma in Gy and from mrad to mGy. The values for 45 mm were obtained by interpolation between adjacent values.

Table I Absorbed dose in mammary gland tissue in mGy per 1 Gy input air kerma free in air. The Table relates to hard compression, even breast thickness, with 50% (% by weight) mammary gland tissue and 50% fat.

HVL Thickness of compressed breast

mm Al	30	40	45	50	60	70	mm
0.3	250	200	180	160	130	110	for Mo anode
0.4	---	250	225	200	165	---	for Mo anode
0.3	250	210	190	170	145	115	for W anode
0.4	---	270	245	220	185	---	for W anode

Legend: --- = no values shown in reference work consulted.

The dose values for the W anode were calculated for conventional filtration. The dose calculation model is not valid for so-called K-edge filtration, where the average radiation

dose absorbed in the mammary gland tissue must be calculated separately. Calculations of this kind can be found to a certain extent in the reference material (Servomaa and Tapiovaara, 1989). Supplementary data are to be published shortly by the same authors.

The following practical advice can be given in respect of the calculation of the dose: The complexity of the situation has unavoidably had to be simplified in order to permit the calculations to be made at all. It may be permissible to make further changes, therefore, on condition that they have only a marginal effect on the results. Such a deviation can be made when determining the input parameters, i.e. the half-value layer and the air kerma free in the air at the input plane.

The values for the two parameters must be determined after the radiation has passed through the compression plate. The half-value layer can certainly be measured with the compression plate in the radiation path, although this would involve an additional measurement since the half-value layer without a plate should be measured in every case in order to determine the radiation quality. The compression plate also lies in direct contact with the breast, which is then also struck by secondary radiation. The radiation dose absorbed in the breast is then not the same as it would be if the plate were a part of the filtration arrangement inside the X-ray tube. Finally: a 4 mm thick outer layer, which is considered not to contain mammary gland tissue, is excluded according to the calculation model, although in reality this layer may be both thinner and thicker.

The following practical approach is recommended: the air kerma free in the air at the input plane to the breast is measured after the radiation has passed the compression plate. The measurement is performed using a flat ionization chamber positioned directly beneath the compression plate. The half-value layer without the compression plate is used for the second parameter contained in the dose calculation model.

Appendix IV: Testing of performance and functioning (status test)

This includes measurement of the tube voltage (peak value and ripple), the dose per set mAs, the half-value layer, the focal spot size, the function of the automatic exposure control system, the sensitivity of the film-screen system, the limitation of the entrance field size, and the compression force. Part of these tests calls for the use of advanced measurement equipment and requires special skills. The quality control should be carried out by or together with the supplier, hospital physicists or radiation protection authorities.

1. X-ray equipment

1.1. Tube voltage

If possible, the tube voltage should be measured on a single occasion using a direct method, at the same time as which an indirect method is calibrated for that particular item of X-ray apparatus. Measurement using a voltage divider is one example of a direct method. This method must only be used by authorized and competent personnel, as it involves intervention in the high-voltage circuit of the X-ray equipment (the method is described in Spri, 1987 in the reference material). The most common indirect method involves measurement with an electronic penetrometer (e.g. DIGI-X). It is difficult to achieve satisfactory accuracy for different types of mammography equipment using indirect methods with the same calibration. The special appearance of the spectrum with the predominant characteristic X-ray radiation at 17 and 20 keV, and with greater attenuation above 20 keV with the help of edge filtration (Mo filter), means that the spectrum is influenced to a less degree by variations in the tube voltage. The indirect methods of measurement are nevertheless capable of producing excellent results with individual calibration.

An indirect method must be used if direct measurement of the tube voltage is not possible (for example, in the case of high-frequency apparatus or when measuring equipment is not available). Calibration performed on X-ray equipment of the same make and model should, as a rule, give small systematic errors which originate from differences between the two X-ray

spectra. It is possible to gain a good idea of whether the measurement result is correct with the help of additional measurements: measurements performed on a number of items of mammography equipment of different makes and models revealed that, at an (actual) 25 kV, the half-value layer (HVL, see 1.3) lies between 0.25 and 0.28 mm Al, and the attenuation factor for 45 mm plexiglass between 40 and 50. The attenuation factor is the ratio of the input dose and the exit dose, including scattered radiation, and standardized to the same focus distance.

If the X-ray tube has two foci (normal focus and microfocus), the tube voltage should be measured for both. The actual tube voltages may differ considerably for the same nominal value when the tube current differs widely between the two foci. The shape of the curve and the ripple for the tube voltage can only be measured by the indirect method if this shows a calculated tube voltage curve. The variation in the dose yield, measured with a semiconductor, ionization chamber or similar, is a function of the tube voltage with an exponent which is greatly dependent on the filtration and is also affected by any variations in the tube current. It should also be noted that most electronic penetrameters do not give correct results with medium- and high-frequency generators; this is true of both the peak value and the ripple.

1.2. Dose per mAs

These measurements serve a number of purposes:

- test of the linearity between the set mAs and the dose;
- dose per mAs at different mAs values for simplified dose determination;
- as a reference for future measurements in order to be able to identify changes early.

The measurements should be made using an ionization chamber suitable for the purpose. Its energy dependence for the different spectra which occur within mammography should be less than $\pm 5\%$. A small, flat chamber has the



advantage that the measurement geometry (e.g. the effective focus distance) is accurately defined, and that the measurements of the transmission through the phantom can be performed and interpreted directly. The disadvantage of the small volume is that it is associated with small signals, especially when taking measurements behind a phantom.

TL dosimeters are not particularly suitable for the measurement of the dose output at regular intervals. On the other hand, they can be used readily for measuring the surface dose and the depth dose curve in a phantom, thereby determining the average absorbed radiation dose. This assumes, of course, that the energy dependence is known for the relevant energy spectra, and that low doses (for example, on the exit side of the phantom) can be measured with sufficient accuracy ($\leq 10\%$).

Dose mAs measurements:

These measurements are carried out free in air without additional filtration. The exposure data should cover the range used clinically: the air kerma is measured for mAs values between approximately 10 mAs and 200 mAs for the one or more tube voltages which are relevant. Absolute calibration of the ionization chamber is not necessary if it is simply wished to determine the conformity between the mAs values and the dose. The energy dependence may be quite poor without having a noticeable influence on the result.

An absolute calibration is required, on the other hand, if it is wished to determine the patient dose or the standard dose (= the average absorbed dose under standardized conditions). The measurement geometry must also be determined accurately. The radiation dose (= air kerma) can then be calculated for different distances between the detector and the focus, with the help of the inverse square law. Ionization chambers are usually calibrated free in the air. Chambers of the transmission type can cause problems. The detection capacity for radiation emerging from the rear is equal to, or almost

as great as from the front, and it may prove difficult from a purely geometrical point of view to instal the chamber in such a way that it is free from back scatter. One solution may be to calibrate the chamber with a radiation absorber fitted to the rear side of the chamber, and to carry out the measurements with the absorber in place.

In the case of modern equipment, the kerma value per mAs generally lies within $\pm 5\%$ for all the mAs settings in the above range. Fluctuations in the mains voltage supply can influence the radiation output per mAs, although probably not to such an extent that they involve unacceptable inaccuracy. Patient dose measurements and other measurements are simplified in this way. It is sufficient simply to note the mAs value. The radiation dose can then be calculated directly from the dose/mAs relationship.

1.3. Half-value layer (HVL)

The half-value layer is used on the one hand for the additional check of the radiation quality (= tube voltage), and on the other hand as one of the variables for calculating the average dose absorbed in the breast. The measurement must be performed in so-called good geometry, with a small entrance field size and the aluminium attenuators half way between the focus and the detector, i.e. in practice at a focus distance of 20 to 30 cm. The degree of purity of the attenuators should be $\geq 99\%$. The energy dependence of the detector for the different radiation qualities within a series of measurements is critical: a deviation of 5% gives an error of 10% in the half-value layer, i.e. typically of 0.03 mm Al.

1.4. Focal spot and spacial resolution

The correct standard method for determining the focal spot is based on the slit method (IEC 336). The measuring equipment for this method is expensive and is not generally available. The star test pattern method is a simpler way to determine the focal spot. This method, too, is described in IEC 366,

Section 7¹. it gives a good idea of the imaging characteristics of the focus, although not always with the strictly correct numerical values in accordance with the standard. A star test pattern with a graduation of 0.5° or 1° and a magnification factor of the order of magnitude of 2 is recommended for nominal focal spots of ≤ 0.6 . Using direct film, 25 kV and 10-20 mAs will then generally provide acceptable film density (with the film at a focus distance of 50-60 cm). Measurement should be performed with radiation aimed at a point close to the wall of the chest (3 cm from the edge), which is the most interesting area from the clinical point of view. A test should be performed using the slit method in order to substantiate - or refuse - the deviation if the result has a value outside the tolerances.

It should also be noted that the reference axis in respect of which the focal spot is defined may be specified differently for different makes of equipment. The reference axis is normally the line perpendicular to the longitudinal axis of the X-ray tube passing through the centre of the focus (and perpendicular to the image plane, which is parallel with the longitudinal axis of the X-ray tube as a rule). The X-ray tube is often installed in mammography equipment at a slight inclination into the tube housing. The direction of the reference axis specified by the manufacturer, which is the direction given in the specification, may thus differ from the standard direction, i.e. it need not be perpendicular to the image plane.

The nominal focal spot does not necessarily exhibit a strict correlation with the spacial resolution of the mammography system. On the one hand the standard

¹ The standard describes how the limiting resolution for a star test pattern is calculated. The focus dimensions are calculated according to the formula

$$f_{W(L)} = \frac{Z_{L(W)} \cdot \pi \cdot 6}{180 \cdot (M - 1)}$$

where $f_{W(L)}$ = focal spot in the transverse (longitudinal) direction, $Z_{L(W)}$ = diameter of the blurring zone in the longitudinal (transverse) direction, σ = angle of the attenuating wedges of the pattern, and M = magnification factor.

permits large tolerances, and on the other hand the measurement procedure for compliance favours the manufacturer very considerably, with the maximum tube voltage and half the maximum tube current as a rule providing smaller focus dimensions than under clinically relevant operating conditions. Measurement of the focal spot should, therefore, be supplemented by a measurement of the spacial resolution of the system. This can be done either with a line test pattern, or with the star test pattern. The line test pattern should be positioned at the centre of a 40 to 45 mm thick phantom, and the resolution in both directions should be at least 15 line-pairs per millimetre. The limiting resolution for a magnification of 1.06 (typical of contact mammography) and of 1.8 (typical of the magnification technique) can be calculated from the aforementioned measurement with the star test pattern. The limiting resolution should be at least 15 pairs of lines per millimetre.

1.5. Automatic exposure control systems

A modern automatic exposure control system should be capable of producing films with the same density to within ± 0.2 irrespective of the thickness of the object, the tube voltage and the examination technique (normal, grid, magnification). This is verified by taking exposures of homogeneous phantoms, preferably made of PMMA, of varying thickness from 20 to 60 mm, using the clinically relevant tube voltages and techniques. The same cassette should be used for all the exposures, since the cassettes can differ in attenuation or sensitivity. The net density, measured 3 cm from the edge on the wall of the chest, should lie within the range 1.0 to 1.5. At least four correction steps should be provided in each direction from the zero point, and adjacent steps should provide a change in density of between 0.1 and 0.2.

1.6. Sensitivity of film-screen-processing system

The sensitivity varies with the radiation quality, the object thickness and the exposure time. Measurements should be made under standardized conditions, i.e. using a 45 mm thick phantom (made of PMMA) and at a tube voltage of

25 kV (unless another value is used clinically). For reasons associated with the measurement technique, it is recommended that the phantom be positioned half way between the focus and the film. Exposure is selected so that net density of 1.0 is obtained on the film at a point 3 cm from the edge on the wall of the chest. It is simpler in practice to take two measurements, with film density above and below 1.0, and then to interpolate between these two values. The exposure or, rather, the air kerma must be determined at the film plane. One method is to measure the kerma close to the film plane directly with a TL dosimeter or ionization chamber for each exposure, and then to make a correction according to the inverse square law. Another method is to measure the input kerma to the phantom, and then to calculate the kerma in the film plane with the help of the separately measured transmission through the phantom. The input kerma is then either measured directly or is calculated with the help of the measured mAs value and the relationship between the dose and the mAs.

Note that it is important to measure the kerma respectively above and below the phantom in the direction of radiation towards the point 3 cm from the edge at the wall of the chest, where the film density is measured for the purpose of calculating the sensitivity.

1.7. Entrance field size limitation

The size and position of the entrance field size in the film plane is determined for all clinically relevant combinations of choice of focus, aperture and focus-film distance. The measurement is performed by exposing one or more cassettes. The front edge of the patient support is marked for this purpose, preferably with a paper clip or a coin, for example. The entrance field size must cover the whole of the film at the wall of the chest, and must not extend beyond the film by more than 3 mm. The boundary edges of the film should not be exceeded by more than 10 mm on the other three sides.

1.8. Compression

The compression force is measured and compared in each case with the indication on the X-ray equipment. An ordinary (flat) pair of bathroom scales is ideal for this purpose. Something soft should be placed between the compression plate and the scales, in order to prevent the whole of the pressure from being applied to a small, hard area or edge, which can lead to damage to the compression plate. For example, plastic bags filled with water or air, or small cushions or pouches filled with pieces of upholstery padding are suitable for this purpose.

The compression must be released immediately when the "release" button is activated, and similarly in the event of the interruption of the mains voltage supply to the X-ray equipment.

2. Intensifying screen, film and processing

2.1. Intensifying screen and cassette

The cassettes shall be marked externally with:

- type of intensifying screen
- delivery date
- cassette number

The cassette number shall also be clearly visible on the film.

Before being taken into clinical service, the cassettes shall be tested with regard to:

- relative sensitivity
- attenuation of X-ray radiation
- film-screen contact

The relative sensitivity and attenuation can be measured at the same time, provided that the automatic exposure system of the X-ray equipment is capable of giving reproducible exposures to within $\pm 5\%$. A homogeneous

phantom (e.g. 45 mm thick) is placed above the cassettes. The cassette is exposed by means of the automatic exposure system, so that net film density of 1.2 ± 0.2 is obtained on the film. The same setting of the automatic exposure is used for exposing the different cassettes. The value for the mAs figure is noted, and the film density is measured. The variation in the mAs figures reflects the variation in the attenuation - any cassettes with values outside $\pm 10\%$ of the mean value should be rejected. The film density for all the cassettes should lie within ± 0.1 relative to the mean value. Any cassettes which lie outside this range should be rejected.

A copper net with a mesh size of around 0.6 mm is placed directly above the cassette for the purpose of checking the contact between the film and the screen. The exposure data are selected so that the density between the meshes is from 2.0 to 2.5. It may be necessary to place a homogeneous attenuation block in the path of the radiation in order to reduce the intensity of the radiation. The developed film is then observed from a distance of 1 to 2 metres, when poor film-screen contact will be revealed by the patchy, blurred representation of the mesh.

2.2. Film and processing

The performance of the processing at the time of optimization is documented. Adjustments such as the total transit time and the time spent in the development bath, the temperature in the developer and fixing bath and in the drier, and the rate of fixing and development replenishment are included in the report. A sensitometer test is performed. The sensitometer should have at least 15 steps and should cover the density range from the base plus fog to maximum density. The difference in exposure between adjacent steps shall remain constant over the entire range, preferably with a value of 0.15 expressed as a logarithm of the quotient of the two exposures. The whole of the sensitometer curve is stored and processed for comparison with future tests. The density for base plus fog, the maximum density, the mean contrast

in the density intervals 0.25 to 0.5, 0.5 to 1.5 and 0.25 to 2.0 over base plus fog are compared with the respective recommended maximum and minimum values in accordance with Sos 1990 in the reference material and Appendix I.

Note that the same sensitometer must be used in all future consistency tests. The sensitometrical results may differ significantly between two sensitometers, even if nominally they have the same performance: the density curve is affected by the exposure time, the accuracy of the differences in exposure between two steps, the spectral distribution of the light source, and the effect on this distribution caused by the absorbers for the different steps and of the spectral sensitivity of the film. Thus, two sensitometers can give different contrast values for the same film-processing system - a factor which should be taken into consideration when evaluating and comparing different film processors one with the other on an absolute basis.

3. Image quality and dose

The physically measurable image quality is determined by imaging a suitable phantom. The phantom should contain structures which permit the measurement of the spacial resolution, the low contrast detectability (contrast-detail diagram), the numerical value of the contrast, and the visibility of anatomical structures such as microcalcification. It is important to keep to a specified area of density for the purpose of image quality tests which are based on the comparison of test images with a reference image: the clarity and the visual impression are influenced greatly by the density of the film.

The average absorbed radiation dose in a standard breast which is achieved by the technique in question is calculated in accordance with the method described in Appendix III. The necessary measurement values are the half-value layer (in mm Al) and the air kerma free in air at the input plane. The latter is either measured directly when imaging or is calculated from known relationships between the dose (= air kerma) and the measured mAs value. The relationship is converted in accordance

