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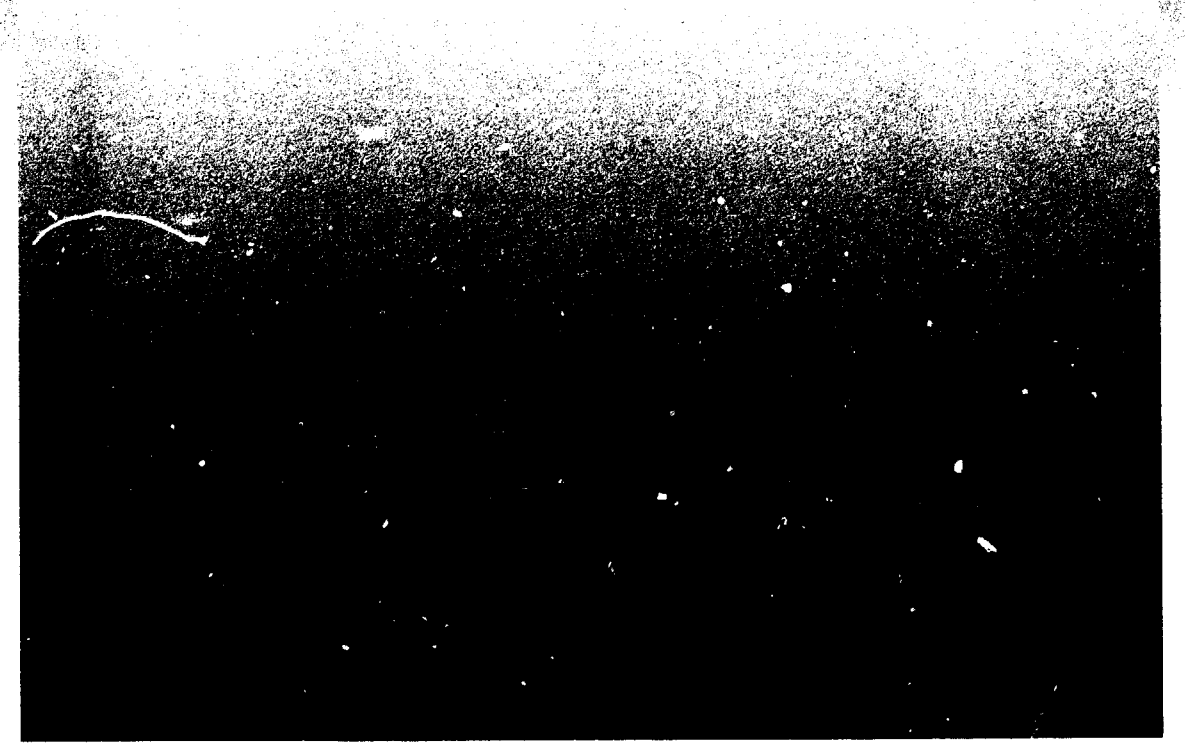
Quality control of diagnostic X-ray equipment and film processing



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Quality control of diagnostic X-ray equipment and film processing

This ST Guide takes effect on 1 January 1992 and will remain in force until further notice.

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Authorization

Under section 70, paragraph 2, of the Radiation Act (592/91), the Finnish Centre for Radiation and Nuclear Safety issues general instructions, known as Radiation Safety Guides (ST Guides), concerning the use of radiation and operations involving radiation.

The Radiation Act stipulates that the party running a radiation practice is responsible for the safety of the operations. The responsible party is obliged to ensure that the level of safety specified in the ST Guides is attained and maintained.

The instructions given in the ST Guides on actions and procedures are not absolutely binding, but if the responsible party intends to use a procedure or method differing from those presented in an ST Guide, he must be able to prove that the procedure or method chosen ensures the same level of safety as that specified in the ST Guide.

Radiation Protection Guides (SS Guides) issued before 1992 and listed at the end of this guide remain in force until further notice. SS Guides will be replaced by ST Guides whenever the need arises to alter their contents.

Translation. Original text in Finnish.

1 General

The purpose of quality control for medical X-ray equipment is to ensure that the equipment works properly and to prevent it from becoming defective. Quality control measures help to reduce radiation exposure of patients and personnel and to maintain high standards in X-ray examinations.

According to section 40 of the Radiation Act (592/92), the licensee is required to make the arrangements to control the function of the radiation equipment and related facilities used for medical procedures.

This guide explains how quality control can be organized for diagnostic X-ray equipment. It also gives recommendations for constancy tests for conventional X-ray radiographic and fluoroscopic equipment and for film processing. The recommendations are based on the publications and statements of the International Committee for Radiation Protection (ICRP) and standardization organizations. The intention is that the operators of X-ray equipment or the maintenance personnel are able to perform the quality control tests presented in this guide.

2 Quality control programme

Quality control must be arranged for the diagnostic X-ray equipment and accessories, radiographic film processors and darkrooms, image recording and viewing facilities, and protective devices. The licensee shall document the quality control programme, naming the persons responsible for quality control and specifying quality control tests, test methods, and operating limits and instructions for individual X-ray installations. The organization of quality control and the responsibilities and tasks of the persons involved are presented in the description of arrangements for the safe use of radiation as set out in ST Guide 1.4.

Quality control comprises acceptance tests, status tests and constancy tests. Appendix A gives a summary of the points for constancy testing, the properties to be tested and the intervals at which tests should be conducted.

A more limited constancy test programme may be adequate if the performance of the equipment is checked by some other realiable means.

All major faults and defects observed during quality control procedures shall be corrected immediately. Even minor defects affecting radiation safety shall be corrected before the next constancy test, or a notification of the defect shall be attached on the equipment or device in question.

3 Evaluation of quality control

The effectiveness, content and extent of quality control must be monitored and analyzed regularly. This helps to avoid unnecessary measurements and costs. The content of the tests and the intervals at which they are carried out are adjusted on the basis of practical experience.

The effectiveness of quality control can be monitored in several ways. As far as radiation safety is concerned, determinations of radiation doses to the patient, the quality of radiographs and the amounts of rejected films are essential. The amount of rejected films should be less than 5 %. Table I shows entrance surface doses for a patient in certain conventional projections used in routine X-ray examinations. When the X-ray equipment and film processor are kept in good condition, these X-ray examinations can usually be carried out using smaller entrance doses than those given in Table I.

Table I. Examples of entrance surface doses for a patient (70 kg) in certain common diagnostic X-ray projections.

Projection	Entrance surface dose (mGy)
Skull AP/PA	5.0
Skull LAT	3.0
Lung PA	0.3
Lung LAT	1.5
Lumbar spine AP	10
Lumbar spine LAT	30
Abdomen AP	10
Pelvis AP	10
Thoracic spine AP	10
Thoracic spine LAT	20

4 Base line values in constancy tests

The aim of constancy tests is to ensure that the performance of the equipment remains constant and that any deviations from the set values remain within the established tolerance range. The base line values are determined when the status of the X-ray equipment and the film processing is as good as possible. Subsequent test results are compared against these base line values. Constancy tests can be planned and base line values determined together with maintenance personnel. Constancy tests shall always be performed in the same way as the base line value measurements. Some base line values should be measured several times to make sure that the results are reliable and to determine the normal variation in the results.

If essential modifications are made to the equipment, a check must be made to see whether the test results are affected to the extent that the base line values have to be redetermined. If the test methods or test equipment are changed, new base line values may have to be determined. To find out whether this is necessary, some tests should be carried out using both the old and the new method.

The constancy test methods and the points to be tested are presented in item 7.

5 Measuring principles

Constancy tests should be carried out periodically, after service, repair and modifications, and whenever defects are suspected.

A record must be kept of constancy tests and the resulting observations so that maintenance of quality can be monitored. The date and the person performing the test shall be included in the record. The records shall be preserved for as long as the equipment and accessories are in use. Information on malfunctions, defects, service and repairs shall be collected for each item of equipment separately.

If the result of a constancy test deviates from the base line value by more than an acceptable amount, a check shall be made to see that the test instructions have been followed and that the measuring instruments have functioned properly. The test should then be repeated. If the result of the new test is not satisfactory, the cause of the deviation shall be established and corrective action taken.

Slow changes are easier to distinguish from normal deviations if the results are presented graphically on a control chart such as that shown in Appendix B.

6 Constancy test instruments

The instruments needed in the constancy tests described in item 7 are as follows:

- A densitometer, the error of measurement of which is less than 0.02 density units.

- A sensitometer; the standard deviation of the reproducibility of the light output must be smaller than 2 % of the mean.
- A homogeneous test device that can be used to cover the fields of the automatic exposure control. The size of the test device must be at least 25 cm x 25 cm; if it is made of plexiglass or water, it must be 10...20 cm thick.
- A riddle or mesh for checking the contact between intensifying screens and radiographic film. The mesh can be made of 0.5 mm copper wire, the appropriate space between wires being 3 mm.
- An aluminium disc to determine the contrast of radiographs. A suitable contrast difference of 0.2...0.3 is usually achieved with a disc that is 0.5...1 mm thick and about 3 cm in diameter.
- A line pair test plate (1...10 line pairs/mm) or close-meshed expanded metal to check resolution.

If a lot of equipment has to be checked, a suitable radiation meter should be used in constancy tests, as well as a digital voltmeter to check the X-ray tube voltage in radiography and fluoroscopy. Measuring equipment should be calibrated at two to three year intervals and always when there is doubt about its reliability.

7 Points for constancy testing

7.1 Darkroom

The darkroom and the box for storing radiographic films must be light-proof. The safelight must be suitable for the type of film used, and the light signals and other lights must not expose the films. The routine processing time for films in the darkroom shall not cause visible changes (about 0.05) in the optical density of pre-exposed film.

The fog density of the film can be determined by pre-exposing the film so that its optical density is in the range 0.7...1.5. This can be done using the X-ray machine. If the machine does not deliver doses small enough, a suitable homogeneous substitute for a patient is used. The pre-exposed film is kept partly covered for 1...2 minutes in the darkroom exposed only to the safelight. Then the film is developed. If the uncovered part of the film is more than 0.05 density units darker than the covered part, the cause of fog density shall be investigated and the fault corrected.

When starting quality control, fogging should be checked for all film types handled in the darkroom. Later, it is sufficient to use only the type most sensitive to the safelight. This check should be carried out at least once a year, and always after changing the bulb of the safelight. Fogging shall also be checked each time a new type of film is introduced.

7.2 Film processing

Changes in the film processing, such as the aging of processing agents, changes in developer temperature and errors in the mixing or replenishment of chemicals, can alter the fog density, speed and contrast of the film.

The film processing should be monitored with the help of control films exposed using a sensitometer (sensitometer films). If no automatic control system is available, the **base + fog density** and **speed** and **contrast indexes** of the film can be determined with the help of a step wedge pattern exposed on a sensitometer film as shown in Figure 1. Suppliers of developers and films provide instructions for measures to be taken if the **speed** or **contrast indexes** or the **fog density** have changed.

In constancy tests, speed and contrast indexes should be determined using the same test methods and step wedges as when determining baseline values. Determinations should be carried out in the same way for all processors. The results are recorded in the

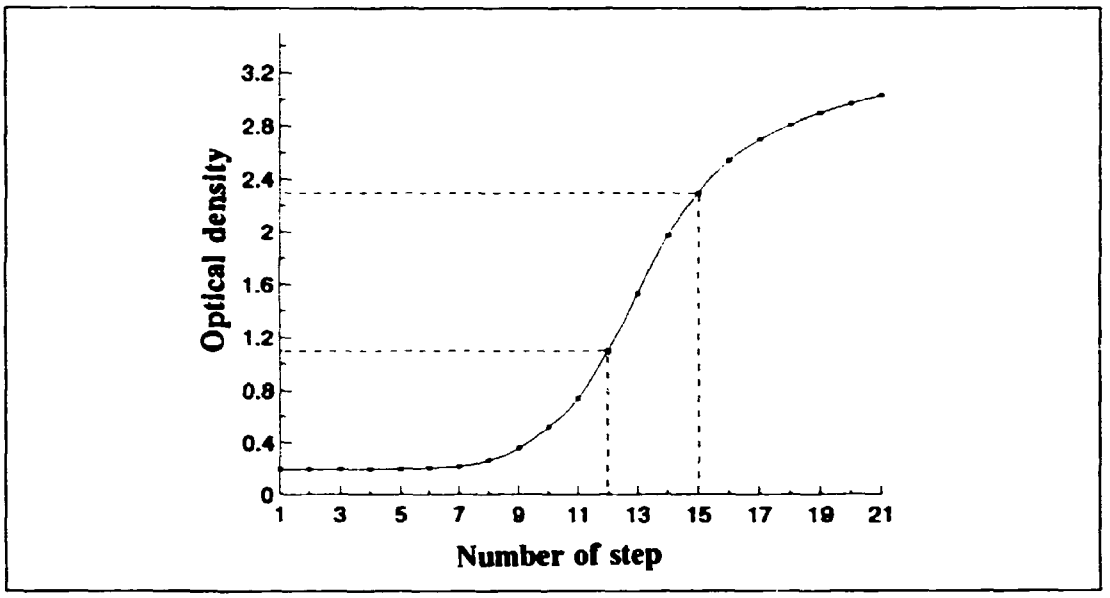

*Figure 1. Determination of base line values with a density curve. **Base + fog density** is determined at step 1 (0.20 in the figure). When the base line value for **speed index** is determined, a step is identified at which optical density is about 1.0 units above base + fog density. The optical density at this step, step 12 in the figure (1.1), indicates the **speed index** value. The **contrast index** is determined with the help of two steps. In measuring base lin values, steps are selected at which the densities are about 1.0 and 2.0 units above the base + fog density, i.e. steps 12 and 15 (1.1 and 2.3, respectively) in the figure. The difference between the densities at these steps is the **contrast index** value (1.2).*

control chart (Appendix B). The fog density of a double emulsion film should not be over 0.30.

The following deviations from base line values in film processing are acceptable:

Speed index	**± 0.20 density units**
Contrast index	**± 0.20 density units**

The performance of the film processor should be first monitored at two-hour intervals during the working day to determine the variations in developing times. At the same time, developer temperature should also be monitored. The same procedure is followed if the test result is close to acceptable deviations.

Further checks should be made after the developing process has stabilized, for example one hour after starting up the unit. In hospitals and other places where a large number of X-rays are taken, checks should be made daily; elsewhere they should be made at least once a week.

The film processor must not damage radiographic films. Processors used to process similar films should give similar results. If this is not the case, the processors shall be adjusted so that at least the speed indexes are the same.

7.3 X-ray equipment for radiography

7.3.1 Radiation beam and light-field indicators

Congruence of the radiation beam and light-field indicators and the centralizing of the beam can be checked from a radiograph taken of metal markings placed in the corners and in the centre of the light field (e.g. 50 kV and 10 mAs). The edges and centre of the radiation beam are compared to the markings indicating the corresponding edges and centre of the light field. The measurement is made by placing the cassette in the cassette holder. The check is made for all focuses used in X-ray examinations as necessary, but at least every six months and always after a light indicator bulb has been changed. Mobile X-ray machines need to be checked more often.

Light indicators must be clearly visible under normal lighting conditions. The deviation between the edges of the light field and the radiation field should not be more than 1.0 % of the focal distance.

7.3.2 Radiation output and X-ray tube voltage

The constancy of the adjustments of X-ray generator can be monitored by measuring the radiation output from the X-ray tube. Changes in radiation output usually indicate a change in voltage, current or exposure time, or aging of the tube. When automatic exposure control is used, radiation output is determined as described in item 7.3.3. An example of a test arrangement is shown in Appendix C.

The reproducibility of radiation output can be checked by measuring the density of the film from a radiograph taken of a test device. The same imaging geometry, imaging values, cassette and film type shall always be used. During the test, the constancy of the film developing process is checked by processing a sensitometer film before and after the test.

A more reliable method for monitoring radiation output and its reproducibility is to use a suitable radiation meter. Radiation output can be measured in the primary radiation beam on the surface of the test device. The measurement is carried out at the normal imaging distance.

Measurements, five of which should be made at a time, should be carried out at least once a year. Set values are deviated between imagings before establishing new values. The value of the radiation output is the mean of the measurement results, and the range is the difference between the highest and the lowest result.

The X-ray tube voltage can be measured with a kVp-meter or penetrometer cassette at least once a year using a few different operating voltages. The acceptance criteria for radiation output and X-ray tube voltage are as follows:

Deviation of radiation output from base line value	**± 20 %**
Reproducibility of radiation output (five measurements)	
*** dose range as compared with the mean**	**20 %**
*** range of film densities**	**0.3**
Deviation of X-ray tube voltage from the preset value	**± 10 %**

If the deviations of radiation output or X-ray tube voltage from the base line values fall outside the permitted range or if the range of variation of radiation output is greater than the permitted range, the reason shall be established and the necessary adjustments and repairs made. Exposure tables shall be updated as necessary.

7.3.3 Automatic exposure control

The performance of automatic exposure control devices can be monitored with the help of radiographs taken of a test device (cf. 7.3.2). The optical densities of the radio-

graphs shall be between 0.7 and 1.8. The optical density of each radiograph is measured at the same point of the test radiographs. The usual detectors of the automatic exposure control device should be used. The test device is placed on the patient support in place of the patient.

The film can be replaced by a radiation meter. The dose can then be measured from the primary beam on either side of the test device depending on the meter.

If the machine is equipped with an after-display of the mAs value or irradiation time, these values can also be used to monitor the constancy of automatic exposure control.

The voltage compensation of the automatic exposure control device can also be tested. Radiographs should be taken of the test device using voltages of, say, 60, 90 and 120 kV and the usual settings of the automatic exposure control, intensifying screens and films. With proper equipment, the range of variation of film density should be less than 0.4.

The acceptance criteria for radiation output using automatic exposure control devices are as follows:

Deviation of radiation output from the base line value	**± 20 %**
Reproducibility of radiation output (five measurements)	
*** range of doses compared with the mean**	**30 %**
*** range of film densities**	**0.4**

The automatic exposure control devices shall be tested at least once a year.

7.4 X-ray equipment for fluoroscopy

Constancy tests for image intensifier-television chain should be carried out as described in ST Guide 3.4 (Quality control of X-ray image intensifier-television chains). Other constancy tests for fluoroscopic units are carried out in the same way as for radiography.

The centralizing of the radiation beam on the image intensifier should be checked. A check must also be made to ensure that the radiation field is not larger than the input screen of the image intensifier. The alignment of the beam can be checked with the help of a fluorescent screen or a large cassette. The timer indicating the fluoroscopic time shall also be checked.

Acceptable deviations in radiation output and time intervals between measurements are the same for both fluoroscopic and radiographic units. Acceptable values and testing intervals for image intensifier-television chains are given in ST Guide 3.4.

7.5 Quality of radiographs

The constancy of the quality of radiographs can be monitored with the help of radiographs taken of the test device described in Appendix C. The optical density, contrast and resolution of the radiograph are compared with a control radiograph. The test radiograph is taken using the same settings as in the control radiograph. This type of test radiograph shows the changes that have occurred throughout the entire imaging chain. The test is easy and quick to perform. If test radiographs are taken frequently, changes affecting the quality of radiographs become apparent more rapidly than in tests carried out once a year. Test radiographs should be taken at 1...4 week intervals and at other times as necesssary.

To determine contrast, an aluminium disc that attenuates radiation is placed on the test device. The disc should cause a density difference within the range of 0.2...0.3 in the radiograph. In this case, contrast is the difference between the optical densities measured from the radiographic film beside the disc and at the disc. The measurements are carried out with a densitometer. If the film has been developed properly, a change

in contrast is usually an indication of a change in the X-ray tube voltage.

Resolution is affected by, among other things, focus size of the X-ray tube, the imaging geometry and by the intensifying screens. To measure the resolution, a line pair test plate (with 1...10 line pairs/mm) or a suitable test mesh is placed on the surface of the test device facing the X-ray tube.

Test plates must not be in front of the detectors of the automatic exposure control device. The location of test plates must be marked on the test device so that the measurement can be repeated using the same imaging geometry.

7.6 Intensifying screens and cassettes

The closure mechanism of the radiographic cassette shall function reliably, and the cassette must be light-proof. The pressing material shall be elastic and the pressure shall be adequate and uniform across the entire film.

The contact between intensifying screen and radiographic film is checked by taking a radiograph of a metal riddle or mesh placed on the cassette. The cassette should not cause areas of uneven density or unsharp areas on the radiograph.

The speed of intensifying screens can be checked by irradiating three cassettes to be tested and a reference cassette at the same time, and then comparing the optical densities of the films. The optical film density of the reference cassette is used to ensure that the results are comparable. If necessary, the cassettes should be reclassified according to speed, and the speed class marked clearly on the cassettes. In the same class, the difference in optical density indicating the speed difference between intensifying screens should not exceed 0.30.

The cleanliness and condition of intensifying screens should be checked visually or under ultraviolet light. Intensifying screens must be cleaned with special cleaning agents as necessary.

The cassettes should be tested once a year and when any changes are suspected.

7.7 Radiation protection devices

Protective clothing may become defective in use. The condition of the clothing can be checked by fluoroscopy or by taking a radiograph of the suspected area. The condition of protective devices can often be determined by feeling with the hands. Small fractures, pinholes etc. do not greatly affect protective capacity. Protective devices in poor condition shall be repaired or discarded.

Protective clothing shall be properly kept in the appropriate racks. They shall be checked as necessary but at least once a year.

7.8 Film storage

The fog density of radiographic films increases during storage. Storage times should be monitored for each film batch. The storage temperature should be below 22 °C, the relative humidity 40...60 % and the background radiation below 0.3 μGy/h. The temperature and humidity in the film store shall be checked at least once a year.

Background radiation should be measured with a special gauge. The measurement is necessary only if the base + fog density of stored, unexposed film is more than 0.30 density units and no other cause can be found.

8 Other checks

The mechanical and electrical safety of the equipment shall also be monitored. The performance of warning and signal lights shall also be checked from time to time.

The film illuminators used for viewing radiographs shall have sufficient light intensity and the illumination shall be even.

Checks shall be made at least once a year, and more often if necessary.

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APPENDIX A

CONSTANCY TESTS

Tests and checks shall be performed periodically, whenever conditions change and when any defects are suspected.

Point to be tested	Property	Method
Daily or weekly		
Film processing	base + fog density speed index contrast–index	control film
Weekly or monthly		
Quality of radiographs	contrast resolution	test device and contol film
Semiannually		
Light indicators	congurence	control film
Annually		
Darkroom	fog density	control film
Preset values	radition output X–ray tube voltage	dosimeter or control film kVp–meter
Automatic exposure control unit	radiation output	dosimeter or control film
Image intensifier – television chain*		
Cassettes	closure mechanism light–proof	visually control radiograph
Intensifying screens	contact cleanliness speed	test plate image visually or with UV light control film
Grids	condition	visually or with radiographs
Protective clothing	condition	visually, with radiographs or by fluoroscopy
Film illuminators	luminosity uniformity	visually photometer
Film store	conditions films	thermometer and hygrometer storage time

* Quality control for X–ray image intensifier–television chains is described in ST Guide 3.4

APPENDIX B

CONTROL CHART FOR FILM PROCESSOR – AN EXAMPLE

Normal graph paper can be used for the control chart

Place _____

Processor _____

Test instruments _____

Date	
Person	
New developer	
New fixative	
New developer replenisher	
New fixative replenisher	
Developer temperature	
SPEED INDEX Base line value 1.08 Optical density at step ____	+ 0.20 - 0.20
CONTRAST INDEX Base line value 1.31 Difference between optical densities at steps 10 and 14	+ 0.20 - 0.20
FOG DENSITY Optical density at step 1	0.40 0.20

APPENDIX C

TEST ARRANGEMENT FOR MONITORING RADIATION OUTPUT AND QUALITY OF RADIOGRAPHS

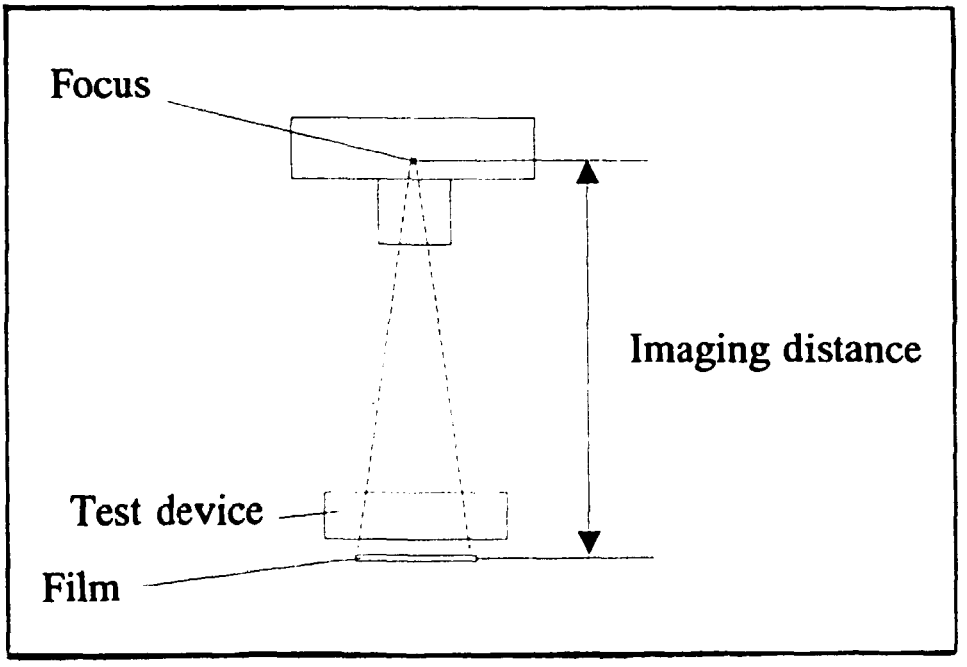

Figure C1. Side view of test arrangement.

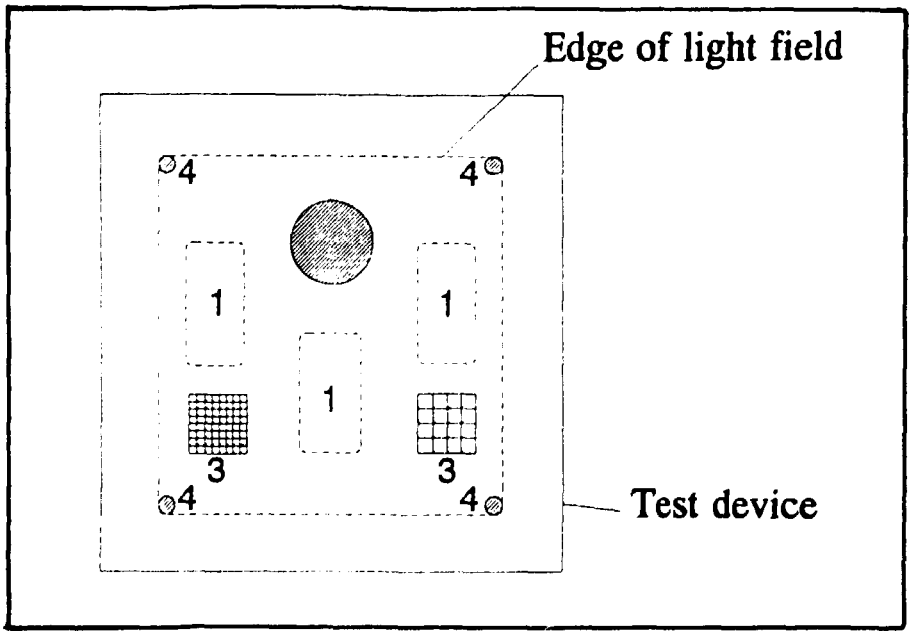

Figure C2. Test arrangement on the test device.
1) Measuring detectors of automatic exposure control, 2) aluminium disc for determining contrast, 3) line pair test plate or mesh for determining resolution, 4) metal markings for checking congruence of radiation beam and light indicators.

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Erweko Painotuote Oy
Helsinki 1993