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REPORT ON NORDIC
RADIATION PROTECTION CO-OPERATION

No. 7
**A Quality Control Programme for Radiodiagnostic
Equipment :
Acceptance tests**

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

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INTRODUCTION

The aim of a quality assurance programme is to assist a radiodiagnostic facility in consistently obtaining adequate radiological information with a minimum of dose and a minimum of cost.

An integrated part of a quality assurance programme is quality control ascertaining quality by measurements and other procedures.

The principle of a quality control programme relating to radiodiagnostic equipment is outlined in figure 1.

When procuring equipment a specification is worked out taking into account all aspects of the performance of the equipment including the desired tolerances of technique factors.

Immediately upon installation or major repair or modification of the equipment an acceptance test is carried out to check the compliance of the equipment with the specifications. The acceptance test comprises many different tests on both components and the equipment as a whole and it consists of absolute measurements. The extent of the test will depend on how far the contractual specifications go into details. Such a test will be the responsibility of a qualified physicist or engineer.

The status test is carried out in order to establish the functional status of the equipment. The test is performed immediately after the acceptance test or as an integrated part of it.

The test will be repeated when repair influencing the functional status has taken place like the

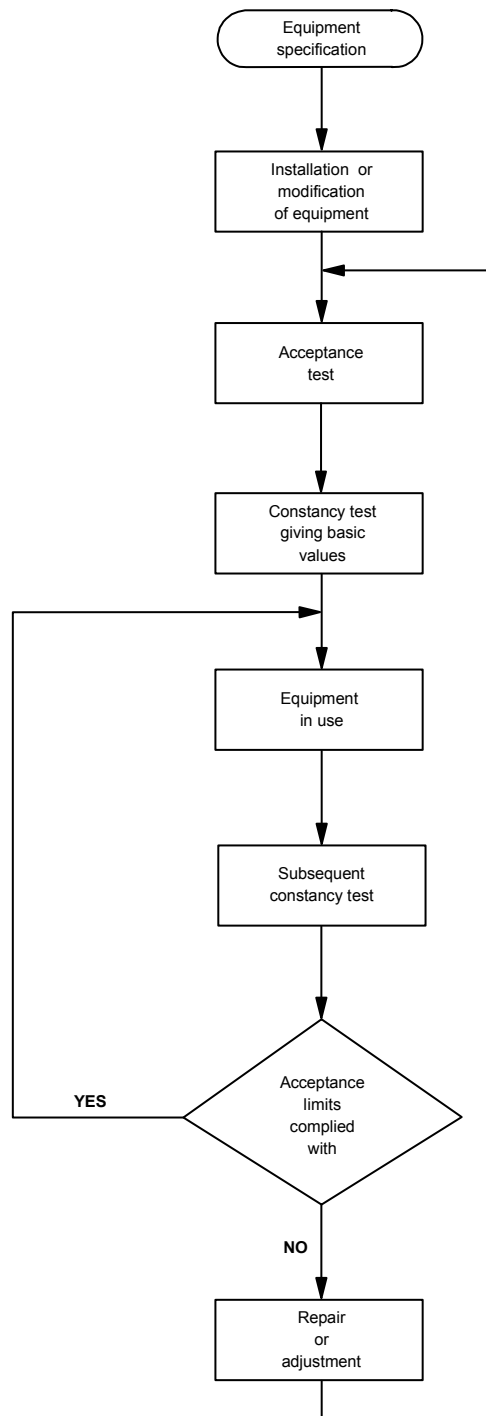
acceptance test, the status test will comprise absolute measurements and will likewise be the responsibility of a qualified physicist or engineer.

The constancy test is carried out as soon as the preceding tests have shown that the equipment is performing satisfactory. This constancy test will form the basis for further constancy tests making it probable that the performance is within the established baseline values. Such tests are carried out at regular intervals or when performance problems are encountered in daily practice. If the baseline values are not met repair or adjustments must be performed and a new status test must be made. The constancy test is a relatively simple and cheap test and will generally be the responsibility of radiographers and technicians. However, when setting up constancy tests the assistance of a qualified physicist or engineer may be needed.

In this report the Nordic Radiation Protection Authorities propose a program for acceptance tests relating to radiodiagnostic equipment but only to items having an influence on dose or image quality leaving out the electrical and mechanical part. The program is not extensive but is aimed at facilities without a waste experience in the field. The tests proposed are described to an extent so an experienced person with knowledge in physics or technology should be able to perform them. In a few cases it will, however, be necessary to consult the literature referenced due to the complexity of the test.

For certain types of equipment some of the tests proposed in this document cannot be applied or are not relevant. In such cases other tests suitable for the purpose should be applied.

Figure 1. Principle of a quality control programme.



LIST OF TERMS

QUALITY ASSURANCE: Planned and systematic actions necessary to provide adequate confidence by ensuring that a product or service will satisfy given requirements for quality.

QUALITY ASSURANCE PROGRAMME: Detailed instruction for carrying out actions of quality assurance for individual items of equipment, systems of equipment or facilities, including quality administrative elements and quality control techniques.

QUALITY CONTROL: Operational techniques and activities that are used to fulfil requirements for quality.

ACCEPTANCE TEST: Test carried out after new equipment has been installed, or major modifications have been made to existing equipment, in order to verify compliance with contractual specifications.

STATUS TEST: Test carried out to establish the functional status of equipment at a given time.

CONSTANCY TEST: Tests, carried out to ensure that the functional performance of

equipment meets established criteria.

BASELINE VALUE: Reference value of functional parameter obtained for this parameter in the initial constancy test immediately following a status test.

ESTABLISHED CRITERIA: In a quality assurance programme, acceptable variations in results of a constancy test which signals satisfactory functional performance of the equipment tested.

General X-ray equipment - Diagnostic X-ray generators

Accuracy of Tube Voltage

Test equipment:	Electronic penetrometer.
Test procedure:	Test is performed at lowest tube voltage, 60 kV, 80 kV, and highest tube voltage, at 50% or more of the highest available tube current and an exposure time of approximately 0.1 s. At 80 kV the measurement shall be carried out also at the lowest and highest available tube current settings. One measurement at each tube voltage. The whole series is performed for each focal spot.
Evaluation:	Comparison of penetrometer measurement and set tube voltage
Tolerance:	Agreement $\# \nabla 5\%$ for each measurement of tube voltage

Reproducibility of Output

Test equipment:	Dosimeter and aluminium absorber 20 mm.
Test procedure:	With the absorber placed in the beam close to the focus five dose measurements are performed at about 80 kV. The five measurements are performed at identical settings each time, however, in between the measurements the settings like focus, tube voltage, current-time-product are moved away from the values used for the measurements. The test is performed for one focus.

General X-ray equipment - Diagnostic X-ray generators

Evaluation: Comparison of the five dose measurements.

Tolerance: Coefficient of variation $\frac{S}{X} < 0.05$

where s is standard deviation of the five measurements
and x is mean of the five measurements

Linearity

Test equipment: Dosimeter and aluminium absorber 20 mm.

Test procedure: With the absorber placed in the beam close to the focus five dose measurements in the interval from the lowest mAs to 400 mAs are made at 90 kV. One measurement for each setting of the current-time-product. The dose per mAs is calculated. Measurements are performed for one focus.

Evaluation: Comparison of dose per mAs between adjacent mAs-settings.

Tolerance: The dose per mAs between any two adjacent settings must not deviate more than 10%.

General X-ray equipment - Diagnostic X-ray generators

Exposure time

Test equipment: Electronic penetrometer providing display of exposure time.

Test procedure: The exposure time is measured at five settings in the interval from the lowest available or 5 ms whichever is higher to 1s. A measurement must be performed at 100 ms. The test is made for one of the focus.

Evaluation: Comparison of measurement and set time.

Tolerance: $t_i \neq 20 \text{ ms: } \frac{|t_m - t_i|}{t_i} < 0.20$

$20 \text{ ms} < t_i \neq 50 \text{ ms: } \frac{|t_m - t_i|}{t_i} < 0.10$

$t_i > 50 \text{ ms: } \frac{|t_m - t_i|}{t_i} < 0.05$

where t_m is measured exposure time
and t_i is indicated exposure time

General X-ray equipment - Automatic exposure control

Overall Reproducibility

Test equipment:	Plexiglass test object 30 cm x 30 cm and 20 cm thick. X-ray films.
Test procedure:	<p>Place the test object close to the imaging system. Adjust the beam size to 20 cm x 20 cm measured at the input surface of the test object.</p> <p>In any case all three ionisation chambers must be within the beam.</p> <p>Select all three chambers to operate in combination. The tube voltage is set at 80 kV. Make one exposure on each of four films. The net densities should be in the range 0.9 to 1.4.</p>
Evaluation:	Compare the densities of the four films.
Tolerance:	The variation in densities from the four exposures $\# \nabla 0.2$.
Reference:	HPA IV

Consistency between Chambers

Test equipment:	Plexiglass test object 30x30 cm and 20 cm thick. X-ray films.
Test procedure:	<p>Same set up as for the test "<u>Overall reproducibility</u>". Perform three exposures selecting each of the three chambers in turn.</p> <p>The net densities should be in the range 0.9 to 1.4.</p>

General X-ray equipment - Automatic exposure control

Evaluation:	Compare the densities of the three films.
Tolerance:	The variation in densities from the three exposures # ∇ 0.2.
Reference:	HPA IV.

Consistency with Change in Tube Voltage

Test equipment:	Plexiglass test object 30 cm x 30 cm 14 cm thick. X-ray films.
Test procedure:	Same set up as for the test " <u>Overall reproducibility</u> ". Perform three exposures with the same chamber selected each time, but at a tube voltage of 60 kV, 80 kV and 100 kV. The net densities should be in the range 0.9 to 1.4.
Evaluation:	Compare the densities of the three films.
Tolerance:	The variation in densities from the three exposures # ∇ 0.2.
Reference:	HPA IV

Consistency with Change in Patient Thickness

General X-ray equipment - Automatic exposure control

Test equipment:	Three plexiglass test objects 30 cm x 30 cm 5 cm thick, 10 cm thick and 20 cm thick.
Test procedure:	Same set up as for the test " <u>Overall reproducibility</u> ". Perform three exposures with the same chamber selected each time but with the three different test objects. The net densities should be in range 0.9 to 1.4.
Evaluation:	Compare the densities of the three films.
Tolerance:	The variation in densities from the three exposures $\# \nabla 0.2$.
Reference:	HPA IV

General X-ray equipment – Diagnostic X-ray tubes

Filtration:

Test equipment:	Data sheet on inherent filtration of X-ray tube, beam limiting device etc. or dosimeter and Al-absorbers for HVL-measurements.
Test procedure:	The beam limiting device etc. is removed for checking filtration of removable filters. Inherent filtration of the tube and filtration of beam limiting device is taken from data sheets or from marking, and total filtration is calculated. Total filtration can also be assessed by measuring the half value layer at a known tube voltage and relate the half value layer to total filtration by means of the data given in the reference.
Evaluation:	Comparing estimated values with requirements.
Tolerance:	Total filtration ≥ 2.5 mm Al (excluding mammography).
Reference:	IPSM 64

Size of Focal Spot

Test equipment:	Star test pattern and holder. X-ray film in cassette with slow screens. A sheet of paper can be placed in the cassette over the back screen absorbing the light emitted from this screen.
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General X-ray equipment – Diagnostic X-ray tubes

Test procedure:	The magnified image of the star test pattern is reproduced on a film. An "effective" size of the focal spot can be estimated from the size of the blurring on the image.
Evaluation:	Calculating the "effective" size F. $F = \frac{2 \cdot \Pi \cdot D}{180} \cdot \frac{1}{(M - 1)}$ <p>(Valid for a star test pattern with a 2 degree spoke angle). where D is the blurring diameter of the test object. M is the geometrical magnification.</p>
Tolerance:	Absolute measurements of the focus size cannot be performed. But the measured "effective size" can be used to detect gross deviations from the first measured "effective" size at subsequent measurements.
Reference:	HPA 1.

General X-ray equipment – Field size and alignment

Light Beam Diaphragm Alignment

Test equipment:	X-ray film in cassette. Alignment tool or short wires bent to form a 90° angle.
Test procedure:	The alignment tool is placed on the cassette according to the instructions for use, or the corners of the light field is marked by the wires. An exposure is made.
Evaluation:	The film demonstrates the position of the light beam relative to the radiation beam.
Tolerance:	Distance between light beam and radiation beam shall be # 1% of the focus-film distance in each direction.
Reference:	HPA 1.

Position and Size of the Radiation Field

The purpose of this test is to confirm that the position (alignment) and the size of the radiation field comply within specified tolerances with the indicated/expected values. It is beyond the scope of this document to describe in detail the tests for all the various and numerous configurations that exist. Only the principles are referred to - for details see the reference.

Test equipment:	Test plate with radio-opaque scales in two orthogonal directions and markers to indicate field edges. Film cassette(s).
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General X-ray equipment – Field size and alignment

Test procedure:

The entire field size is visible on the film exposed in a cassette in the cassette holder:

Position the test plate between the X-ray tube and the loaded film cassette close to the cassette (i.e. on the table top for stands with over-couch tubes). Adjust the field size according to the mode to be tested (light field indicator, numeric indicators, automatic field limitation).

The entire field size is not visible on the film exposed in a cassette in the cassette holder:

Proceed as for a) but place a second cassette (large enough to cover the entire radiation field) in close contact with the test plate, on the exit side. Adjust the field size according to the mode to be tested (light field indicator, numeric indicators, automatic field limitation).

Evaluation:

Determine on the processed film the field size and the position of its centre and compare with the expected values. Measure the distance between two markers on both films and calculate the magnification factor. Determine the field size on the processed film from the cassette close to the test plate and multiply these dimensions with the magnification factor in order to get the dimensions in the position of the cassette holder. Determine the position of the centre of the radiation field (relative to the markings from the test plate) and identify the corresponding position on the film from the cassette in the cassette holder. Measure the misalignment relative to the centre of the film.

Tolerance:

All field sizes should comply with what is indicated/expected within 1% of the focal spot image

General X-ray equipment – Field size and alignment

distance. The alignment to the image receptor should be within 1% of the focal spot image distance.

Reference: IEC 61223-3-1.

General X-ray equipment - Image intensifier and television systems

The tests stated for image intensifier and television systems are based on the Leeds TORFG test object described in ref: LEEDS. The test object is obtainable from FAXIL, Academic Unit of Medical Physics, University of Leeds, UK.

Exposure Rate at Image Intensifier

Test equipment:	Copper sheet 1.5 mm or aluminium 25 mm thick. Dosemeter.
Test procedure:	<p>The copper or aluminium absorber is placed as close to the focus as possible and the measuring chamber as close to the input screen of the image intensifier as possible. The measuring chamber should be of the transmission type in order not to influence the dose rate regulation of the imaging system.</p> <p>The grid should be removed during the measurement. If this is not possible information from the manufacturer about the extent of the effect of the grid on primary beam absorption should be obtained. The automatic brightness control should be set to the highest dose rate and the intensifier input field size closest to 25 cm should be selected.</p>
Evaluation:	The measured dose rate and the values indicated under tolerance are compared.
Tolerance:	Dose rate # 0.5 $\mu\text{Gy/s}$. For intervention, angiography and the like # 1.0 $\mu\text{Gy/s}$.
Reference:	IPEMB 32.

General X-ray equipment - Image intensifier and television systems

Useful Fieldsize

Test equipment:	Copper sheet 1 mm. Rectangular wire grid with pitch 2 cm.
Test procedure:	Place the copper sheet as close to the focus as possible. The wire grid is placed in close contact with the input screen of the image intensifier.
Evaluation:	Compare the image field size displayed on the video monitor with the nominal size stated by the manufacturer. Corrections due to magnification of the image are to be made.
Tolerance:	Ratio of image field size diameter to nominal field size diameter should be in the range 0.85 to 1.0 for a 25 cm nominal field size.
Reference:	IPEMB 32.

Distortion

Test equipment:	Leeds TORFG test object. Copper sheet 1 mm.
Test procedure:	Fix the test object as near as possible to the input screen of the image intensifier. If possible the anti-scatter grid should be removed and the resolution grid of the test object should be oriented at right angles to the monitor lines. If this is impossible the lines of the resolution grid shall be at 45° to

General X-ray equipment - Image intensifier and television systems

the monitor lines. Place the copper sheet as near as possible to the focus. Select 70 kV and set the brightness and contrast controls of the monitor so that the black circle is visible in the dark grey square and the white circle is visible in the light grey square. It is important that tube voltage and tube current have the same value each time the test is performed. The measurement is performed at the largest intensifier input field, it must, however, not be set larger than the field closest to a field diameter of 25 cm. For digital systems the measurements are performed without any image processing.

Evaluation: The structure of the test objects are surrounded by a circle. If this appears non-circular on the monitor the system needs adjusting.

Reference: LEEDS and IPEMB 32.

Low Contrast

Test equipment: Leeds TORFG test object. Copper sheet 1 mm.

Test Procedure: Same set up as for the test "Distortion".

Evaluation: Starting with the darkest count the number of discs that are visible.

Tolerance: Low contrast better than 4%.

Reference: LEEDS and IPEMB 32.

General X-ray equipment - Image intensifier and television systems

Resolution

Test equipment:	Leeds TORFG test object.
Test procedure:	Same set up as for the test " <u>Distortion</u> ". However, the 1 mm copper sheet is removed. Select a tube voltage of 50 kV, and adjust the tube current to give as bright an image as possible without saturating the monitor.
Evaluation:	Starting with the coarsest count the number of line-pair groups that can be resolved.
Tolerance:	Resolution \exists 1.12 lp/mm.
Reference:	LEEDS and IPEMB 32.

Automatic Beam Limitation

Test Equipment:	Film in cassette
Test Procedure:	The cassette is placed as close as possible to the input screen of the image intensifier. For equipment with variable focus-screen distance measurements are performed at the shortest,

General X-ray equipment - Image intensifier and television systems

the one normally used and the longest distance.

Evaluation:

The field size on the film is compared to the field size measured under "Useful Fieldsize".

Tolerance:

For a rectangular X-ray field neither the length nor the width of the X-ray field shall exceed the diameter of the field size measured under "Useful fieldsize".

For equipment for surgery and for a non rectangular X-ray field see ref: IEC 60601-1-3.

Reference:

IPEMB 32.

General X-ray equipment – Digital subtraction angiography systems

The tests stated for digital subtraction angiography are based on the AAPM test object described in ref: AAPM 15. The test object is available from Nuclear Associates NY, USA.

Dose

Test equipment:	Copper sheet 1.5 mm or aluminium 25 mm thick. Dosemeter.
Test procedure:	<p>The copper or aluminium absorber is positioned as close to the focus as possible and the measuring chamber as close to the input screen of the image intensifier as possible. The measuring chamber should be of the transmission type in order not to influence the dose regulation of the imaging system.</p> <p>The grid should be removed during the measurement. If this is not possible information from the manufacturer about the extent of the effect of the grid on primary beam absorption should be obtained. During the measurement the dose regulation system should be set to the highest dose and the largest intensifier input field should be selected.</p> <p>The dose per frame is obtained by division of the measured dose rate by the frame rate.</p> <p>Exposure time should be long enough to permit the automatic brightness control to reach stable values.</p>
Evaluation:	The measured dose per frame is compared with the values indicated under tolerance.
Tolerance:	Range 1 μ Gy to 5 μ Gy per frame.

General X-ray equipment – Digital subtraction angiography systems

Reference: AAPM 15.

Resolution

Test equipment: 15 cm thick plexiglass object. Insert with 3 bar test patterns up to 5 lp/mm. The lead thickness should not be greater than 0.1 mm. If this causes dynamic range problems a lead pattern of 0.01 mm may be used.

Test procedure: A magnification of 1.25 of the bar test pattern should be used.

The resolution is determined horizontally, vertically and at an angle of 45°. Both the subtracted and unsubtracted resolution should be determined.

Evaluation: The resolution is determined at the monitor normally to be used by the radiologist and compared with the theoretical limit of resolution.

Tolerance: There should be no gross deviation from the theoretical limit of resolution as given in the reference.

Reference: AAPM 15.

General X-ray equipment – Digital subtraction angiography systems

Low Contrast

Test equipment:	15 cm thick plexiglass test object with blank insert and low-contrast iodine line pair insert.
Test procedure:	<p>The test object is set up in a geometry similar to that used for patients. The tube voltage should be close to 70 kV. A mask image with the blank insert is taken. Then the low-contrast iodine line pair insert is put into the test object instead of the blank insert.</p> <p>Subtracted images are taken without change of any parameters. When determining the resolution the setting of display and window controls should be optimized.</p>
Evaluation:	The measured low contrast resolution is compared with the resolution needed in the clinical situation taking into account the different vessel size and iodine concentrations.
Tolerance:	The resolution needed in the clinical situation.
Reference:	AAPM 15.

Contrast Uniformity

Test equipment:	Test object assembled as a step wedge, blank insert, low contrast iodine line pair insert and bone section.
Test procedure:	The bone section is placed under the step wedge. The

General X-ray equipment – Digital subtraction angiography systems

direction of the bones should be parallel to the steps whereas the iodine lines should be perpendicular to the steps. The test is performed in the same way as the test "Low Contrast".

Evaluation: The subtracted image is evaluated.

Tolerance: The iodine lines should appear uniform in density and width under the bones and steps. There will, however, be an increase in noise under the thickest part of the test object.

Reference: AAPM 15.

Spatial Uniformity

Test equipment: Test object assembled as a step wedge, blank insert, low contrast iodine line pair insert and bone section.

Test procedure: The test procedure is the same as for the test "Low Contrast".

Evaluation: The difference in distance between any two lines is measured.

Tolerance: When size measurements are performed the distortion found here should be taken into consideration.

Reference: AAPM 15.

Contrast Linearity

General X-ray equipment – Digital subtraction angiography systems

Test equipment:	15 cm plexiglass object, blank insert and linearity insert.
Test method:	As for the test " <u>Low Contrast</u> " a subtracted image is taken.
Evaluation:	An average pixel value is obtained for each of the 6 linearity sections. The pixel values are plotted as a function of the iodine thickness (mg/cm^2) in each section.
Tolerance:	The pixel values as a function of the iodine thickness should fall on a reasonably straight line.
Reference:	AAPM 15.

Artefacts

Test equipment:	15 cm plexiglass test object, misregistration insert.
Test method:	The misregistration insert is placed in the test object. The so assembled test object is used for the mask and the live image, so that two "identical" images are subtracted.
Evaluation:	The auto-subtraction is viewed.
Tolerance:	There should be no evidence of a structure like hole edges, only noise.
Reference:	AAPM 15.

Darkroom and film storage

Light Leaks

Test equipment:	None
Test procedure:	The safelights are switched off. The eyes are dark-adapted for 20 minutes.
Evaluation:	Search for light leaks.
Tolerance:	No visible light leaks.
Reference:	HPA IV.

Darkroom Safelights

Test equipment:	X-ray film, material to cover portions of the film, for example a coin.
Test procedure:	Preexpose the film to either X-rays or light so a uniform density of approximately 1 is obtained. Use a step procedure and cover portions of the film placed on the darkroom work bench so that different strips of the film are exposed to safelights for 0, 0.5, 1, 2, 4 and 8 minutes. In addition place a coin on that strip of the film which is exposed for 4 minutes.
Evaluation:	Visual examination of the film.
Tolerance:	No increase in density. No shadow from the coin.

Darkroom and film storage

Reference: HPA IV.

Illuminators and viewing rooms

Gross Mismatches in Brightness or Colour

Test equipment:	None
Test procedure:	The front of the viewing box is cleaned.
Evaluation:	Check visually for gross mismatches in either colour or brightness.
Tolerance:	No gross mismatch is acceptable.
Reference:	BIR 18.

Brightness Level of Illuminators

Test equipment:	Lightmeter
Test procedure:	Measure the brightness at the centre of the illuminator.
Evaluation:	Compare measured luminance level with tolerance.
Tolerance:	1500-3000 cd/m ² .
Reference:	BIR 18.

Illuminators and viewing rooms

Homogeneity of Illuminator

Test equipment:	Light meter.
Test procedure:	Measure the brightness in the middle of each quadrant of the illuminated surface of the viewing box.
Evaluation:	Calculate the deviation of the measurements from the measurement under " <u>Brightness Level of Illuminators</u> ".
Tolerance:	Maximum deviation < 15%.
Reference:	BIR 18.

Level of Lighting in the Room

Test equipment:	Luxmeter.
Test procedure:	Switch off the illuminator and measure the level of the room illuminance in the viewing position.
Evaluation:	Compare measured illuminance and the tolerance.
Tolerance:	Level of illuminance < 100 lux.
Reference:	BIR 18.

X-ray films, intensifying screens and cassettes

Characteristic Curve of Film

Test equipment:	Sensitometer, densitometer and three films.
Test procedure:	Each of the three films is exposed in the sensitometer, developed and the densities measured with the densitometer.
Evaluation:	The average of speed index, contrast index and base + fog for the three films are established and compared with established values from former badges.
Tolerance:	The difference in speed index and contrast index should be < 0.15.
Reference:	HPA IV.

Film - Screen Contact

Test equipment:	Test grid.
Test procedure:	Place the test grid in contact with the cassette to be tested and expose to X-rays to a density about 2. Allow five minutes from loading the cassette to testing for air bubbles to escape.
Evaluation:	View the film from a distance of 2 to 3 metres.
Tolerance:	No dark areas or spots and blurring of the image of the grid.

X-ray films, intensifying screens and cassettes

Reference: HPA IV.

Relative Screen Sensitivity

Test equipment: Films, densitometer.
X-ray equipment with reproducibility # 5%.

Test procedure: Test cassettes with the same nominal speed together. Load cassettes with film from the same box. Place four cassettes in a square with their corners touching.
One of the cassettes is chosen as reference and all other cassettes with the same nominal speed are tested against this one.
Expose all four cassettes at the same time in order to produce a net film density 0.8 to 1.5.
Measure the densities near the corners, where the cassettes are touching.

Evaluation: Compare all densities to the density of the reference.

Tolerance: Densities should be within \forall 0.1 of the reference.

Reference: HPA IV.

Processors

Appropriate Temperature for Optimum Development.

Test equipment:	X-ray film, sensitometer, densitometer, thermometer.
Test procedure:	<p>Set the temperature of the developer to 28° C. Check the temperature with the thermometer. When the temperature is steady produce a test film by means of the sensitometer. Establish speed index, contrast index and base + fog. Repeat the procedure at developer temperatures of 30, 32, 34, 36 and 38° C. Plot each of the measured values for the three parameters against temperature to obtain three graphs.</p>
Evaluation:	From these graphs the appropriate temperature can be established giving an acceptable base + fog and contrast.
Tolerance:	None.
Reference:	HPA IV.

Mammography – X-Ray source

Size of Focal Spot

Test equipment: None

Test procedure: Compliance of the nominal focal spot value according to IEC 60336 shall be certified and demonstrated by the manufacturer. An indirect check of the focal size value is performed with a high resolution test (see IEC 60336).

Evaluation: Compare size specified by the manufacturer with the tolerance.

Tolerance: The nominal focal value should be # 0,4 according to IEC 60336.

Source to Image Distance

Test equipment: Measuring tape

Test procedure: Measure the distance between the focal spot indication and the top of the bucky. Add distance between bucky surface and top of the image receptor.

Evaluation: Compare measured and nominal value.

Tolerance: Within ∇ 10 mm relative to the nominal value; should be # 600 mm.

Mammography - X-Ray source

Alignment X-ray Field/Image Receptor

- Test equipment:** Film cassettes, X-ray ruler
- Test procedure:** Insert a loaded cassette into the cassette holder, and place an additional cassette on top of the cassette holder in such a way that it overlaps all sides of the cassette beneath with sufficient margins. The cassette may be rotated as to cover the cassette below. Place radio-opaque markers, e.g. graduated rulers, on top of the upper cassette. Make an exposure and process the radiographic films.
- Evaluation:** Determine the deviation between the lower film and the radiation field at all four edges.
- Tolerance:** The radiation field should cover the entire film in the cassette holder and should not exceed the film along the edge towards the thorax wall by more than 5 mm, and along the remaining 3 edges by not more than 10 mm.

Radiation Leakage

- Test equipment:** Dose meter.
- Test procedure:** Block the primary radiation with a beam stopper e.g. lead sheet at the end of the diaphragm. Determine the directions with maximum leakage radiation by wrapping loaded radiographic cassettes around the tube housing and performing exposures with high tube voltage and tube loading. Quantify the leakage by measurements with a

Mammography - X-Ray source

suitable detector in these directions at a specified distance to the focal spot. Extrapolate the readings to the maximum rating of the tube during one hour and to a distance from the focal spot of 1 meter.

Evaluation: Compare extrapolated value with requirement.

Tolerance: Not more than 1 mGy (kerma free in air) during 1 hour at 1 m distance from the focal spot at the maximum rating of the tube, averaged over an area not exceeding 100 cm².

Tube Output

Test equipment: Dose meter, exposure timer.

Test procedure: Measure the specific tube output rate (mGy/s) free in air along the reference axis at a specific distance to the focal spot. Correct these values to the distance from the focal spot to the image receptor plane.

Evaluation: Compare corrected values with requirement.

Tolerance: Acceptable > 7,5 mGy/s, desirable 10 - 30 mGy/s.

Tube Voltage

Test equipment Electronic penetrometer.

Test procedure: The tube voltage is measured for all clinical relevant values

Mammography - X-Ray source

for the tube voltage and over the clinical range of tube loading.

Evaluation: Calculate accuracy and reproducibility and compare with requirement.

Tolerance: The accuracy should be $< \nabla 1$ kV, the reproducibility $< \nabla 0,5$ kV.

Mammography – automatic exposure control

Optical Density Control Setting

Test equipment:	PMMA standard phantom, 45 mm thick, dosimeter.
Test procedure:	<p>Expose the standard phantom with the density correction step in the mid position. Measure the density on the processed film at the reference point (midline lateral, 6 cm from the edge at the chest wall).</p> <p>Select different density correction steps (at least 3 in either direction) and repeat the procedure above.</p>
Evaluation:	Compare measured density with requirement.
Tolerance:	The optical density for the standard phantom shall correspond to the preference at the facility, normally in the interval between 1,3 and 1,8 (base plus fog included). One density correction step should cause a change in the density between 0,1 and 0,2.

Short Term Reproducibility

Test equipment:	PMMA standard phantom, 45 mm thick, densitometer.
Test procedure:	Place the standard phantom on the breast support. Position the dose meter on top of the phantom without shadowing the AEC-sensor. Perform 10 subsequent exposures with the same settings.
Evaluation:	Calculate the standard deviation of the readings and compare

Mammography – automatic exposure control

with requirement.

Tolerance: The standard deviation should be # 5%.

Object Thickness Compensation

Test equipment: PMMA slabs of thickness 20, 40 and 60 mm and densitometer.

Test procedure: Perform exposures with the three phantom thicknesses.

Evaluation: Measure the optical density on the processed films at the reference point and compare with requirement.

Tolerance: All measured densities should be within \forall 0,15 OD.

Tube Voltage Compensation

Test equipment: PMMA standard phantom, 45 mm thick, densitometer.

Test procedure: Perform exposures with the standard phantom using AEC with all clinical relevant tube voltages, filters and target materials.

Evaluation: Measure the optical density on the processed films at the reference point and compare with requirement.

Tolerance: All measured densities should be within \forall 0,15 OD.

Mammography – compression

Compression

Test equipment:	Compression test device (scales).
Test procedure:	Place the scales on top of the breast support. Between the compression paddle and the scales soft material like a tennis boll, waterbag is positioned. Apply the motorized compression and measure the force on the scales. In the case that the force is displayed at the X-ray equipment, record these values as well.
Evaluation:	Compare recorded forces with requirement.
Tolerance:	The maximum force should be at least 200 N. The agreement between indicated and measured force should be within \forall 10 N.

Mammography – anti scatter grid

Anti Scatter Grid

Test device:	PMMA standard phantom, 45 mm thick, densitometer.
Test procedure:	Perform two exposures, one with the loaded cassette in the bucky tray and the standard phantom on top of the breast support, and one with the cassette on top of the breast support and the standard phantom on top of the cassette. Adjust the exposures as to achieve the same optical density on both films. Record the tube loading (mAs) for both exposures.
Evaluation:	The ratio between these mAs-values, corrected according to the inverse square law for the different distance from the focal spot, is the grid factor which is compared with the requirement.
Tolerance:	The grid factor should be # 3.

Mammography – System properties

Exposure Time:

Test equipment:	Exposure time meter, PMMA standard phantom, 45 mm thick.
Test procedure:	Place the standard phantom on top of the breast support. Perform an exposure with the settings used clinically.
Evaluation:	Record the exposure time and compare it with the requirement.
Tolerance:	The exposure time should be # 1 s.

Patient Dose

Test equipment:	Dose meter, PMMA standard phantom, 45 mm thick.
Test procedure:	Perform an exposure as described for the test " <u>Exposure Time</u> ". Record the mAs-value. Measure the air kerma free in air in the entrance plane of the standard phantom for that mAs-value.
Evaluation:	Compare the measured air kerma with the requirement.
Tolerance:	The entrance surface dose free in air should be # 8 mGy.

Mammography – System properties

Spatial resolution

Test equipment:	Line test pattern up to 20 lp/mm, PMMA standard phantom, 45 mm thick.
Test procedure:	The resolution test device is positioned within the PMMA phantom 20-25 mm above the exit plane. Perform an exposure.
Evaluation:	Determine visually the highest frequency that is resolved on the film and compare it with the requirement.
Tolerance:	The resolution should be ≥ 15 lp/mm.

Computed Tomography

The aim of this section is to describe a set of tests which should be a part of the acceptance testing of any diagnostic CT scanner. It is focused on tests that are based on technical image quality phantoms, and the assessments of dose. In addition to these tests, the following measurements should be made during acceptance testing (HPA 1981, IEC 1998a) : (a) radiation safety, (b) mechanical function, (c) electrical safety, (d) tube output, (e) size of focal spot, (f) kilovolt calibration, (g) alignment of scanner geometry, and (h) geometric image distortion. For radiotherapy applications there may be other features that also are of importance, such as the accuracy of alignment lights, integrity of the CT numbers for all clinically used scanning options and any dimensions and labelling of orientation.

Each of the physical parameters of the scanner may have to be measured for a range of operating conditions to detail fully scanner performance. These should include the settings that are normally used in the clinic : (a) all combinations of kV and filtration, (b) all kV/mAs combinations, and all tube rotation times (axial scans), (c) all pitch values (helical scans), (d) all nominal tomographic section thicknesses, detector arrays and collimators, (e) all reconstructed slice thicknesses (helical scans), (f) all appropriate scanner field sizes and reconstruction areas, and (g) all z-interpolation algorithms (helical scans), reconstruction- and post processing- algorithms. However, this procedure would be very comprehensive and time consuming, and unless specified otherwise, the tests may as a minimum be performed at two representative settings , one related to head- and one to body examinations, using the general reconstruction algorithm : The tube voltage should be close to 120 kV and the nominal tomographic section thickness 5 mm for both cases. The other physical parameters and the two selected mAs values are typically used for head and abdominal CT, respectively.

Mean CT Number, Noise, Uniformity and Decentering

Test equipment : Two homogenous PMMA phantoms with diameter 160 and 320 mm, respectively, and a length of not less than 140 mm. Cylindrical water phantoms or water equivalent materials may also be used for this test.

Computed Tomography

Test procedure :	Scan with phantoms positioned centrally using the representative settings. The uniformity and decentring are evaluated by determining the mean of CT numbers in several circular regions of interest (ROI) in the displayed image of the phantom. The noise is given in terms of the standard deviation (SD) of CT numbers. The centre of each peripheral ROI shall be 15 mm inside the phantom periphery. The ROIs may be defined as a certain number of pixels (>100 pixels, ROI diameter <10% of the phantom diameter) or as a defined area (same size for head and body).
Evaluation:	<ul style="list-style-type: none">-Determine the mean CT number and SD in a central ROI-Determine the mean CT numbers and SD in four peripheral ROIs at the positions 45°, 135°, 225°, and 315°-Determine the mean CT number and SD in a ROI placed on the zero degree position at a distance of 25 mm from the centre of the phantom.-Calculate the differences in mean CT numbers to the central ROI.
Comment :	The noise (SD) in central and peripheral ROIs are related to $CTDI_{100}$ and low contrast detectability (described in later tests).
Tolerance:	Uniformity : ≤ 8 HU between central and each peripheral ROI. Decentering : ≤ 8 HU between central and decentred ROI.
Reference :	IEC 1998b; DIN 1990

Computed Tomography

Linearity of CT-numbers

Test equipment : The Catphan phantom (The Phantom Laboratory, New York) or any similar phantom of 160 mm or 200 mm diameter.

Test procedure : Samples of air, water, plexiglas (PMMA), bone substitute or any other similar materials of known composition and density, are scanned at the position in the phantom where the effective energy of the X-ray beam has been estimated using representative setting for head examinations.

Evaluation : The linear attenuation coefficients, μ , for the various tissue samples are calculated from the measured CT numbers :

$$CT_{number} = \frac{\mu_{tissue} - \mu_{water}}{\mu_{water}} \cdot 1000 (HU)$$

Tolerance: A plot of CT numbers against the linear attenuation coefficient should be a straight line. In practise this plot may deviate from the linear relationship in the high CT number region.

CT number : 0 ± 4 HU for water

Reference : White and Speller 1980; HPA 1981; DIN 1990

Computed Tomography

Sensitivity Profile (axial scanning)

Test equipment :

The Catphan phantom (The Phantom Laboratory, New York) or any similar phantom of 160 or 200 mm diameter, containing two ramps of a material with a linear attenuation coefficient not less than that of aluminium. Each ramp is angled 23° to the tomographic plane, or other angles in some phantoms.

Test procedure :

Scan the phantom positioned centrally at representative settings for head examinations. Information shall be provided for at least the minimum and maximum value of nominal tomographic slice thickness, in addition to one midrange value (5 mm). The CT numbers across the image of both ramps are plotted against pixel number, that gives the sensitivity profile.

Evaluation :

The full width at half maximum (FWHM) of the sensitivity profile for both ramps is calculated in terms of the number of pixels. When multiplied by the factor $\cotan 23^\circ$ (p is the pixel size in mm) these values give the tomographic section thickness in mm. The values of tomographic section thicknesses quoted are the average of values from the two ramps.

The FWHM is a measure of the imaged slice width. In addition, the profile shape should be examined, as can give valuable information on collimation, detector geometry and

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focal spot.

Tolerance:

Referring to the values of FWHM:

nominal tomographic section thickness ≥ 8 mm: $\pm 10\%$

nominal tomographic section thickness < 8 mm and > 2 mm :
 $\pm 25\%$

nominal tomographic section thickness ≤ 2 mm : $\pm 50\%$

Reference :

HPA 1981; DIN 1990

Sensitivity Profile (helical scanning)

Test equipment :

Delta phantoms (beads or disks of highly absorbing material) would be preferable for the evaluation of the imaged slice thickness using helical scan techniques. A suggested phantom consists of a 0.1 mm thin disc of a high CT number material, PTFE (polytetrafluoroethylene), sandwiched between pieces of rigid foam.

Test procedure :

A helical scan is performed and images are reconstructed at small intervals (between 0.1 mm and 1 mm depending on the slice thickness). Information should be provided for all pitch values and z-interpolation algorithms that are in clinical use.

Evaluation :

A region of interest (ROI) is placed over the central portion of each image, and the CT number obtained. The partial volume effects of the PTFE disc and the relative sensitivity of sequential imaged slices to this thin piece of PTFE are

Computed Tomography

used to identify the sensitivity profile. The mean CT number value of the ROI is plotted against the distance to give the line spread function in the z-direction. The shape of the z-sensitivity profile broadens and changes for helically obtained images relative to axial scans, and depends on pitch and interpolation algorithm. The full width at tenth maximum (FWTM) or the full width tenth area (FWTA) have been suggested as additional indices to describe this characteristic.

Reference : ImPACT 1997, Polacin et al 1994

Dose Profile and Geometrical Efficiency

Test equipment : Thermoluminescent dosimeters (TLD) in a holder for larger slice widths or film for the smallest slice widths (e.g radiotherapy verification film, dental film or industrial films) and preferably a micro densitometer.

Test procedure: The TLDs are placed, inside a holder, with the narrow edge vertically, and stacked so that the TLDs can be placed along the z-axis of the scanner. This array of TLDs is then placed free in air at the iso-centre and a single axial scan is performed. Information shall be provided for at least the minimum and maximum value of nominal tomographic slice thickness, in addition to one midrange value (5 mm).

For the smallest nominal slice widths (1 to 2 mm) use instead a wrapped film, placed horizontally either directly on

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the couch top, or suspended free in air with an appropriate holder.

Evaluation:

The TLD readouts are plotted against the z-axis position to demonstrate the dose profile. For the small slice width the edge of the beam may easily be seen on the film. For greater accuracy the profile obtained using film can be read using a micro densitometer. It is then essential that the film is calibrated for the actual mean X-ray energy blackening the film.

The geometrical efficiency in the z-direction is the ratio of sensitivity profile (axial scanning) to the dose profile in terms of FWHM. If there is more than one linear array of detectors the sum of the sensitivity profiles of each array should be used.

Tolerance:

Nominal tomographic slice thicknesses that show geometrical efficiency < 70% should be noted. This indicates poor collimation on the detector side of the patient.

Reference:

HPA 1981; IEC 1998a; Czajka 1994

CT Dose Index and Dose Length Product

Test equipment:

A pencil shaped ionisation chamber of 100 ± 5 mm length and a diameter not more than 10mm, calibrated for CT radiation qualities. The response of the detector along the active length shall be constant within $\pm 5\%$. Two

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homogenous PMMA phantoms with diameter 160 and 320 mm, respectively, and a height of not less than 140 mm. The CT number for the PMMA shall be 125 ± 20 HU.

Test procedure:

The measurements are done (a) free in air along the axis of rotation, and (b) in the centre and periphery (10 mm interior to the surface at locations 0° , 90° , 180° , and 270°) of the phantoms. Information shall be provided for all values of tube voltage and filtration in clinical use, and at least the minimum and maximum value of nominal tomographic slice thickness, in addition to one midrange value (5 mm).

Information on dose to the patient are collected from CT examinations of selected anatomical regions and examination procedures, and compared to the CEC 1998 quality criteria.

Evaluation:

The CT dose index, given in units of mGy, is defined as:

$$CTDI_{100} = \int_{-50mm}^{+50mm} \frac{D(z)}{N \cdot T} dz$$

- $D(z)$ is the dose profile along a line perpendicular to the tomographic plane, where dose is measured as absorbed dose to air.
- N is the number of tomographic sections produced in a single 360° rotation of the X-ray tube. $N \neq 1$ only for CT scanners with multiple detector systems.
- T is the nominal tomographic section thickness.

National Radiological Protection Board in UK has provided conversion coefficients between the CT dose index free in air at the axis of rotation and organ doses “per tomographic

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section” based on Monte Carlo techniques. By the use of appropriate software, the organ doses and effective dose for complete CT procedures may be assessed from the input values of scanner model, the normalised CT dose index free in air, CTDI (mGy/mAs), and the exposure parameters (kV, mAs, tomographic section thickness, total scan length). The Impact Group at St. Georges Hospital, London, provides a conversion table of new to old scanners which enables you to use the NRPB datasets for new scanner models (www.sghphy.demon.co). The National Institute of Radiation Hygiene in Copenhagen and the Department of Biomedical Engineering Aarhus Universitetshospital have also provided conversion coefficients based on measurements on CT-scanners and Monte Carlo techniques to be downloaded from <http://www.mta.au.dk>

(b) The weighted and normalised CTDI_w (in phantom) is defined as:

$${}_nCTDI_w = \frac{1}{C} \cdot \left(\frac{1}{3} \cdot CTDI_{100}(centre) + \frac{2}{3} \cdot CTDI_{100}(peripheral) \right)$$

where the weighted quantity is normalised by division with the current time product per tomographic section, C (mAs), and the CTDI₁₀₀ (peripheral) represent an average of measurements at the four different peripheral locations. The actual CTDI_w is obtained by multiplying with the mAs value used in the clinic. The dose-length product DLP, in units of mGy·cm, for a complete CT examination is defined

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for conventional axial CT and for helical CT, respectively, as:

$$DLP_{Axial} = \sum_i^n CTDI_w \cdot T \cdot n \cdot C$$

$$DLP_{Helical} = \sum_i^n CTDI_w \cdot T \cdot A \cdot t$$

where T is the tomographic section thickness, n the number of tomographic sections, A the tube current, and t the total acquisition time.

Tolerance:

Considering the four peripheral measurements of $CTDI_{100}$ in phantom, the maximum value are compared to manufacturers specifications for different combinations of kV, filtration and tomographic section thicknesses. The weighted CT dose index measured in head and body phantom, and the values of dose length products for four

routine examinations (head, chest, abdomen and pelvis) are compared to CEC 1998 quality criteria :

Examination:	Reference dose value	
	$CTDI_w$ (mGy)	DLP (mGy·cm)
Routine head	60	1050
Routine chest	30	650
Routine abdomen	35	800
Routine pelvis	35	600

Diagnostic reference dose values should not be applied

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locally on an individual patient basis, but rather to the mean dose observed for representative groups of patients. Typical levels of dose in excess of reference dose value should be thoroughly justified or reduced. Further dose reduction below reference values may be achievable without compromising the diagnostic value of an individual examination, and this should always be pursued.

Reference: Jones and Shrimpton 1991; IEC 1997a; CEC 1998

Low Contrast Detectability / IEC 1998b Forced Four Choice Method

Test equipment: The same phantoms (diameter 160 and 320 mm) that are used for measurement of CT dose index. The phantoms must also have tapered inserts for test devices in centre and in four radial symmetric positions 50 mm off centre. The test devices for low contrast detectability consist of a 10 mm diameter rod aligned along the z-axis with 5 HU (head) and 10 HU (body) difference to the PMMA, respectively.

Test procedure: Scan the head and body phantoms > 12 times at representative settings for head and body scans, respectively. For each scan the phantom is oriented centrally in the gantry so that the test device is in one of the positions 45°, 135°, 225°, 315° (randomly assigned). Blank plugs shall be inserted in the positions not used. Each of the four target regions shall be used for approximately 25% (\pm repetition) of the acquisitions.

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Evaluation:	The human observer shall not receive any information about which target region contains the actual target, but shall clearly state the location of the perceived target in one of the four target regions in every trial.
Tolerance:	Head (160 mm) : $CTDI_w \leq 60$ mGy shall allow ≥ 10 mm (5HU) Body (320 mm) : $CTDI_w \leq 35$ mGy shall allow ≥ 10 mm (10 HU) The system passes the task if the observer correctly identifies the object in at least 9 of 12 trials.
Reference:	IEC 1998b

Low Contrast Detectability / Based on Catphan or Alternative Phantom

Test equipment:	The Catphan phantom (The Phantom Laboratory, New York) or any similar phantom of 160 mm diameter, with a sufficient number of periodic inserts with diameter and contrast in the range 2 to 15 mm and 3 to 10 HU, respectively. An acrylic body annulus should be optional, so that the total phantom diameter can be increased to 320 mm for body scans.
Test procedure:	Scan the 160 and 320 mm PMMA phantoms used for measurements of noise at representative settings for head and body scans, respectively. Measure the noise close to the

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positions where the 5 mm and 10 mm test object would be in the Catphan phantom. Scan the Catphan phantom (160 and 320 mm) at the same settings and measure the noise in the same positions. Change the exposure settings (mAs), preserving the same beam quality, until the noise is equal or larger than in the PMMA phantom, and use these images for the test.

Evaluation:	Subjective recognition of the periodical patterns.
Tolerance:	Head (160 mm) : $CTDI_w \leq 60$ mGy shall allow ≥ 5 mm (5HU) Body (320 mm) : $CTDI_w \leq 35$ mGy shall allow ≥ 10 mm (5HU)
Reference:	CEC 1998

Spatial Resolution Detectability Based on IEC 1998b

Test equipment:	The same phantoms (diameter 160 and 320 mm) that are used for measurement of CT dose index. The phantoms must also have tapered inserts for test devices in centre. The test device for spatial resolution contains of periodic patterns of elements, with >1000 HU difference to the PMMA. Each pattern shall consist of bars and spaces, the number of each being at least five, covering the range from 5 to 10 lp/cm.
Test procedure:	Scan the phantom positioned centrally at representative settings for head and body examinations, with the test device positioned in centre. Do the test both for 5 and 2 mm slice

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thickness using general and high resolution reconstruction algorithm, respectively. The angle of bars and spaces shall be 45° with respect to the pixel matrix. Record the highest frequency that is resolved by visual evaluation of the radiogram. The window level is set at the value for the average of bars and spaces, and the window width at 10 percent of this value.

Evaluation: A periodic pattern is regarded resolved if the bars and spaces are distinguishable at least in one part of the pattern.

Tolerance: Spatial resolution detectability in centre of the phantoms ≥ 5 lp/cm (general) and ≥ 10 lp/cm (high resolution)

Reference: IEC 1998b

Spatial Resolution Based on DIN

Test equipment: A test device with periodic patterns of elements, approximately five bars and spaces with contrast of at least 100HU covering the range from 3 to 10 cycles/cm, and two reference zones of the same material. The patterns should be positioned in central parts as well as in peripheral parts in the phantom (for evaluation of partial scans and helical scanners). Wire phantoms for measurements of the modulation transfer function (MTF) would offer the most objective and comprehensive information. Many manufacturers now supply software for the analysis of data and the production of the MTF.

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Test procedure:	Scan the phantom positioned centrally at representative settings for head examinations. The spatial resolution is evaluated through determination of the modulation of periodical patterns.
Evaluation:	Record the mean CT number and the standard deviation (SD) of a circular ROI placed over each of the periodic patterns. Record the mean CT number of the reference zones. Calculate the modulation by dividing the SD in the periodical pattern by the difference in mean values.
Tolerance:	In central parts of the phantom: Periodic patterns : ≤ 0.8 mm for head and ≤ 1.2 mm for body MTF 10% value : ≤ 6.25 lp/cm for head and ≤ 4.2 lp/cm for body In peripheral parts of the phantom as specified by the manufacturer.
Comments:	Generally, the distribution of resolution is radial symmetric, with a slight decrease of towards the periphery. Helical scanners may have an off-center resolution that modulates with the z-axis position of the reconstructed images (180° z-interpolation algorithms).
Reference:	DIN 1990; Kalender 1994

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