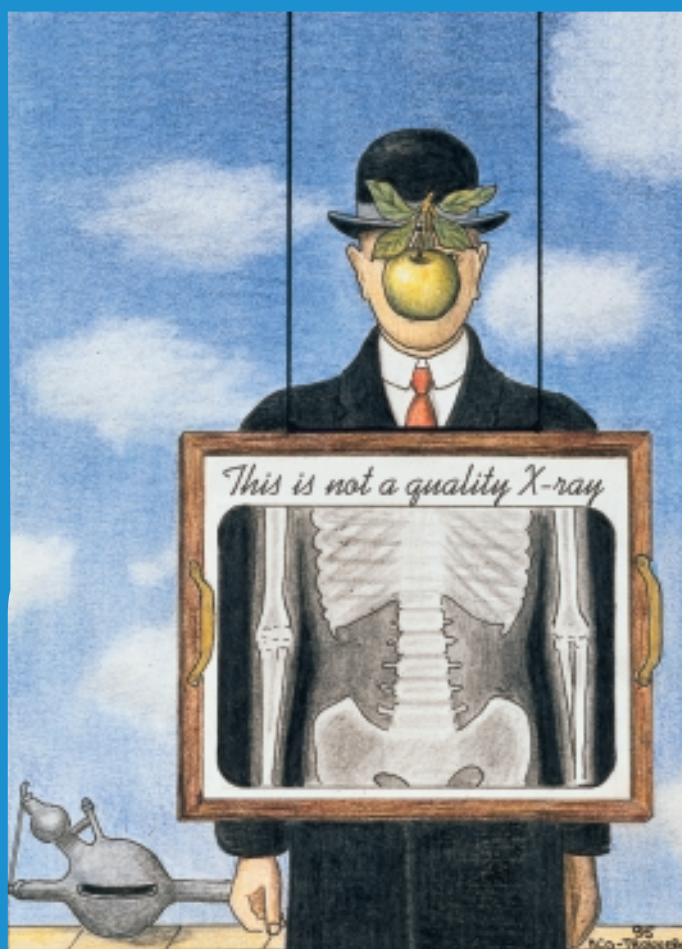


EUROPEAN COMMISSION

EUROPEAN GUIDELINES ON QUALITY CRITERIA FOR DIAGNOSTIC RADIOGRAPHIC IMAGES



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Let alone a MAGRITTE

EUROPEAN GUIDELINES ON QUALITY CRITERIA FOR DIAGNOSTIC RADIOGRAPHIC IMAGES

une 1996

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EUROPEAN GUIDELINES ON QUALITY CRITERIA FOR DIAGNOSTIC RADIOGRAPHIC IMAGES

These Guidelines result from a European-wide cooperation between the various professionals and authorities involved in Diagnostic Radiology (see Chapter 4).

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EUROPEAN GUIDELINES ON QUALITY CRITERIA FOR DIAGNOSTIC RADIOGRAPHIC IMAGES

PREAMBLE

Quality and safety have become hallmarks for efficient and successful medical intervention. A comprehensive quality and safety culture has been progressively developed throughout the European Union with regard to the medical use of ionizing radiation, and has been integrated into the various branches of diagnosis and treatment.

The Commission of the European Communities has contributed to this evolution by the establishment of legal requirements for the radiation protection of persons undergoing medical examination or treatment,¹ as well as safety requirements for medical devices,² and by participating in research for the implementation and updating of these requirements.

The establishment of the Quality Criteria for Diagnostic Radiographic Images is one of the milestones of these European initiatives. It started in 1984, when the first Directive on Radiation Protection of the Patient¹ was adopted by the Member States of the European Union.

These Quality Criteria have been elaborated in a common effort by radiologists, radiographers, physicists, radiation protection experts, health authorities and professional, national and international organizations. They were first set up for conventional radiography, concentrating on examinations of high frequency or with relatively high doses to the patient. It is the aim of the Quality Criteria to characterize a level of acceptability for normal basic radiographs which could answer to any clinical indication. Furthermore, it has been recognized that the Quality Criteria must be specifically adapted to paediatric radiology.³

The applicability of the Quality Criteria for adult radiology has been checked in European-wide trials, involving some hundred radiological departments and about 3 000 radiographic images and dose measurements. The results have been discussed at workshops, by working parties and by dedicated study groups; advice and comments have been collected from professional associations, individual experts and healthcare authorities. **The conclusions have been integrated into the present Document and provided elements for the improvement of the lists of Quality Criteria.**

The European Guidelines on Quality Criteria for Diagnostic Radiographic Images contains four chapters: the first one concerns the updated lists of the Quality Criteria for six conventional examinations: Chest, Skull, Pelvis, Lumbar Spine, Urinary Tract and Breast.

It defines Diagnostic Requirements for a normal, basic radiograph, specifying anatomical image criteria and important image details; it indicates Criteria for the Radiation Dose to

Council Directive 84/466/Euratom, OJ L 265/1, 5.10.1984.
Council Directive 93/42/EEC, OJ L 169/1 12.7.1993.
Report EUR 16261, 1996.

the Patient and gives an Example for Good Radiographic Technique by which the Diagnostic Requirements and the dose criteria can be achieved.

The second chapter summarizes the analysis of the findings of the European-wide Trials⁴ and explains the updating of the Quality Criteria, as listed in Chapter 1.

The third chapter outlines a procedure for implementing and auditing the Quality Criteria. A sample questionnaire and scoring tables for the six examinations, which were elaborated during the evaluation of the Trials, have been reproduced and could become tools for self-education and performance checking.

The fourth chapter presents all those to whom the European Commission's services wish to express their sincere thanks for their cooperation and creative criticism, from which the European Commission's Radiation Protection Actions drew their encouragement to concentrate on the development of this Quality Criteria concept.

These efforts will continue in the near future in the framework of the coming research programmes and in the up-dating of the EURATOM Directive.¹ The ongoing revision of this Directive proposes the establishment of quality assurance measures including criteria that can be employed and checked in a comparable way so that the radiation dose to the patient can be linked to the required image quality and to the performance of the radiographic procedure. The indication of reference dose values is also recommended.

Therefore, it is with great satisfaction that the services of the European Commission present these 'European Guidelines on Quality Criteria for Diagnostic Radiographic Images'. The Guidelines do not claim to give strict instructions on day-to-day radiological practice, but attempt to introduce basic criteria that have been proved to lead to the necessary quality of the diagnostic information with reasonable dose values applied to the patient. This is a first step in the optimization of medical exposures, whereby a lower quality standard should ideally be associated to lower dose. Compliance with these Guidelines will help to protect the patient and staff against unnecessary radiation exposure, and will prevent any degradation of the equipment or faulty use of the imaging procedure from resulting in unsatisfactory images.

It is the hope of the European Commission's services that the Guidelines will stimulate the professionals involved in diagnostic radiology to look for improvements in the criteria and their extension to other types of examination or new techniques.

The Guidelines will be available in nine official languages of the European Union.

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⁴ For detailed results and findings see Report EUR 16635, in press.

CHAPTER 1

QUALITY CRITERIA FOR DIAGNOSTIC RADIOGRAPHIC IMAGES

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INTRODUCTION

The two basic principles of radiation protection of the patient as recommended by ICRP are justification of practice and optimization of protection, including the consideration of dose reference levels (1,2,3,). These principles are largely translated into a legal framework by the EURATOM Directive (4).

Justification is the first step in radiation protection. It is accepted that no diagnostic exposure is justifiable without a valid clinical indication, no matter how good the imaging performance may be. Every examination must result in a net benefit for the patient. This only applies when it can be anticipated that the examination will influence the efficacy of the decision of the physician with respect to the following:

- diagnosis,
- patient management and therapy,
- final outcome for the patient.

Justification also implies that the necessary result cannot be achieved with other methods which would be associated with lower risks for the patient.

As a corollary, justification requires that the selected imaging procedure is acceptably reliable, i.e. its results are reproducible and have sufficient sensitivity, specificity, accuracy, and predictive value with respect to the particular clinical question.

Justification also necessitates that a person, trained and experienced in radiological techniques and in radiation protection (as recognised by the competent authority), normally a radiologist, takes the overall clinical responsibility for an examination. This person should work in close contact with the referring physician in order to establish the most appropriate procedure for the patient management and therapy. The responsible person can — as appropriate — delegate responsibility to perform the examination to a qualified technician, who must be suitably trained and experienced.

Guidance on referral criteria for adult and paediatric patients can be found in WHO reports 689 (5), and 757 (6), respectively, and guidelines for making the best use of a department of radiology are available from the Royal College of Radiologists London, (7a) and from the German Federal Medical Board (7b).

In respect of diagnostic examinations ICRP does not recommend the application of dose limits to patient irradiation but draws attention to the use of dose reference levels as an aid to optimisation of protection in medical exposure. Once a diagnostic examination has been clinically justified, the subsequent imaging process must be optimized. The optimal use of ionizing radiation involves the interplay of three important aspects of the imaging process:

- the diagnostic quality of the radiographic image,
- the radiation dose to the patient,
- the choice of radiographic technique.

This document provides guidelines on all three of these aspects. As it is not practicable to assess the full range of radiodiagnostic procedures, examinations have been chosen which are either common or give significant patient dose, or both. The examinations are: chest, skull, lumbar spine, pelvis, urinary tract and breast. No attempt has been made to define the procedure for complete examinations. These are often a matter of personal preference of a radiologist and will be determined by local conditions and particular clinical situations. Instead, Quality Criteria have been drawn up for representative radiographs from the six routine examinations listed above. Compliance with the criteria for these radiographs is a first but important step in ensuring satisfactory overall performance.

Similar documents have been prepared for conventional radiodiagnostic procedures in paediatric radiology (8) and for computed tomography (9). The need for a comparable effort for fluoroscopy employing image intensification is recognized.

OBJECTIVES

The objectives of the guidelines presented in this document are to achieve:

- adequate image quality, comparable throughout Europe; and
- reasonably low radiation dose per radiograph.

They will also provide the basis for accurate radiological interpretation of the image.

The European Guidelines are primarily directed at the technical and clinical staff involved in taking the radiographs and in reporting on them. They will also be of interest to those responsible for the design of X-ray imaging equipment and for the maintenance of its functional performance. They will be helpful to those who have responsibility for equipment specification and purchase.

The Guidelines represent an achievable standard of good practice which can be used as a basis for further development by the radiological community.

The DIAGNOSTIC REQUIREMENTS presented as image criteria for a particular type of radiograph are those deemed necessary to produce an image of standard quality. No attempt has been made to define acceptability for particular clinical indications.

The CRITERIA FOR RADIATION DOSE TO THE PATIENT are expressed in terms of a reference dose value for each type of radiograph which is based on the third quartile (75. percentile) value seen in earlier European patient dose surveys. Its purpose, if it is exceeded, is to initiate an immediate investigation into the reasons for using relatively high dose techniques and to trigger appropriate corrective action. The reference dose value can be taken as a ceiling from which progress should be pursued to lower dose levels in line with the ALARA (as low as reasonably achievable) principle.

The EXAMPLES OF GOOD RADIOGRAPHIC TECHNIQUE included in this document have evolved from the results of two European trials of the Quality Criteria. Compliance with the image and patient dose criteria was possible when the recommended techniques were used.

To encourage widespread use, the image criteria have been expressed in a manner requiring personal visual assessment rather than objective physical measurements which need sophisticated equipment unavailable to most departments. However, the assessment of compliance with the criteria for radiation dose to the patient for a specific radiograph unavoidably involves some form of dose measurement. This requires representative sampling of the patient population. A number of dose measurements methods are described in Appendix I.

GENERAL PRINCIPLES ASSOCIATED WITH GOOD IMAGING PERFORMANCE

The following general principles are common to all radiographic X-ray examinations. All those who either carry out or report on the results should be aware of them. Specific aspects of these principles are discussed in greater detail in a number of publications by national and international organizations, some of which are listed in references (11) to (15) (see page 9).

1. Image Annotation

The patient identification, the date of examination, positional markers and the name of the facility must be present and legible on the film. These annotations should not obscure the diagnostically relevant regions of the radiograph. An identification of the radiographers on the film would also be desirable.

2. Quality Control of X-ray Imaging Equipment

Quality control programmes form an essential part of dose-effective radiological practice. Such programmes should be instigated in every medical X-ray facility and should cover a selection of the most important physical and technical parameters associated with the types of X-ray examination being carried out. Limiting values for these technical parameters and tolerances on the accuracy of their measurement will be required for meaningful application of the Examples of Good Radiographic Technique presented in these Guidelines. BIR Report 18 (12) provides useful information on this subject.

3. Patient Positioning

Correct patient positioning plays a major role in determining the success of any radiological examination. Routine positioning may need to be altered in the light of specific clinical circumstances, in order to delineate an area of special interest. Correct positioning of the patient is the responsibility of the person who is physically directing the examination. The use of suitable immobilization and compression techniques can have an important role to play in the production of satisfactory images. Training programmes as well as ongoing multidisciplinary evaluation and audit programmes within a medical X-ray facility should regularly address these areas.

4. X-ray Beam Limitation

Image quality is improved and the radiation dose to the patient is reduced by limiting the X-ray beam to the smallest field giving the required diagnostic information. Limitation of the radiation beam should also consider the need to exclude radiosensitive organs from primary irradiation whenever possible. On no occasion should the X-ray beam fall outside the image receptor area. It is desirable for there to be evidence on the radiograph of beam limitation. An automated beam limitation device would be of help.

5. Protective Shielding

For radiation protection purposes, standard protection devices should be available to shield radiosensitive tissues or organs whenever possible. In particular, for patients of reproductive capacity, testes or ovary shields should be used in examinations when these organs are likely to be in or near the primary beam.

6. Radiographic Exposure Conditions

Knowledge and correct use of appropriate radiographic exposure factors, for example, radiographic voltage, nominal focal spot value, tube filtration, and film-focus-distance is necessary because they have a considerable impact on patient dose and image quality. Permanent parameters of the apparatus such as total tube filtration and grid characteristics should also be taken into consideration.

7. Screen Film System

The sensitivity of screen film systems is defined in terms of speed (see ISO 9236-1, DIN 6867, Section 1 (1995)). The speed of the screen film system is one of the most critical factors affecting the radiation dose to the patient. The variation in sensitivity which can occur with changes in X-ray beam energy for individual screen film systems (BIR Report 18 12)) is recognized. Therefore, for convenience in this document only broad speed categories (nominal speed classes) are used. Users should be encouraged to measure the real speeds of their screen film systems under standard conditions resembling those used in practice, to see how closely they match up to the manufacturers quoted values. Speed classes of 200 and above usually require the use of rare earth or equivalent intensifying screens. Users are also encouraged to measure the resolution of their screen film system since this varies within any speed class.

8. Film Blackening

Film blackening (optical density) has a major influence on image quality. For the same radiographic projection it depends on many factors: radiation dose, radiation quality, patient size, radiographic technique, image receptor sensitivity and film processing. It determines the optical densities of a radiographic film. The range of the mean optical density (D) of a clinical radiograph should normally lie between $D = 1.0$ and $D = 1.4$ (for the breast examination 1.3 - 1.8 are recommended) and the optical densities of fog and film base should not exceed $D = 0.25$. For the diagnostically relevant parts of the film, the overall range of optical densities should lie between 0.5 and 2.2.

Whereas the total density above fog and base can be easily — and should be routinely — measured, objective measurement of the mean optical density of the film of a patient requires some expenditure and is not practicable in daily work. Even in external quality control programmes assessors usually base their judgment on subjective and global impression rather than measurements. For a more precise assessment, the definition of one or a few critical points of the particular radiographic projections would be desirable where the optical density of a specific anatomical feature — and its contrast relative to the surrounding image — could be measured.

Film blackening is subject to personal preference of the individual radiologist. A darker film may be associated with a relatively higher patient dose. In this respect, the preference for darker films should be supported by rational arguments. A film which has been found to be too dark should be viewed with a bright spotlight before a decision is made to repeat the examination.

9. Radiographic Exposures per Examination

The number of radiographic exposures within one examination must be kept to a minimum consistent with obtaining the necessary diagnostic information.

10. Film Processing

Optimal processing of the radiographic film has important implications both for the diagnostic quality of the image and for the radiation dose to the patient. Film processors

should be maintained at their optimum operating conditions as determined by regular and frequent (i.e. daily) quality control procedures. Consistent imaging performance is not necessarily an indication of optimal performance, for example the developer temperature may well be set too low.

11. Image Viewing Conditions

The proper assessment of image quality and accurate reporting on the diagnostic information in the radiographs can best be achieved when the viewing conditions meet the following requirement:

- (a) The light intensity incident on the viewer's eye should be about 100 cd/m². To achieve this, the brightness of the film illuminator should be between 2 000 and 4 000 cd/m² for films in the density range 0.5 to 2.2.
- (b) The colour of the illumination should be white or blue and should be matched throughout a complete set of film illuminators.
- (c) Means should be available to restrict the illuminated area to the area of the radiograph to avoid dazzling.
- (d) Means for magnifying details in the displayed radiographic image should be available. These means should magnify by a factor of 2 to 4 and contain provisions to identify small image details of sizes down to 0.1 mm.
- (e) For viewing exceptionally dark areas in the radiographic image an additional spotlight with iris diaphragm providing a brightness of at least 10 000 cd/m² should be available.
- (f) A low level of ambient light in the viewing room is essential.

12. Reject Analysis

Rejected films should be collected, the reasons for rejection should be analysed and corrective action should be taken.

GUIDANCE ON IMPLEMENTATION

Quality Criteria are presented for a number of selected radiographic projections used in the course of routine types of X-ray examination. They apply to adult patients of standard size (70 kg, or 5 cm compressed breast) with the usual presenting symptoms for the type of examination being considered. These Quality Criteria are to be used by radiologists, radiographers and medical physicists as a check on the routine performance of the entire imaging process.

However, the Quality Criteria cannot be applied to all cases. For certain clinical indications a lower level of image quality may be acceptable, but this should ideally always be associated with a lower radiation dose to the patient.

Under no circumstances should an image which fulfils all clinical requirements but does not meet all image criteria ever be rejected.

For each selected radiographic projection the Quality Criteria are divided into three parts:

1. DIAGNOSTIC REQUIREMENTS

Image criteria

These list image criteria which in most cases specify important anatomical structures that should be visible on a radiograph to aid accurate diagnosis. Some of these criteria depend fundamentally on correct positioning and cooperation of the patient, whereas others reflect technical performance of the imaging system. Awareness of the positional and technical dependence of the criteria can stimulate further work aimed at gaining a more detailed understanding of those factors which can influence image quality (see for example 'Evaluation of the European Image Quality Criteria for Chest Examinations', E. Vañó et al. BJR 68, 1349-1355, 1995). This should lead to improved mechanisms for auditing both existing as well as new and/or modified radiographic techniques and training programmes for radiological staff.

A qualitative guide to the necessary degree of visibility of these essential structures is provided in the following Description of Terms. These criteria can be used by radiologists as they report on radiographs to make a personal visual assessment of the image quality as well as an audit mechanism for radiographic procedures within a department.

Important image details

These provide quantitative information on the minimum sizes at which important anatomical details should become visible on the radiograph. Some of these anatomical details may be pathological and therefore may not be present.

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Reference values are provided for the entrance surface dose to a standard-sized patient for each type of radiograph considered. The derivation of these values is discussed in Appendix 1.

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

This provides an example of one set of radiographic technique parameters that has been found to result in good imaging performance that is capable of meeting all the above Quality Criteria. Details are also given of a suitable combination of accessory devices, geometrical conditions and loading factors using current X-ray imaging technology. If radiologists and radiographers find that Diagnostic Requirements or Criteria for Radiation Dose to the Patient are not met then the Example of Good Radiographic Technique can be used as a guide to how their techniques might be improved.

1. DIAGNOSTIC REQUIREMENTS

Image Criteria

These refer to characteristic features of imaged anatomical structures with a specific degree of visibility. At the present time there are no internationally accepted definitions. For the purpose of this document the degree of visibility is defined as follows:

Visualization:

Characteristic features are detectable but ***details are not fully reproduced***; features just visible.

Reproduction:

Details of anatomical structures are visible but not necessarily clearly defined; details emerging.

Visually Sharp Reproduction:

Anatomical ***details are clearly defined***; details clear.

Important Image Details

These define the minimum limiting dimensions in the image at which specific normal or abnormal anatomical details should be recognized.

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

The entrance surface dose for standard-sized patient is expressed as the absorbed dose to air (mGy) at the point of intersection of the X-ray beam axis with the surface of a standard-sized adult patient (70 kg bodyweight or 5 cm compressed breast thickness), backscatter radiation included. For further information see Appendix I.

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- 3.1. **Radiographic device** — device supporting the film-screen cassette and the anti-scatter grid.
- 3.2. **Nominal focal spot value** — as indicated by the manufacturer.
- 3.3. **Total filtration** — the aluminium equivalence in mm of the inherent and added tube filtration.
- 3.4. **Anti-scatter grid** — specified in terms of grid ratio 'r' and number of absorbing strips per cm for moving grid.
- 3.5. **Screen film system** — the sensitivity of screen film systems is defined in terms of speed (see ISO 9236-1, DIN 6868, Section 50 (1995)). Since this sensitivity might vary with changes in X-ray beam energy, only nominal speed classes are indicated.
- 3.6. **Focus-to-film distance** — FFD (cm). Numbers shown in brackets are less desirable but acceptable. If a focused grid is used, FFD must be within the range indicated by the manufacturers.
- 3.7. **X-ray tube voltage** — expressed as the peak kilo-voltage (kV) applied to the X-ray tube, preferably 12-pulse or high frequency multi-pulse (so-called converter) generator.
- 3.8. **Automatic exposure control** — the recommended selection of the measurement chamber in the automatic exposure control device.
- 3.9. **Exposure time** — the time indicated for the duration of the exposure (ms).
- 3.10. **Protective shielding** — additional protection devices to reduce exposure of sensitive organs and tissues.

LIST OF REFERENCES FOR CHAPTER 1

The following is a limited reference list. References (11) to (15) contain extensive reference lists.

- (1) ICRP Publication 60, '1990 Recommendations of the International Commission on Radiological Protection', Annals of the ICRP Vol. 21, Nos 1-3 (Pergamon Press, Oxford), 1991.
- (2) ICRP Publication 34, 'Protection of the Patient in Diagnostic Radiology', Annals of the ICRP Vol. 9, Nos 2-3 (Pergamon Press, Oxford), 1982.
- (3) ICRP Publication 73, 'Radiological Protection and Safety in Medicine', (Pergamon Press, Oxford), in press.
- (4) Council Directive of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment (84/466/EURATOM) OJ L 265, p. 1, 5.10.1984, under revision: COM(95) 560 final 1995.
- (5) WHO Technical Report 689 'A Rational Approach to Radiographic Investigations', (World Health Organization, Geneva), 1986.
- (6) WHO Technical Report 757 'Rational Use of Diagnostic Imaging in Paediatrics', (World Health Organization, Geneva), 1987.
- (7a) Making the Best Use of a Department of Radiology, Royal College of Radiologists, London, 3rd edition, 1995.
- (7b) Guidelines of the German Federal Medical Board on 'Quality Assurance in Diagnostic Radiology', Dt. Ärztebl.92, Heft 34-35, 1995, in German.
- (8) Quality Criteria for Diagnostic Radiographic Images in Paediatrics, (Office for Official Publications of the European Communities, Luxembourg), Report EUR 16261, 1996.
- (9) Quality Criteria for Computed Tomography, (Office for Official Publications of the European Communities, Luxembourg), Report EUR 16262, 1996.
- (10) WHO Report 'Quality Assurance in Diagnostic Radiology', (World Health Organization, Geneva), 1982.
- (11) 'Criteria and Methods for Quality Assurance in Medical X-ray Diagnosis', BJR Supplement No 18, 1985.
- (12) 'Technical and Physical Parameters for Quality Assurance in Medical Diagnostic Radiology; Tolerances, Limiting Values and Appropriate Measuring Methods', BIR Report 18, 1989.
- (13) 'Optimization of Image Quality and Patient Exposure in Diagnostic Radiology', BIR Report 20, 1989.
- (14) 'Test Phantoms and Optimization in Diagnostic Radiology and Nuclear Medicine; Radiation Protection Dosimetry', Vol. 49, Nos 1-3, 1993.
- (15) 'Quality Control and Radiation Protection of the Patient in Diagnostic Radiology and Nuclear Medicine; Radiation Protection Dosimetry', Vol. 57, Nos 1-4, 1995.

LIST OF QUALITY CRITERIA FOR DIAGNOSTIC RADIOGRAPHIC IMAGES

PA PROJECTION

1. DIAGNOSTIC REQUIREMENTS

1.1. Image criteria

- 1.1.1. Performed at full inspiration (as assessed by the position of the ribs above the diaphragm — either 6 anteriorly or 10 posteriorly) and with suspended respiration
- 1.1.2. Symmetrical reproduction of the thorax as shown by central position of the spinous process between the medial ends of the clavicles
- 1.1.3. Medial border of the scapulae to be outside the lung fields
- 1.1.4. Reproduction of the whole rib cage above the diaphragm
- 1.1.5. Visually sharp reproduction of the vascular pattern in the whole lung, particularly the peripheral vessels
- 1.1.6. Visually sharp reproduction of:
 - (a) the trachea and proximal bronchi,
 - (b) the borders of the heart and aorta,
 - (c) the diaphragm and lateral costo-phrenic angles
- 1.1.7. Visualisation of the retrocardiac lung and the mediastinum
- 1.1.8. Visualization of the spine through the heart shadow

1.2. Important image details

- 1.2.1. Small round details in the whole lung, including the retrocardiac areas:
 - high contrast: 0.7 mm diameter
 - low contrast: 2 mm diameter
- 1.2.2. Linear and reticular details out to the lung periphery:
 - high contrast: 0.3 mm in width,
 - low contrast: 2 mm in width

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for a standard-sized patient: 0.3 mGy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- | | |
|----------------------------------|---|
| 3.1. Radiographic device: | vertical stand with stationary or moving grid |
| 3.2. Nominal focal spot value: | ≤ 1.3 |
| 3.3. Total filtration: | ≥ 3.0 mm Al equivalent |
| 3.4. Anti-scatter grid: | $r = 10$; 40/cm |
| 3.5. Screen film system: | nominal speed class 400 |
| 3.6. FFD: | 180 (140-200) cm |
| 3.7. Radiographic voltage: | 125 kV |
| 3.8. Automatic exposure control: | chamber selected — right lateral |
| 3.9. Exposure time: | < 20 ms |
| 3.10. Protective shielding: | standard protection |

LATERAL PROJECTION

if indicated after viewing PA film)

1. DIAGNOSTIC REQUIREMENTS

1.1. Image criteria

- 1.1.1. Performed at full inspiration and with suspended respiration
- 1.1.2. Arms should be raised clear of the thorax
- 1.1.3. Superimposition of the posterior lung borders
- 1.1.4. Reproduction of the trachea
- 1.1.5. Reproduction of the costo-phrenic angles
- 1.1.6. Visually sharp reproduction of the posterior border of the heart, the aorta, mediastinum, diaphragm, sternum and thoracic spine

1.2. Important image details

- 1.2.1. Small round details in the whole lung:
 - high contrast: 0.7 mm diameter
 - low contrast: 2 mm diameter
- 1.2.2. Linear and reticular details out to the lung periphery:
 - high contrast: 0.3 mm in width
 - low contrast: 2 mm in width

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for a standard-sized patient: 1.5 mGy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- 3.1. Radiographic device: vertical stand with stationary or moving grid
- 3.2. Nominal focal spot value: ≤ 1.3
- 3.3. Total filtration: ≥ 3.0 mm Al equivalent
- 3.4. Anti-scatter grid: $r = 10; 40/\text{cm}$
- 3.5. Screen film system: nominal speed class 400
- 3.6. FFD: 180 (140-200) cm
- 3.7. Radiographic voltage: 125 kV
- 3.8. Automatic exposure control: chamber selected — central
- 3.9. Exposure time: < 40 ms
- 3.10. Protective shielding: standard protection

PA PROJECTION

or AP projection if PA not possible

1. DIAGNOSTIC REQUIREMENTS**1.1. Image criteria**

- 1.1.1. Symmetrical reproduction of the skull, particularly cranial vault, orbits and petrous bones
- 1.1.2. Projection of the apex of the petrous temporal bone into the centre of the orbits
- 1.1.3. Visually sharp reproduction of the frontal sinus, ethmoid cells and apex of the petrous temporal bones and the internal auditory canals
- 1.1.4. Visually sharp reproduction of the outer and inner lamina of the cranial vault

1.2. Important image details: 0.3-0.5 mm

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for a standard-sized patient: 5 mGy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- 3.1. Radiographic device: grid table, special skull unit or vertical stand with stationary or moving grid
- 3.2. Nominal focal spot value: 0.6
- 3.3. Total filtration: ≥ 2.5 mm Al equivalent
- 3.4. Anti-scatter grid: $r = 10; 40/\text{cm}$
- 3.5. Screen film system: nominal speed class 400
- 3.6. FFD: 115 (100-150) cm
- 3.7. Radiographic voltage: 70-85 kV
- 3.8. Automatic exposure control: chamber selected — central
- 3.9. Exposure time: < 100 ms
- 3.10. Protective shielding: standard protection

LATERAL PROJECTION

1. DIAGNOSTIC REQUIREMENTS

1.1. Image criteria

- 1.1.1. Visually sharp reproduction of the outer and inner lamina of the cranial vault, the floor of the sella, and the apex of the petrous temporal bone
- 1.1.2. Superimposition respectively of the contours of the frontal cranial fossa, the lesser wing of the sphenoid bone, the clinoid processes and the external auditory canals
- 1.1.3. Visually sharp reproduction of the vascular channels, the vertex of the skull and the trabecular structure of the cranium
- 1.1.4. Superimposition of the mandibular angles and ascending rami

1.2. Important image details: 0.3-0.5 mm

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for a standard-sized patient: 3 mGy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- 3.1. Radiographic device: grid table, special skull unit or vertical stand with stationary or moving grid
- 3.2. Nominal focal spot value: 0.6
- 3.3. Total filtration: ≥ 2.5 mm Al equivalent
- 3.4. Anti-scatter grid: $r = 10 ; 40/\text{cm}$
- 3.5. Screen film system: nominal speed class 400
- 3.6. FFD: 115 (100-150) cm
- 3.7. Radiographic voltage: 70-85 kV
- 3.8. Automatic exposure control: chamber selected — central
- 3.9. Exposure time: < 100 ms
- 3.10. Protective shielding: standard protection

AP/PA PROJECTION

1. DIAGNOSTIC REQUIREMENTS

1.1. Image criteria

- 1.1.1. Visually sharp reproduction, as a single line, of the upper and lower-plate surfaces in the centred beam area
- 1.1.2. Visually sharp reproduction of the pedicles
- 1.1.3. Reproduction of the intervertebral joints
- 1.1.4. Reproduction of the spinous and transverse processes
- 1.1.5. Visually sharp reproduction of the cortex and trabecular structures
- 1.1.6. Reproduction of the adjacent soft tissues, particularly the psoas shadows
- 1.1.7. Reproduction of the sacro-iliac joints

1.2. Important image details: 0.3-0.5 mm

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for a standard-sized patient: 10 mGy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- 3.1. Radiographic device: grid table or vertical stand with stationary or moving grid
- 3.2. Nominal focal spot value: ≤ 1.3
- 3.3. Total filtration: ≥ 3.0 mm Al equivalent
- 3.4. Anti-scatter grid: $r = 10; 40/\text{cm}$
- 3.5. Screen film system: nominal speed class 400
- 3.6. FFD: 115 (100-150) cm
- 3.7. Radiographic voltage: 75-90 kV
- 3.8. Automatic exposure control: chamber selected — central
- 3.9. Exposure time: < 400 ms
- 3.10. Protective shielding: where appropriate, gonad shields should be employed for male patients, and for female patients, if possible.

LATERAL PROJECTION

1. DIAGNOSTIC REQUIREMENTS

1.1. Image criteria

- 1.1.1. Visually sharp reproduction, as a single line, of the upper and lower-plate surfaces with the resultant visualization of the intervertebral spaces
- 1.1.2. Full superimposition of the posterior vertebral edges
- 1.1.3. Reproduction of the pedicles and the intervertebral foramina
- 1.1.4. Visualization of the spinous processes
- 1.1.5. Visually sharp reproduction of the cortex and trabecular structures

1.2. Important image details: 0.5 mm

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for a standard-sized patient: 30 mGy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- 3.1. Radiographic device: grid table or vertical stand with stationary or moving grid
- 3.2. Nominal focal spot value: ≤ 1.3
- 3.3. Total filtration: ≥ 3.0 mm Al equivalent
- 3.4. Anti-scatter grid: $r = 10; 40/\text{cm}$
- 3.5. Screen film system: nominal speed class 400
- 3.6. FFD: 115 (100-150) cm
- 3.7. Radiographic voltage: 80-95 kV
- 3.8. Automatic exposure control: chamber selected — central
- 3.9. Exposure time: < 1000 ms
- 3.10. Protective shielding: where appropriate, gonad shields should be employed for male patients.

LATERAL PROJECTION OF LUMBO-SACRAL JOINT

This Projection may be indicated if the lumbo-sacral joint is not adequately visualized on the Lateral Projection of the lumbar spine

1. DIAGNOSTIC REQUIREMENTS

1.1. Image criteria

- 1.1.1. Reproduction by tangential projection of the inferior end plate of L 5 and the superior end plate of S 1
- 1.1.2. Visualization of the spinous process of L 5
- 1.1.3. Visualization of the anterior border of the upper sacrum
- 1.1.4. Reproduction of vertebral pieces of the upper sacrum

1.2. Important image details: 0.5 mm

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for a standard-sized patient: 40 mGy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- 3.1. Radiographic device: grid table or vertical stand with stationary or moving grid
- 3.2. Nominal focal spot value: ≤ 1.3
- 3.3. Total filtration: ≥ 3.0 mm Al equivalent
- 3.4. Anti-scatter grid: $r = 10 ; 40/\text{cm}$
- 3.5. Screen film system: nominal speed class 800
- 3.6. FFD: 115 (100-150) cm
- 3.7. Radiographic voltage: 80-100 kV
- 3.8. Automatic exposure control: chamber selected — central
- 3.9. Exposure time: < 1000 ms
- 3.10. Protective shielding: where appropriate, gonad shields should be employed for male patients.

AP PROJECTION

1. DIAGNOSTIC REQUIREMENTS

1.1. Image criteria

- 1.1.1. Symmetrical reproduction of the pelvis as judged by the imposition of the symphysis pubis over the midline of the sacrum
- 1.1.2. Visually sharp reproduction of the sacrum and its intervertebral foramina
- 1.1.3. Visually sharp reproduction of the pubic and ischial rami
- 1.1.4. Visually sharp reproduction of the sacroiliac joints
- 1.1.5. Visually sharp reproduction of the necks of the femora which should not be distorted by foreshortening or rotation
- 1.1.6. Visually sharp reproduction of the spongiosa and corticalis, and of the trochanters

1.2. Important image details: 0.5 mm

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for a standard-sized patient: 10 mGy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- 3.1. Radiographic device: grid table
- 3.2. Nominal focal spot value: ≤ 1.3
- 3.3. Total filtration: ≥ 3.0 mm Al equivalent
- 3.4. Anti-scatter grid: $r = 10; 40/\text{cm}$
- 3.5. Screen film system: nominal speed class 400
- 3.6. FFD: 115 (100-150) cm
- 3.7. Radiographic voltage: 75-90 kV
- 3.8. Automatic exposure control: chamber selected — central or lateral
- 3.9. Exposure time: < 400 ms
- 3.10. Protective shielding: where appropriate, gonad shields should be employed for male patients, and for female patients, if possible.

AP PROJECTION

Either as plain film or before administration of contrast medium

1. DIAGNOSTIC REQUIREMENTS

1.1. Image criteria

- 1.1.1. Reproduction of the area of the whole urinary tract from the upper pole of the kidney to the base of the bladder
- 1.1.2. Reproduction of the kidney outlines
- 1.1.3. Visualisation of the psoas outlines
- 1.1.4. Visually sharp reproduction of the bones

1.2. Important image details: calcifications of 1.0 mm

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for a standard-sized patient: 10 mGy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- 3.1. Radiographic device: grid table
- 3.2. Nominal focal spot value: ≤ 1.3
- 3.3. Total filtration: 1.3 mm Al equivalent
- 3.4. Anti-scatter grid: $r = 10; 40/\text{cm}$
- 3.5. Screen film system: nominal speed class 400
- 3.6. FFD: 115 (100-150) cm
- 3.7. Radiographic voltage: 75-90 kV
- 3.8. Automatic exposure control: chamber selected — central or lateral
- 3.9. Exposure time: < 200 ms
- 3.10. Protective shielding: where appropriate, gonad shields should be employed for male patients.

AP PROJECTION

After administration of contrast medium

1. DIAGNOSTIC REQUIREMENTS

1.1. Image criteria

Image criteria are to be referred to a series of radiographs, taken at intervals after contrast administration, tailored to the individual patient.

- 1.1.1. Increase in parenchymal density (nephrographic effect)
- 1.1.2. Visually sharp reproduction of the renal pelvis and calyces (pyelographic effect)
- 1.1.3. Reproduction of the pelvi-ureteric junction
- 1.1.4. Visualization of the area normally traversed by the ureter
- 1.1.5. Reproduction of the whole bladder area

1.2. Important image details

- 1.2.1. Calyceal detail: 0.3 mm
- 1.2.2. Calcifications: 1.0 mm

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for a standard-sized patient: 10 mGy per radiograph

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- 3.1. Radiographic device: grid table
- 3.2. Nominal focal spot value: ≤ 1.3
- 3.3. Total filtration: 1.3 mm Al equivalent
- 3.4. Anti-scatter grid: $r = 10; 40/\text{cm}$
- 3.5. Screen film system: nominal speed class 400
- 3.6. FFD: 115 (100-150) cm
- 3.7. Radiographic voltage: 75-90 kV
- 3.8. Automatic exposure control: chamber selected — central or lateral
- 3.9. Exposure time: < 200 ms
- 3.10. Protective shielding: standard protection

REMARKS: Compression is usually indicated. Satisfactory reduction of overlying bowel gas and faeces is essential for adequate urinary tract reproduction.

MLO (MEDIO-LATERAL OBLIQUE) PROJECTION

1. DIAGNOSTIC REQUIREMENTS

1.1. Image criteria-related to positioning

- 1.1.1. Pectoral muscle at correct angle (1 in Fig. 1 and A in Fig. 2)
- 1.1.2. Infra-mammary angle visualised (2 in Fig. 1)
- 1.1.3. Visually sharp reproduction of cranio-lateral glandular tissue (3 in Fig. 1)
- 1.1.4. Visually sharp reproduction of retroglandular fat tissue (4 in Fig. 1)
- 1.1.5. Nipple in full profile, clear of overlying breast tissue and/or indicated by marker (5 in Fig. 1)
- 1.1.6. No skinfolds seen
- 1.1.7. Symmetrical images of left and right breast

Image criteria related to exposure parameters

- 1.1.8. Visualization of skin outline with bright light (but barely without it)
- 1.1.9. Reproduction of vascular structures seen through most dense parenchyma
- 1.1.10. Visually sharp reproduction of all vessels and fibrous strands and pectoral muscle margin (absence of movement)
- 1.1.11. Visually sharp reproduction of skin structure (rosettes from pores) along the pectoralis muscle

1.2. Important image details: micro-calcifications of 0.2 mm

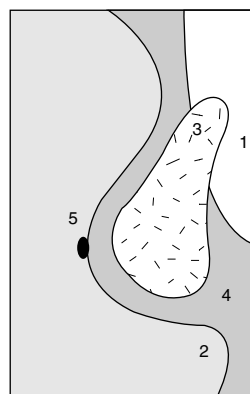


Figure 1: Schematic drawing of breast in MLO projection

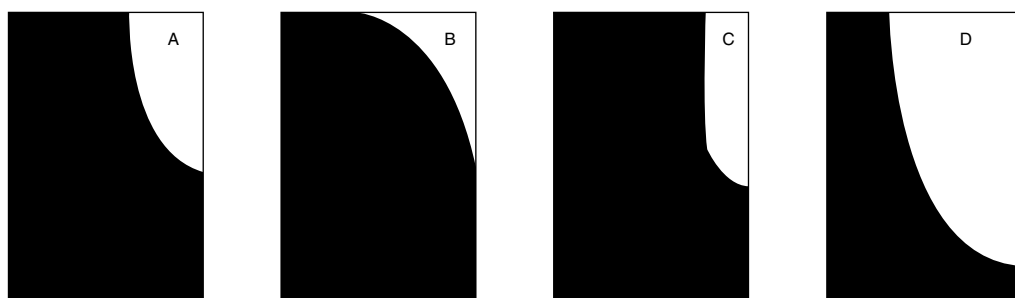


Figure 2: Potential configurations of the pectoral muscle in MLO

A = correct positioning, B, C and D = sub-optimum positioning

MLO (MEDIO-LATERAL OBLIQUE) PROJECTION

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for a standard-sized patient, 5 cm compressed breast, with grid: 10 mGy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

3.1.	Radiographic device:	dedicated equipment (anode material: Mo)
3.2.	Nominal focal spot value:	0.3
3.3.	Total filtration:	(0.03 mm Mo or 0.5 mm Al equivalent)
3.4.	Anti-scatter grid:	dedicated moving grid $r = 5; 27 / \text{cm}$
3.5.	Screen film system:	dedicated high resolution screen film system with dedicated processing
3.6.	FFD:	≥ 60 cm
3.7.	Radiographic voltage:	28 kV
3.8.	Automatic exposure control:	chamber selected to put as close as possible to the nipple and to coincide with parenchyma
3.9.	Exposure time:	< 2 s
3.10.	Protective shielding:	standard protection

- REMARKS**
- Breast compression should be applied to a level which the patient can tolerate.
 - The choice of anode material, total filtration and tube voltage required to obtain satisfactory image quality at an acceptable level of average entrance surface dose will be greatly affected by the density and thickness of the breast under investigation:
 - For denser and/or thicker breasts (in excess of 6 cm compressed) a tungsten or rhodium anode, aluminium or other special filtration and higher tube voltages might be preferable.
 - Handling and maintenance of the imaging equipment should be such that artefacts generated in the cassette (dust, etc.), processing and film handling artefacts are eliminated. Grid lines should not be visible.

CC (CRANIO-CAUDAL) PROJECTION

1. DIAGNOSTIC REQUIREMENTS

1.1. Image criteria related to positioning

- 1.1.1. Visually sharp reproduction of pectoral muscle at image margin (1 in Fig. 3)
- 1.1.2. Visually sharp reproduction of retroglandular fat tissue (2 in Fig. 3)
- 1.1.3. Visually sharp reproduction of medial breast tissue (3 in Fig. 3)
- 1.1.4. Visually sharp reproduction of lateral glandular tissue (4 in Fig. 3)
- 1.1.5. No skinfolds seen
- 1.1.6. Symmetrical images of left and right breast

Image criteria related to exposure parameters

- 1.1.7. Visualization of skin outline with bright light (but barely without it)
- 1.1.8. Reproduction of vascular structures seen through most dense parenchyma
- 1.1.9. Visually sharp reproduction of all vessels and fibrous strands and pectoral muscle margin (absence of movement)
- 1.1.10. Visually sharp reproduction of skin structure (rosettes from pores) along the pectoralis muscle

- 1.2. **Important image details:** micro-calcifications of 0.2 mm

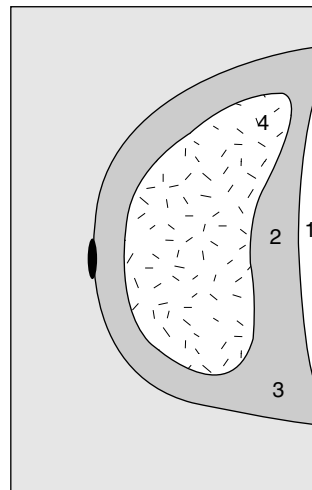


Figure 3: Schematic drawing of breast in CC projection

CC (CRANIO-CAUDAL) PROJECTION

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for a standard-sized patient,
5 cm compressed breast, with grid: 10 mGy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

3.1.	Radiographic device:	dedicated equipment (anode material: Mo)
3.2.	Nominal focal spot value:	0.3
3.3.	Total filtration:	0.03 mm Mo or 0.5 mm Al equivalent
3.4.	Anti-scatter grid:	dedicated moving grid $r = 5; 27 / \text{cm}$
3.5.	Screen film system:	dedicated high resolution screen film system with dedicated processing
3.6.	FFD:	$\geq 60 \text{ cm}$
3.7.	Radiographic voltage:	28 kV
3.8.	Automatic exposure control:	chamber selected to put as close as possible to the nipple and to coincide with parenchyma
3.9.	Exposure time:	$< 2 \text{ s}$
3.10.	Protective shielding:	standard protection

REMARKS — Breast compression should be applied to a level which the patient can tolerate.

— The choice of anode material, total filtration and tube voltage required to obtain satisfactory image quality at an acceptable level of average entrance surface dose will be greatly affected by the density and thickness of the breast under investigation:

For denser and/or thicker breasts (in excess of 6 cm compressed) a tungsten or rhodium anode, aluminium or other special filtration and higher tube voltages might be preferable.

— Handling and maintenance of the imaging equipment should be such that artefacts generated in the cassette (dust, etc.), processing and film handling artefacts are eliminated. Grid lines should not be visible.

CHAPTER 1

APPENDIX I

GUIDELINES ON RADIATION DOSE TO THE PATIENT

Objective

The Criteria for Radiation Dose to the Patient given for each of the selected radiographic projections in this Document are expressed in terms of a reference value of the Entrance Surface Dose for a standard-sized patient. It is intended that this reference dose value is used as a guide to the level of radiation protection of the patient and as an aid to its optimization. If the reference dose value is significantly exceeded then immediate investigations should be made to justify this relatively high level of patient exposure or, if it cannot be justified, to reduce it.

The reference dose value does not signify an optimum level of performance, and reduction of doses below the reference value should always be pursued in line with the ALARA (As Low As Reasonably Achievable) principle, but with due attention to the potential loss of clinical information with any dose reduction. This objective is in line with the recommendation in paragraph 180 of ICRP Publication 60 that consideration should be given to the use of 'dose constraints or investigation levels' for application in some common diagnostic procedures (1).

The reference dose values have been derived from the observed distributions of patient doses in surveys and trials conducted in European hospitals over the past 10 years. They have been set at approximately the level of the third quartile in these dose distributions, as is described in Chapter 2, Part 2. It was argued that if 75% of X-ray departments can operate satisfactorily below this dose level, then the remaining 25% should be made aware of their considerably less than optimal performance and should be encouraged to alter their radiographic equipment or techniques to bring their doses in line with the majority. At the same time, adherence to the Diagnostic Requirements for each radiographic projection will ensure that diagnostic effectiveness does not suffer from this form of dose reduction.

Methods of Dose Measurement to Check Compliance with the Criteria

The objective of the measurements is to obtain a reliable indication of the Entrance Surface Dose that would be delivered to a standard-sized adult patient using the radiographic technique parameters that are being tested against the Quality Criteria. Due to the different types of X-ray and dosimetric equipment that will be available in the various radiology departments, two alternative methods are suggested for measuring entrance surface dose to patients, using either TLDs or ionization chambers.

Both of these are considered equally valid, which should lead to comparable results as long as the dosimeters are suitably calibrated, all measurements are quoted in terms of absorbed dose to air and the effect of backscattered radiation from the patient is included.

Measurements on patients are most easily achieved by TLDs attached directly to the patients' skin at a point coincident with the centre of the incident X-ray beam. Since a patient of exactly standard size (assumed to be 20 cm AP trunk thickness and 70 kg weight) is unlikely to be available, measurements on a statistically significant sample of patients (minimum of 10) of close to standard size are recommended, preferably with an average weight that is 70 ± 3 kg. For mammography, the sample of patients should have compressed breast thicknesses in the range 4 to 6 cm. The mean value of these dose

measurements can be taken as an estimate of the dose to a standard-sized patient for comparison with the reference dose value in the Quality Criteria. Such measurements should form part of an ongoing quality assurance programme.

Entrance surface doses for a representative sample of patients can also be estimated from knowledge of the exposure factors used (kV and mAs) and a measurement of the output of the X-ray tube as a function of the exposure factors. The output can be measured with an ionization chamber dosimeter calibrated in terms of absorbed dose to air or air kerma. It should be held in a scatter free support on the X-ray beam axis at a known distance from the tube focus. The measurement of absorbed dose to air, free-in-air, will have to be corrected to Entrance Surface Dose by applying the inverse square law to obtain the dose at the focus to skin distance and by multiplying by an appropriate backscatter factor. Backscatter factors vary between about 1.3 and 1.4 for the X-ray qualities used for the projections included in the List of Quality Criteria (except for mammography), so a single average value of 1.35 can be used in most situations without appreciable error. For mammography using X-ray tubes with molybdenum anodes, a backscatter factor of 1.09 would be appropriate (2).

References

(1) ICRP Publication 60. '1990 Recommendations of the International Commission on Radiological Protection'. Annals of the ICRP Vol. 21, Nos 1-3 (Oxford, Pergamon Press).

(2) Zoetelief, J., Fitzgerald, M., Leitz W. and Säbel M. 'European Protocol on Dosimetry in Mammography', Report EUR 16263, 1996.

CHAPTER 2

SUMMARY OF THE EVALUATION OF TWO EUROPEAN TRIALS OF THE QUALITY CRITERIA FOR DIAGNOSTIC RADIOGRAPHIC IMAGES

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INTRODUCTION

The Quality Criteria for Diagnostic Radiographic Images presented in Chapter 1 have been developed over a period of about 10 years during which two European-wide trials have been conducted in order to assess their relevance, acceptability and ease of use for the technical and clinical staff of diagnostic X-ray departments. In this Chapter, the results of these trials, undertaken in 1987 and 1991, are summarized, in particular those of the most recent trial. The detailed results and findings of the 1991 Trial are presented elsewhere [Maccia et al. (1996)], and together with results of the 1987 Trial [Maccia et al. (1990)] form a supplementary scientific background to Chapter 1 and the Quality Criteria concept.

1987 Trial

In the first European Trial, conducted in 1987/88, 24 X-ray departments from 10 European countries provided information on their radiographic techniques and on their compliance with and the relevance of the Image Criteria for all six examinations in the preliminary Quality Criteria Working Document [CEC 1987]. Thermoluminescent dosimeters (TLDs) were also sent to the participants to measure the entrance surface dose for each of the radiographs being assessed. Although the Trial did not include an independent analysis of the image quality of the radiographs, a number of valuable conclusions were drawn.

First of all, Trial results confirmed the validity of the Quality Criteria concept as a tool for approaching the optimization of patient radiation protection. In particular, they permitted the identification of suitable technical modalities achieving the 'best possible' compromise between the essential medical information of an image and the patient dose.

Secondly, apart from mammography, entrance surface dose values measured in the Trial for each examination type were consistent with the corresponding dose criteria listed in the preliminary 1987 Quality Criteria Document. Provisional maximum acceptable entrance surface dose values based on the third quartile values observed in the British survey in 1983-84 [Shrimpton et al. (1986)] were, therefore, considered as suitable reference dose values against which to check the compliance of the criteria.

Thirdly, the need for establishing quality assurance programmes and quality control protocols in diagnostic radiology was clearly highlighted by the trial results:

quite large variations in dose were found for the same type of X-ray projection,

incomplete knowledge of radiological equipment performances as well as technical characteristics were observed among the participating X-ray departments.

The results of this Trial were analysed in detail [Maccia et al. (1989, 1990)] and, together with extensive comments from both individuals and professional bodies throughout Europe, they were used to modify the Quality Criteria to form the 1990 Working Document [CEC (1990)].

1991 Trial

In order to assess the validity of the revised Document [CEC, 1990] and to overcome some of the limitations of the first Trial, a second, larger Trial was carried out in 1991. This Trial involved 83 X-ray departments in 16 countries but concentrated on only three examinations; chest, lumbar spine and breast. The original X-ray films, after having been checked locally, were also sent to an independent panel of radiologists for assessment against the Image Criteria. As before, TLDs were used to measure the entrance surface doses and details of the radiographic equipment and technique factors used were collected by questionnaire. Detailed evaluation of the results will be published [Maccia et al. (1996)].

However, a summary follows. This is divided into three parts dealing with radiographic technique, patient dose and image quality respectively.

It must be pointed out that the discussion presented in this chapter is based upon results obtained when using the 1990 version of the Quality Criteria [CEC (1990)] which does differ in a number of respects from the version presented in Chapter 1 of the present document. The results of the 1991 Trial presented in this chapter have in fact helped in formulating the revisions.

PART 1 — RADIOGRAPHIC TECHNIQUE

The following information on radiographic technique was collected:

1. Type and make of X-ray equipment
2. Tube filtration and focal spot size
3. Automatic or manual exposure control
4. Exposure time and tube current.
5. Grid
6. Focus-to-film distance (FFD)
7. Type of film, cassette and processor
8. Speed class of the screen film system and age
9. Patient thickness in the centre of the beam
10. Radiographic voltage
11. Film size

RESULTS AND DISCUSSION

General Aspects of Trial Data

The response rate by the X-ray departments participating in the Trial for information concerning the technical parameters employed, relating purely to X-ray production, namely items 1-4 in the above list, varied for each type of examination. In particular, both tube filtration and focal spot size were generally less frequently reported. For the chest and breast examinations the filtration was only reported by 70% and 45% of departments respectively. This is surprising, given that both European and International Standards [earlier versions and EN/IEC (1993)] require that both pieces of information should be indicated on the X-ray tube housing. Consequently, either manufacturers are not providing this information as required, or users of the equipment are not aware that it is readily available. Since both parameters have a direct bearing on either patient dose (tube filtration) or image quality (focal spot size), this lack of information is a serious omission.

The response rate for information on intensifying screens, films and processors, items 7 and 8, in the above list, also showed a general lack of awareness by the user. In particular, the response rate for equipment employed in examinations of the breast was generally lower than for that employed in chest and lumbar spine examinations. For example, for breast examinations only 50% of departments appeared to know the speed class of the screen film system employed. However, even for such common parameters as the processing time and temperature of the processor, over 10% of departments were unable to provide this information. Article 3 of the EURATOM Directive 84/466, laying down basic measures for the radiation protection of persons undergoing medical examination or treatment, requires the drawing up of inventories of medical radiological equipment as well as the strict surveillance of all installations. **Awareness and knowledge of the technical information on X-ray equipment should be an integral component of such actions.**

It is known that the sensitivity of intensifying screens diminishes with age. This, therefore, will have a direct bearing on patient doses in respect of both their actual magnitude and spread.

Information provided on the type of X-ray generator presently in use indicates that 6-pulse generators are still employed routinely, especially for chest examinations where 29% of examinations utilized this waveform. The most common type of generator was a 12-pulse, which, on average, represented about 50% of installed equipment. The advent of rare-earth intensifying screens has meant that extremely short exposure times can be employed, particularly for examinations of the chest. Such exposures are most efficiently provided by either 12-pulse or the high frequency multi-pulse (so-called converter) generators, which operate with transformer frequencies > 1 kHz. In respect of the latter form of generator, this newer technology appears to be increasingly well diffused and in use in

lumbar spine and breast examinations. These findings were supported by an analysis of equipment age, being on average 4.2, 2.8 and 1.6 years for the chest, lumbar spine and breast examinations, respectively.

Processing conditions play an important role in determining both patient dose and image quality in diagnostic radiology. According to manufacturers' recommendations, most modern processors operate in the temperature range 32-35 °C. However, 30% indicated that they operated outside this range. Similarly, 90 seconds was the most common processing time. However, for mammography, where dedicated processing is most likely, approximately 63% employed extended processing times greater than 90 seconds.

It is, perhaps, worth noting that for chest and lumbar spine films, which in most X-ray departments would tend to be processed in the same processor, roughly 22% of departments employ extended processing times greater than 90 seconds, whereas only 10% of departments utilise processing temperatures less than 32 °C. This implies that roughly 12% of departments employ extended processing times at normal processing temperatures or above. This situation would normally lead to higher fog densities, higher speed but a decreased contrast [Moores et al. (1987)]. However, if weak chemistry was being employed also, then these effects would be compensated for.

Chest

The PA and lateral projections were included in the Trial and approximately 85% of departments indicated that they employed tube voltages within the range 100 to 150 kV recommended in the Quality Criteria Document. The remaining 15% of examinations were performed at significantly lower values (Fig. 1.).

For chest examinations, a nominal focal spot value less than 1.3 is recommended for all projections. Approximately 90% of examinations employed values less than or equal to 1.3. Similarly, focus to film distance (FFD) also affects resolution; generally in direct proportion to the inverse distance. Almost 50% of examinations are performed at 170 cm or less, whereas 10% were performed at FFDs greater than 200 cm. It should be borne in mind that the benefits of a small focal spot can be eliminated by the use of a shorter FFD and vice versa, larger spots can be compensated by larger FFDs. The results indicated no correlation between focal spot size and FFD, so that departments do not appear to consciously attempt to compensate for a large focal spot-size by the use of larger FFD.

Approximately 40% of departments employed manual selection of exposure for chest examinations, the remaining 60% utilize automatic exposure control (AEC). Over 95% of departments employed screen film systems with nominal speed classes in the range 200 - 400 with roughly 52% of class 200 and 40% of class 400. Both the operating radiographic voltage and speed class fundamentally affect patient dose and image quality. (Warren-Forward and Bradley (1993)).

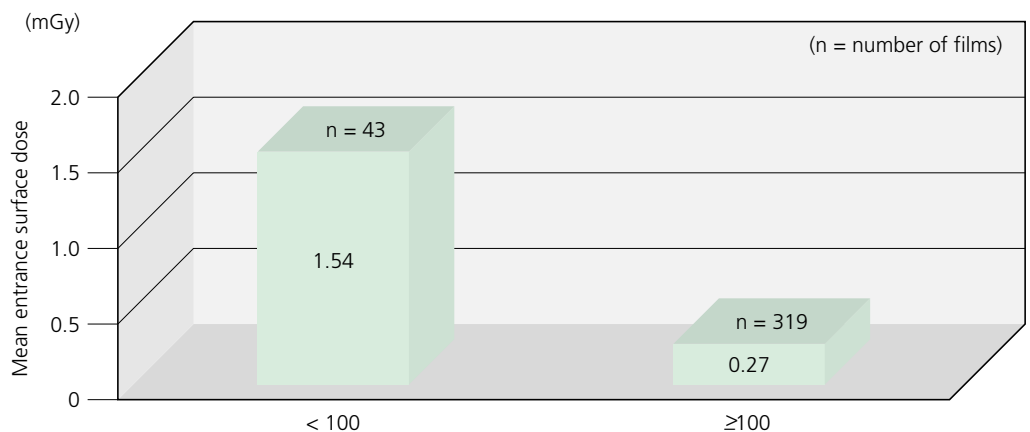


Figure 1: Mean entrance surface dose for high and low ranges of tube voltage: Chest PA.

Lumbar Spine

Three types of lumbar spine projections were included in the Trial: AP or PA, lateral and lateral lumbo-sacral joint. For the AP/PA projection, good radiographic technique involved tube voltage in the range 70-90 kV. Approximately 70% of all such examinations complied with this practice. However, roughly 30% involved lower values which can give rise to higher doses. These results may be compared with a previous study (Shrimpton et al. 1986) where roughly 50% of AP lumbar spine examinations employed a tube voltage less than 75 kV.

For the lateral lumbar spine examination, the 1990 Quality Criteria Document recommended a range of 90-100 kV. Only approximately 20% of examinations were found to be within this range, whereas roughly 70% were lower. In a previous study (Shrimpton et al. (1986)) the majority of lateral lumbar spine examinations were also performed using tube voltages below 90 kV. These results implied that either the values proposed in the 1990 Quality Criteria Document were too high, or an educational programme is required throughout Europe in order to bring about a change of practice. The revised version in Chapter 1 opted for 80-95 kV.

The recommended radiographic voltage for the lateral lumbo-sacral joint was 90-110 kV. Only approximately 50% of examinations were in this range, and 35% employed settings of up to 10 kV lower. In a previous study, up to 50% of examinations of this type also employed settings less than 90 kV [Shrimpton et al. (1986)]. The revised version opted for 80-100 kV.

Almost 90% of all lumbar spine examinations recorded nominal focal spot values of less than or equal to 1.3. In all 40% of examinations employed manual selection of the exposure whereas 60% utilized AEC (Fig. 2).

The 1990 Quality Criteria Document recommended screen film systems with a nominal speed class range of 400-800 for all three lumbar spine projections. However, roughly 30% of examinations employed the slower speed class 200. Presumably, this reflected the possible importance of resolution in this type of examination, particularly in the AP/PA and lateral views. On the other hand, the positioning of the patient appeared to play a key role in the acceptability of the lateral projection of the lumbo-sacral joint (see page 41, part 3 — Image Quality).

Breast

Approximately 80% of examinations were performed using a tube voltage ranging from 26 to 31 kV. Since 90% of patients examined as part of the Trial had compressed breast thicknesses of between 4 and 6 cm, then most examinations were performed within the recommended kV range. For both cranio-caudal and lateral projections approximately 50% of examinations were performed in the range 28-29 kV.

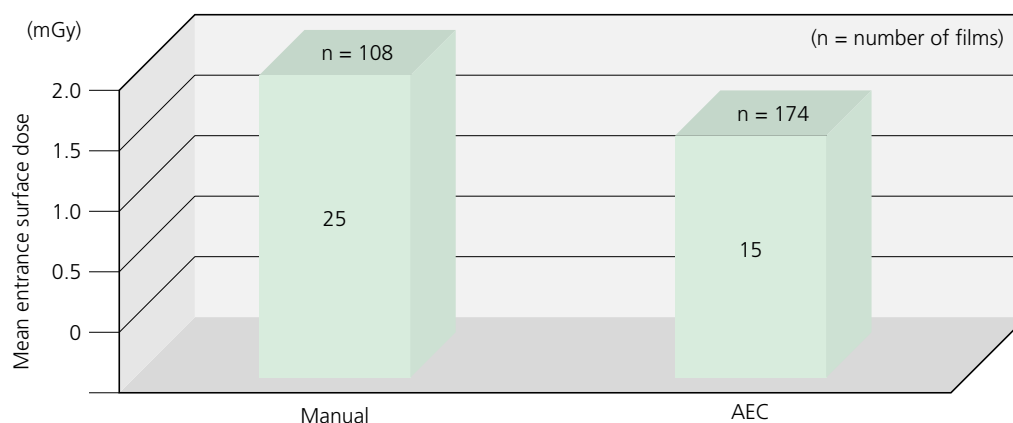


Figure 2: Mean entrance surface dose for manual and automatic exposure control. (Lateral Lumbar Spine)

In breast examinations, a small focal spot is necessary for the high resolution required. Approximately 60% of those 80% of departments which provided the necessary information indicated that they employed a nominal focal spot value of 0.3 for mammography with a range of 0.1-0.6.

Only two departments indicated that they employed manual exposure control in X-ray examinations of the breast. The remainder employ AEC. Only 50% of departments indicated the nominal speed class of the screen film system employed in this type of examination.

CONCLUSIONS

The results of the 1991 Trial of the 1990 Quality Criteria Document highlighted a number of important aspects concerning radiographic practice in Europe.

1. Information concerning the technical aspects of radiographic equipment, such as filtration, nominal focal spot value etc., was still in many cases not sufficiently known by staff in X-ray departments. In particular, 50% of departments did not know the speed class of screen film systems employed in breast examinations. Availability and awareness of this information forms an integral part of fulfilment of Article 3 of the EURATOM Directive 84/466. Every effort should be made by manufacturers and X-ray department staff to ensure this information forms part of the technical database of an X-ray department. The EN/IEC (1993) guidelines concerning presentation of this information should be fully implemented, for example presentation of nominal focal spot value and total tube filtration on the tube housing.
2. As expected, extended processing times were employed for breast examinations. However, they were also employed for other examinations, particularly the chest.
3. The choice of FFD, screen film speed class and focal spot size should be rationalized to ensure that larger focal spot sizes are employed with longer FFD's or smaller foci are employed with faster screen film speeds.
4. Approximately 40% of departments still employed manual exposure control for chest and lumbar spine examinations.
5. Approximately 50% of examinations of the lumbar spine employed radiographic voltages lower than those recommended in the CEC (1990) Quality Criteria. The reasons for this require further consideration due to the importance of radiographic voltage to both image quality and patient dose.
6. A significant proportion (30%) of examinations of the lumbar spine employed screen film systems with the lower nominal speed class of 200 (recommended range 400-800). The justification for continued use of speed class 200 needs further consideration, particularly in view of the panel of independent radiologists' assessment of film density for this type of examination.

PART 2 — PATIENT DOSE

One of the criteria for good imaging performance defined in the 1990 Quality Criteria Document is a reference value for the entrance surface dose for each type of radiograph. The reference dose values in the 1990 Document were selected on the basis of the doses measured on patients in a random sample of 20 British hospitals in 1983/84 (Shrimpton et al., 1986) and at the 20 European hospitals taking part in the 1987 Trial of the Quality Criteria (Maccia et al., 1990). They were set to coincide approximately with the third quartile values seen in these earlier surveys. The one exception was for breast examinations where a national survey of entrance surface doses measured on patients had not been made, the preferred technique being to measure the incident air kerma (without backscatter) on a standard 4 cm thick polymethylmethacrylate (PMMA) phantom representing the breast. In this case, a provisional reference entrance surface dose for breast examinations was based on the third quartile value observed in a 1989 survey of 30 British

breast examinations screening centres, having converted the incident air kerma into entrance surface dose by applying a suitable backscatter factor.

The purpose of the reference doses is to act as local investigation levels, promoting action to reduce or thoroughly justify what are essentially excessive doses, if the mean entrance surface dose measured on a representative sample of patients and for a particular type of radiograph is seen to exceed the corresponding reference dose value. The reference dose values are not intended to be a guide to optimum performance, but more of a trigger to investigate situations that are considerably away from the optimum. It may well be possible to reduce doses further without detriment to the diagnostic value of the examination and such reductions should always be pursued in line with the ALARA (As Low As Reasonably Achievable) principle.

Since entrance surface doses might be expected to vary according to the size of the patient, participants in the Trial were asked to select patients of between 65 and 75 kg weight or, for breast examinations, of between 4 to 6 cm compressed breast thickness.

Such a tight restriction on patient size was not always possible. However, as 10 patients were to be measured for each type of radiograph at each hospital, the mean of these 10 measurements could still provide a good indication of the typical dose used in that hospital for a standard-sized patient. This is particularly true in view of the low degree of correlation that was actually observed between entrance surface dose and either patient weight or thickness in the Trial results.

The distribution of patient doses measured in the 1991 Trial is described below and comparisons are made with the 1990 Quality Criteria reference dose values. The relationship between the doses observed and the radiographic techniques employed was investigated to see whether low doses are compatible with the 'Example of Good Radiographic technique' given in the 1990 Quality Criteria Document.

Distribution of Individual Doses

The sample sizes and the mean and third quartile values for the individual patient dose measurements are shown in Table 1. There were 16 countries participating in the 1991 Trial with between 18 and 42 hospitals providing about 300 dose measurements for each type of radiograph. The overall mean and third quartile dose values for each type of radiograph in the 1991 Trial can be compared with the corresponding values from the original British surveys on which the reference doses were based, also shown in Table 1. The agreement between these simple measures of the dose distributions is remarkably close for the chest and lumbar spine examinations, but not so good for breast examinations. This is not surprising, as the British values for breast examinations were based on dose estimates for a 4 cm PMMA phantom (representing a 4.5 cm thick compressed breast) at 30 breast examinations screening centres in 1989 and did not take into account the variations in breast

Table 1: Individual Patient Dose Statistics

Radiograph	1991 European Trial				1983-89 British surveys	
	No of measurements	No of hospitals	Mean dose (mGy)	Third quartile (mGy)	Mean dose (mGy)	Third quartile (mGy)
Chest PA	354	34	0.36	0.39	0.23	0.26
Chest LAT	257	29	1.3	1.2	1.5	1.5
Lumbar spine AP	301	31	7.8	10	9.2	11
Lumbar spine LAT	308	33	19	27	23	30
Lumbar spine LSJ	139	18	35	46	39	50
Breast CC	369	38	7.8	10	5.6	7.1
Breast LAT	408	42	9.2	12	5.6	7.1

thickness seen in practice. Participants in the Trial were asked to select patients with compressed breast thickness between 4 and 6 cm, and in fact achieved this for 90% of the patients. There was a slight tendency for breasts to be thicker when compressed laterally (mean thickness = 5.3 cm) than when compressed cranio-caudally (mean thickness 5.1 cm).

Comparison of Hospital Mean Doses With Reference Dose Values

The range of the hospital mean doses for each type of radiograph and the percentage of hospitals for which the mean dose exceeded the corresponding 1990 Quality Criteria reference dose value are shown in Table 2. It can be seen that the mean doses range over factors of between 5 and 17 depending on the type of radiograph, with PA chests showing the lowest spread. Table 2 also shows that between 14 and 69% of hospitals in the Trial have mean dose values in excess of the 1990 Quality Criteria reference values. In the earlier surveys, on which the reference dose values were based, the corresponding figure was, of course, 25%. Lateral chest and lateral lumbar spine radiographs in the 1991 Trial show an improvement on this earlier figure whereas the other chest and lumbar spine projections show a slightly worse performance. These relatively small differences in performance observed in a fairly small sample of hospitals are not thought to provide sufficient evidence for changing the reference dose values for these two types of examination.

However, for the breast radiographs, over half the hospitals in the 1991 Trial exceeded the reference dose values. The reference dose for breast radiographs consequently needs revising to a higher value to allow for the variations in breast thickness and the average thickness higher than 4.5 cm, encountered in a sample of patients when they are selected to be within the most commonly occurring range of 4 to 6 cm.

The third quartile values for the hospital mean entrance surface doses are 9 mGy for the cranio-caudal projection and 12 mGy for the lateral projection (close to the corresponding third quartile values for the **individual** entrance surface dose measurements of 10 mGy for the cranio-caudal projection and 12 mGy for the lateral projection shown in Table 1). Consequently, the 1991 Trial lends support to a new reference value for directly measured breast entrance surface doses on patients of about **10 mGy** for either projection (Fig. 3).

There is no need for the reference dose values to be precise or specific as they are intended to act as a trigger to investigation and corrective action only for situations in most urgent need of better quality control. A rounded value of **10 mGy** for both projections is therefore considered to be suitable.

The European Protocol on Dosimetry in Mammography (Zoetelief et al. (1996)) also recommends a reference Entrance Surface Air Kerma (ESAK) of **10 mGy** for the mean of 10 measurements made on a sample of patients with breast thickness of between 4 and 6 cm. ESAK is defined in the Protocol as not to include backscattered radiation from the

Table 2: Compliance with 1990 Quality Criteria Reference Dose Levels

Radiograph	1990 Quality Criteria Reference Dose (mGy)	Hospital mean dose values		Hospitals with mean dose > Reference Dose (%)
		Range (mGy)	Ratio max/min	
Chest PA	0.3	0.1-0.5	5	29
Chest LAT	1.5	0.3-3.2	11	14
umbar spine AP	10	2-20	10	26
umbar spine LAT	30	4-54	14	15
umbar spine LSJ	40	10-80	8	33
Breast CC	7	2-22	11	53
Breast LAT	7	1.5-2.6	17	69

patient, and is consequently derived from the measured entrance surface dose by dividing by an appropriate backscatter factor. However, the backscatter factor is typically only about 1.09 for breast examinations, so that the difference between the measured entrance surface dose and the ESAK is considered to be insufficient to warrant numerically different reference values for the two quantities.

Relationship Between Patient Dose and Radiographic Technique

For each type of radiographic examination included in the 1990 Quality Criteria there is an Example of Good Radiographic Technique in which values are recommended for a list of radiographic technique parameters which should enable the image and dose criteria to be met. Those radiographic technique parameters which, if acting independently, would be expected to have an effect on patient entrance surface doses, are:

- speed class of the screen film system;
- radiographic voltage ;
- total filtration;
- focus-to-film distance (FFD);
- type of anti-scatter grid;
- automatic exposure control (AEC) or manual;

The information collected in the 1991 Trial on these technique parameters was analysed to see if their impact on patient entrance surface dose could be observed. Unfortunately, it was not possible to observe the effect of each parameter independently, by selecting subsets of the data in which the effects of all other confounding factors had been removed by holding their values constant, without reducing the sample to an insignificantly small size. Instead, all the available data for each type of radiograph were analysed together by plotting scatter diagrams and calculating the correlation coefficients between the entrance surface doses and the first four of the technique factors listed above. However, little correlation was evident in the scatter diagrams and the correlation coefficients were low; most being below 0.2 and sometimes of the opposite sign to that expected; no doubt due to the confounding influence of other parameters. There was a disappointingly low correlation seen, for example, between the nominal speed class of the screen film system and dose for M projections, and the expected relationship between radiographic voltage and dose was only apparent to a slight degree for the chest radiographs.

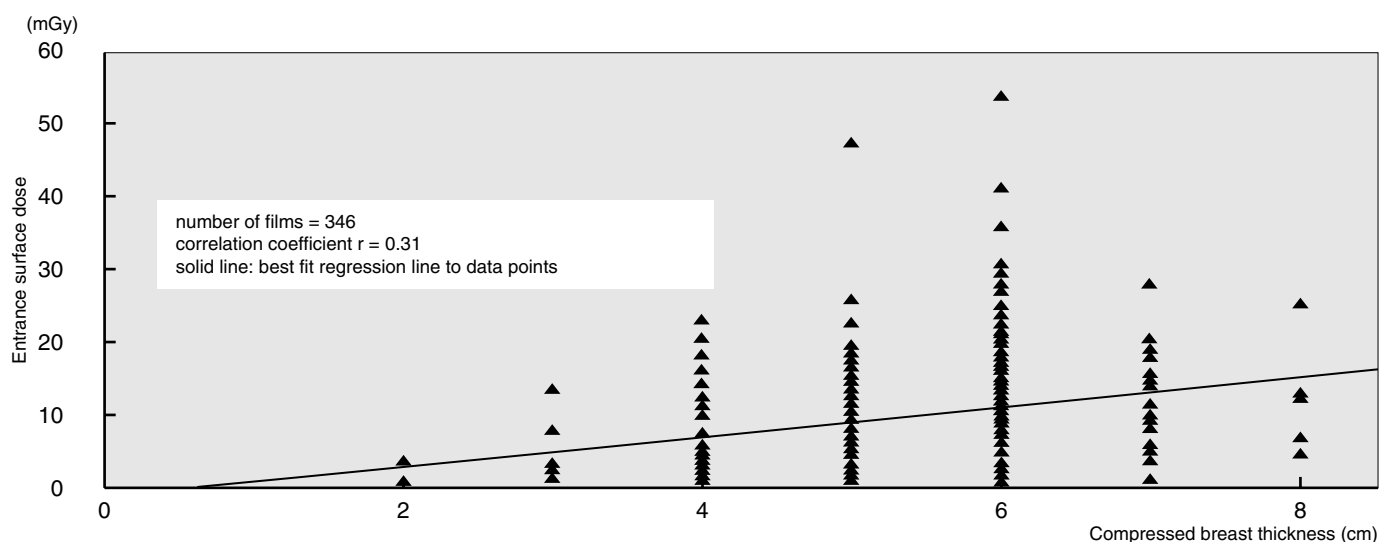


Figure 3: Scatter diagram of entrance surface dose for different compressed breast thicknesses. (Lateral projection)

An analysis of the technique parameters used by the hospitals at the top and bottom of the dose distributions did, however, reveal some clear causes for their bad or good performance. For example, the highest dose hospital for PA chest radiographs was using an exceptionally low level of tube voltage (mean value = 49 kV) together with a low FFD of 100 cm. The lowest dose hospital for PA chest used a fast screen film system (800) together with a high tube voltage (mean value = 125 kV) and the second lowest dose hospital used the longest FFD recommended in the 1990 Quality Criteria Document (200 cm). For the AP and lateral lumbar spine projections, one of the highest dose hospitals was using a slower nominal speed class of the screen film system than recommended in the 1990 Quality Criteria and another was using a lower than recommended tube voltage. The lowest dose hospital for the AP lumbar spine projection used the highest FFD of all hospitals in the Trial (130 cm) and all its other technique parameters were within recommended levels. For the lumbo-sacral joint (LSJ) projection the highest dose hospital used a lower than recommended tube voltage (mean = 73 kV).

However, no consistent trends were seen in the mean entrance surface dose as a function of the number of the radiographic technique criteria in the 1990 Quality Criteria which were fulfilled. There was, however, clear evidence that higher doses were obtained when there was little or no compliance with the criteria given in the Example of Good Radiographic Technique (Fig. 4).

CONCLUSIONS

The distribution of patient doses measured in the 1991 Trial, from 83 X-ray departments in Europe, is sufficiently similar to that seen in earlier surveys for the chest and lumbar spine projections not to warrant any changes in the relevant reference dose values. For breast examinations, on the other hand, entrance surface doses measured in the Trial on representative samples of patients, were sufficiently different from those derived in the past from standard phantom measurements to warrant a revision in the reference dose value from 7 mGy to 10 mGy.

It is difficult to observe the influence of individual radiographic technique parameters on patient entrance surface dose in surveys of this nature which were not designed primarily with this purpose in mind. **The Trial has demonstrated, however, that the mean entrance surface dose to a representative sample of patients for a particular type of radiograph, provides a useful measure of the level of patient protection achieved in an X-ray department and that there still exist wide variations in performance throughout Europe.**

There was, moreover, clear evidence from the limited analyses performed that it was not difficult to meet the entrance surface dose criteria in the 1990 Quality Criteria for chest and lumbar spine radiography, while complying with the Example of Good Radiographic Technique. Conversely, many hospitals failing to meet the dose criteria were found not to be following the Example of Good Radiographic Technique in its entirety. In particular, increasing the nominal speed class of the screen film system, the radiographic voltage and the FFD to the upper values given in the Example of Good Radiographic Technique will generally result in lower doses to the patient while retaining satisfactory image quality.

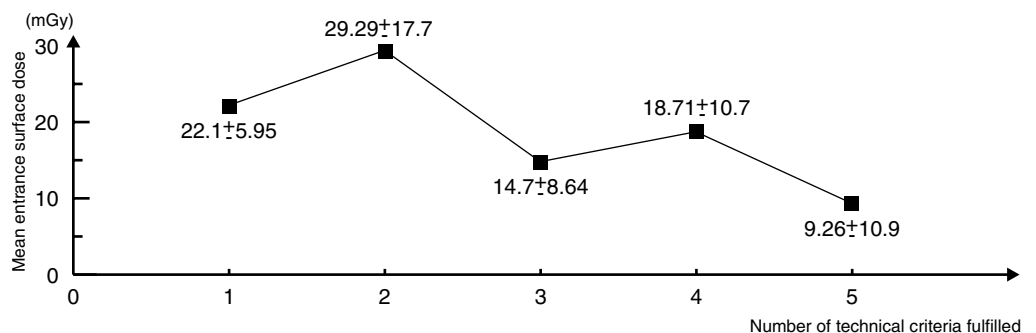


Figure 4: Impact of good radiographic technique on entrance surface dose. (Lateral Lumbar Spine)

PART 3 — IMAGE QUALITY

One of the most important objectives of the 1991 Trial was to validate and demonstrate the usefulness of the image criteria, for the chest, lumbar spine and breast examinations, elected from the 1990 Quality Criteria Working Document.

In order to achieve this goal, a panel of 15 independent European radiologists (five radiologists for each examination) met for one week and reviewed the original X-ray films collected during the Trial. In this way, they provided independent analysis of the image quality of these examinations using the same Quality Criteria and questionnaires which had been used by the field radiologists (see Chapter 3: Quality Criteria Implementation and Audit Guidelines). Each member of the panel, working separately, received sets of films which were reorganized randomly between each reading. The panel members completed as many film readings as possible within the week, with the objective of eventually reviewing all collected films in their particular speciality (chest, lumbar spine or breast). Thus each film was checked once on a local level, and from two to five times by independent panel radiologists.

RESULTS AND DISCUSSION

Relevance of the Image Criteria

The compliance rates with the 1990 Quality Criteria for each type of film as assessed by both the field and panel radiologists are presented in Table 3.

As can be seen, the greater the number of criteria to be met then, generally, the lower the percentage of films which met all of them. Thus the PA chest projection with nine criteria showed the lowest percentage of films meeting all criteria for both field and panel radiologists.

However, the fact is that, overall, a high percentage of criteria were met (see final column, Table 3). Thus all films met between 85.8% and 93% of criteria. The 5th and 6th columns of Table 3 indicate that between 33% and 81% of films met all criteria. The criteria are, therefore, not only visible, but the field as well as the panel radiologists confirmed that they saw most of them.

Obviously, it is important to know whether or not all the panel radiologists saw the same criteria in that subset of films which had been viewed independently by them all (inter-

Table 3: Compliance Rates with the Image Criteria of the 1990 Quality Criteria

Examination type	Projection	Number of films	Number of Image Criteria	Films meeting all Image Criteria (%)		Image Criteria met by all films as assessed by field radiologists (%)
				Field Radiologists	Panel Radiologists	
Chest	PA	364	9	33.1	35.2	85.8
	Lateral	267	4	80.8	80	93
Lumbar Spine	AP/PA	305	7	57.3	59.2	89.2
	Lateral	312	7	53.6	51.4	87.4
Breast	LSJ	161	4	70.9	70.8	91.9
	CC	320	4	72.9	79.3	91.3
	Lateral	359	4	67.8	64.3	89.6

viewer reliability). Also, it is important to compare the average response rates of the panel radiologists to those of the field radiologists (inter-group reliability). These considerations are fundamental in attempting to define relevant and universally applicable criteria. Perfect agreement between the panel and field radiologists would indicate that both groups define and apply the criteria in the same way. It would also demonstrate that both groups see the criteria in a similar manner, a matter of experience and training. On the other hand, disagreement between the two groups may indicate:

- there is some disagreement about the actual definition of one or more criteria
- judgement is subjective rather than according to stable decision rules common to all
- one group has insufficient experience or training in scoring a criterion reliably

Inter-Viewer Reliability

In order to test the inter-viewer reliability of the panel radiologists, comparisons were made between their five readings of each projection and examination. In order to ensure that the viewing conditions were strictly comparable amongst the panel of viewers, new matched viewing boxes were employed. The inter-viewer reliability is considered separately for each examination before drawing general conclusions.

Chest

The panel radiologists' scores for the chest PA projection showed considerably greater variation than either the lumbar spine or breast assessments. There was a high level of agreement on only one third of the criteria, namely:

- performed at deep inspiration and with suspended respiration
- reproduction of the vascular pattern in the whole lung, particularly in the peripheral vessels
- visually sharp reproduction of the trachea and proximal bronchi, the borders of the heart and aorta.

It can be recognized that the first criteria concerns the positioning of the patient and co-operation, while the other two depend to a large extent upon the radiographic technique itself; field size (second) and resolution (third).

For the remaining criteria there was significant disagreement with up to 100% on certain criteria. The disagreement highlighted a number of revealing problems associated with the criteria:

- judgments relating to degree of symmetry and/or completeness, for example:
 - symmetrical reproduction of the thorax
 - reproduction of the whole rib cage above the diaphragm;
- assessments of technical prowess including good positioning and choice of kV, exposure time etc., for example:
 - visualization of the retrocardiac lung and mediastinum.

The panel members also made a subjective assessment of film blackening and the chest images with non-optimal scores for the Image Criteria tended also to be assessed as being too dark. However, roughly 70% of all the chest images were deemed to be of optimal film density.

When comparing the panel and field radiologists, both groups scored films similarly. However, the greatest level of disagreement concerned the criterion:

symmetrical reproduction of the thorax.

the only two criteria for which there was agreement between the assessments of both groups were:

performed at deep inspiration and with suspended respiration;

visually sharp reproduction of the trachea and proximal bronchi, the borders of the heart and aorta.

The lateral projection is a non-routine examination normally used to confirm findings of the PA view. Fewer Image Criteria are employed since less information is normally gathered from this image. Nevertheless, results for this projection were, in essence, similar to those noted for the PA projection.

lumbar Spine

There were seven Image Criteria for either the AP or PA views when film blackening was included. The panel members agreed that 80% or more of all films fulfilled four out of the six anatomical Image Criteria. However, there was considerable disagreement on the other two criteria:-

visually sharp reproduction of the pedicles;

visualization of the intervertebral joints.

Visualization of the intervertebral joints and reproduction of the spinous and transverse processes depend upon careful positioning of the patient, which is not always easy to achieve.

The criterion:

reproduction of the adjacent soft tissues, particularly the psoas shadow

is also difficult to visualize, even on a perfect image. Therefore, it is perhaps not surprising that 'average' compliance among the panel members for this criterion was roughly 85%, somewhat less than the overall Image Criteria compliance of 89% shown in Table 3.

In respect of film blackening, the panel members tended to prefer a darker film, in general, in order to ensure adequate contrast between different bony structures. Hence, non-optimal films were predominantly considered to be too light. Far fewer films, approximately 60%, were considered optimal for this projection. It was interesting to note that generally there was again little disagreement between the average responses of the panel and field radiologists.

For the lateral projection, the same pattern of responses was found for those criteria in common with the AP or PA projections. However, for three criteria, there was considerable disagreement among the panel members on the degree to which films fulfilled the criteria. For the criterion:

full superposition of the posterior vertebral edges

acceptability ranged between 35 and 90% among the panel members in terms of percentage of films fulfilling the criterion. Obviously, the panel members had to apply their own personal definition of 'full'. This type of problem eventually led the panel members to devise a scoring mechanism for individual criteria analogous to that often applied in visual detection tests. (See Chapter 3).

The criterion:

- visually sharp reproduction of the cortex and trabecular structures

received the lowest compliance rating of all the criteria for this projection for all panel members (on average approximately 72%).

Also, on average, even fewer films were considered to be of optimal optical (film) density for this view (only approximately 50%). All panel members, on average, considered that roughly 42% of films were too light.

The panel and field radiologists showed generally good agreement for most criteria. However, the field radiologists in this projection tended to find that criteria were fulfilled a little more often. In the case of an assessment of film blackening, the field radiologists deemed radiographs to be of optimal film density in 75% of cases on average, whereas the panel assessed only 50% to be in this category.

The lateral projection of the lumbo-sacral joint is, in general, a less frequent projection used to confirm the findings of the other two projections. There are, therefore, fewer criteria to be met. However, in general, the criterion:

- reproduction by tangential projection of the inferior end plate of the L5 and the superior end plate of S1

was only deemed to be met on average in approximately 80% of films. This criterion is dependent to a large extent upon careful positioning of the patient. The remaining two criteria were deemed to be fulfilled in a high percentage of cases. But again, on average, only roughly 75% of images were deemed to be of optimum film density.

For this projection there was good agreement between panel and field radiologists assessments.

Breast

The panel radiologists showed almost perfect agreement for the first two criteria of the cranio-caudal projection image. For the third criterion:

- nipple should be parallel to the film

the inter-viewer variability was large (40-80%) among the panel members. Also, the average acceptability (67%) for this criterion, among the whole panel, was poor. It would appear that this criterion is too vague, since strict parallelism is hard to verify.

In respect of optimal film blackening, approximately 75% of films were, on average, deemed to be of optimal film density, with the remaining 25% assessed as being too light.

For this projection, the panel radiologists generally assessed criteria as being fulfilled more frequently than the field radiologists, including strict parallelism of the nipple. However, for the lateral view, the reverse situation existed.

CONCLUSIONS

The results of the 1991 Trial of the 1990 Quality Criteria highlighted a number of important aspects concerning the assessment of image quality by means of Image Criteria employing anatomical details.

1. Radiologists find it difficult to unequivocally interpret criteria which:

involve some form of assessment of symmetry, for example symmetrical reproduction of the thorax

involve assessment of field coverage, for example reproduction of the whole rib cage above the diaphragm

involve assessment of fulfilment of technical requirements, for example visualisation of the retrocardiac lung and the mediastinum.

2. The set of Image Criteria defined for evaluation of the quality of diagnostic films for the chest, lumbar spine and breast examinations in general could be applied consistently by both a panel of expert radiologists and those working in the field.

3. Seven out of 29 criteria failed to meet validation requirements for inter-viewer reliability. Three types of weakness were indicated:

definition was too vague, employing words such as 'full' and 'symmetric' without providing limits of acceptable deviation or any measurement technique

criteria are non-exclusive whereby categories of response could be interpreted in at least two ways

criterion such as film blackening is rather subjective and produced a highly variable assessment.

4. Clearer compartmentalization of Image Criteria into positioning and technical categories is required in order to more easily link the image quality, patient dose and radiographic technique.

All of these observations have been taken into account in the revised lists of Quality Criteria presented in Chapter 1.

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Chapter 3

QUALITY CRITERIA IMPLEMENTATION AND AUDIT GUIDELINES

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Quality Criteria Implementation and Audit Guidelines

The Quality Criteria are designed to be easily applied in practice in any X-ray department without the need for special equipment apart from a means of measuring or estimating the dose to the patient. They are intended to provide a demonstrably achievable standard of good practice both in terms of a satisfactory level of image quality and an acceptably low radiation dose to the patient.

However, the Quality Criteria will only be of real benefit to an X-ray department if they allow inadequate levels of performance to be readily identified and corrected. The impact of applying the Quality Criteria in a particular X-ray department in terms of the level of improvement in performance achieved, can only be properly assessed through a correctly structured process of medical audit.

The essential components of the medical audit process can be summarized as:

- Set standards
- Check compliance
- Correct bad practice
- Set new standards
- Repeat.

The Quality Criteria essentially provide the initial 'standards' for image quality and patient dose audit: a special case of 'medical' audit.

More detailed steps in the audit process specific to this special case are:

1. Choose a type of radiograph and X-ray facility (room or individual X-ray unit) to audit.
2. Take a random sample of at least 10 standard-sized patients (60-80 kg or 4-6 cm breast thickness).
3. Take the chosen type of radiograph on each patient using established techniques.
4. Record all the technique and equipment parameters for each radiograph. (See example questionnaire in Appendix I to this chapter for relevant details to record.)
5. Measure or estimate the entrance surface dose for each radiograph using the methods described in Appendix I of Chapter 1. Compare the mean value for the sample of at least 10 standard-sized patients with the corresponding reference dose value in the Quality Criteria.
6. At least two observers should check compliance of each radiograph with the Image Criteria independently. Appendix II to this chapter contains copies of the Image Criteria Assessment forms used by the panel radiologists for scoring films in the trials of the Quality Criteria. Observers taking part in this audit process might find these forms useful. There is a form or set of forms for each type of radiograph for which Quality Criteria are provided in these Guidelines. As well as providing a system for scoring compliance with the Image Criteria and the visibility of important image details, these forms also include a system for scoring more general aspects of the image, such as blackening, contrast, sharpness, beam limitation and diagnostic acceptability.

To help in judging these features, both during this audit process and more generally at any time, X-ray departments should consider having available a set of 'ideal' films in which all these aspects are optimized and against which any other films can be directly visually compared. It is essential, of course, that the 'ideal' film can be produced with a dose to the patient below the corresponding reference value.

7. Identify where the standard (image quality or dose criteria) are not being met.
8. Investigate the cause(s) of any consistent non-compliance with the criteria. The 'Example of Good Radiographic Technique' may be useful to help identify those aspects of the established technique or equipment which are responsible.
9. Take corrective action by changing techniques or equipment in a manner likely to remedy the non-compliance.
10. After a short period of using the revised techniques or equipment, repeat steps 2-7.
11. If no improvement, repeat steps 7-10.
12. If initial standards (Quality Criteria) are now being met in full, consider improving standards, for example, by setting lower reference dose values in line with the optimization principle ALARA (As Low as Reasonably Achievable).

o help establish a more uniform and more widespread level of performance in diagnostic radiology, it would be desirable to extend the audit process to include independent observers, external to the X-ray department being audited, and to progressively apply the process to larger groupings than individual X-ray departments.

CHAPTER 3

APPENDIX I

**SAMPLE QUESTIONNAIRE FOR
RECORDING RADIOGRAPHIC TECHNIQUE, EQUIPMENT AND DOSE DATA**

Chest Examination

A) Radiographic Technique ⇨ to be filled in by the radiographer

A.1. Is the examination performed on:

- Vertical stand with stationary grid
- Vertical stand with moving grid
- Other: _____

A.2. X-ray Generator

- Manufacturer/Type: _____ / _____
- Wave form: 6 Pulse 12 Pulse
- Constant Potential Capacitor Discharge
- Other: _____

A.3. X-Ray tube

- Manufacturer/Type: _____ / _____
- Inherent filtration mm Al equivalent
- mm Cu equivalent
- mm other equivalent
- mm mm
- Nominal focal spot values
- Is the X-ray unit equipped with
- an Automatic exposure control ? Yes No
- an Anti-scatter grid? Yes No
- If Yes, Grid ratio 'r'? Strips per cm?

A.4. Screen-Film System

- Film Manufacturer/Type: _____ / _____
- Screen Manufacturer/Type: _____ / _____
- In use since (date) _____

A.5. Film Processor

- Manufacturer/Type: _____ / _____
- Processing Time: s
- Developer Temperature: °C

Patient Number

B) Patient-related data ⇨ to be filled in by the radiographer

- B.1. Age Years
- B.2. Sex M F
- B.3. Height cm
- B.4. Weight kg

C) Dose-related data

PA PROJECTION

- Patient thickness in the centre of the beam cm
- Additional filtration mm AL equivalent
- Radiographic voltage kV
- Applied nominal focal spot value
- FFD. cm
- Film size cm x cm
- Automatic exposure control Yes No
- Chamber selection left central right
- Exposure time ms
- Tube current mA or mAs
- Nominal speed class of screen film system: _____
- Type and age of screen: _____

TLD sachet: (please attach here)

LATERAL PROJECTION

- Patient thickness in the centre of the beam cm
- Additional filtration mm AL equivalent
- Radiographic voltage kV
- Applied nominal focal spot value
- FFD. cm
- Film size cm x cm
- Automatic exposure control Yes No
- Chamber selection left central right
- Exposure time ms
- Tube current mA or mAs
- Nominal speed class of screen film system: _____
- Type and age of screen: _____

TLD sachet: (please attach here)

CHAPTER 3

APPENDIX II

IMAGE QUALITY ASSESSMENT FORMS

Chest

Skull

Lumbar Spine

Pelvis

Urinary Tract

Breast

Name of radiologist:

Hospital code:

Patient No:

Image criteria *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Performed at full inspiration (as assessed by the position of the ribs above the diaphragm — either 6 anteriorly or 10 posteriorly) and with suspended respiration															
Symmetrical reproduction of the thorax, as shown by the central position of a spinous process between the medial ends of the clavicles															
Medial border of the scapulae to be outside the lung fields															
Reproduction of the whole rib cage above the diaphragm															
Visually sharp reproduction of the vascular pattern of the lungs, particularly the peripheral vessels															
Visually sharp reproduction of the:															
(a) trachea and proximal bronchi															
(b) borders of the heart and the aorta															
(c) diaphragm and lateral costo-phrenic angles															
Visualization of the retrocardiac lung and the mediastinum															
Visualization of the spine through the heart shadow															
Total:															

Important image details **

Small round details in the whole lung, including the retrocardiac areas: high contrast: 0.7 mm; low contrast: 2 mm diameter															
Linear and reticular details out to the lung periphery: high contrast: 0.3 mm; low contrast: 2 mm in width															

Scoring: * 1: yes; 0: no; where any area is obscured by a pathological condition, then 'P' should be placed in the appropriate box.

Maximum total score: 10.

** +: yes; if 'no' indicate minimum visible detail (in mm).

Name of radiologist:

Hospital code:

Patient No:

Image criteria *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Performed at full inspiration and with suspended respiration															
Arms should be raised clear of the thorax															
Superimposition of the posterior lung borders															
Reproduction of the trachea															
Reproduction of the costo-phrenic angles															
Visually sharp reproduction of the:															
(a) posterior border of the heart and the aorta															
(b) mediastinum															
(c) diaphragm															
(d) sternum															
(e) thoracic spine															
Total:															

Important image details **

Small round details in the whole lung: high contrast: 0.7 mm; low contrast: 2.0 mm diameter															
Linear and reticular details out to the lung periphery : high contrast: 0.3 mm; low contrast: 2.0 mm in width															

Scoring: * 1: yes; 0: no; where any area is obscured by a pathological condition, then 'P' should be placed in the appropriate box.

Maximum total score : 10.

** +: yes; if 'no' indicate minimum visible detail (in mm).

Name:

Hospital code:

Complete image annotation (see p.4) must be available on each film

Patient No:

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Appropriate film density (blackening): Lungs*															
Appropriate film density (blackening): mediastinum*															
Contrast **															
Sharpness ***															
Appropriate beam limitation ****															
Film acceptability *****															

Scoring:

* Film density: +: optimum; ↑: too much; ↓: too little

** Contrast: +: optimum; ↑ : too high; ↓ : too low

*** Sharpness: +: optimum; ↓: sub-optimum; 0: unacceptable

**** Beam limitation: +: optimum; ↑: field size too large; ↓: field size too small

***** Film acceptability: 1 = fully acceptable; 2 = probably acceptable; 3 = only acceptable under limited clinical conditions; 4 = unacceptable (give reasons)

Film No	Not accepted because of:

1. Comments specific to an individual film: _____

2. General comments on a group of films from one source: _____

Name of radiologist:

Hospital code:

Patient No:

Image criteria *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Symmetrical reproduction of the skull, particularly cranial vault, orbits and petrous bones															
Projection of the apex of the petrous temporal bone into the centre of the orbits															
Visually sharp reproduction of:															
(a) the frontal sinus and ethmoid cells															
(b) the apex of the petrous temporal bones															
(c) the internal auditory canals															
Visually sharp reproduction of the outer and inner lamina of the cranial vault															
Total:															

Important image details **

0.3-0.5 mm															
------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Scoring: * 1: yes; 0: no; where any area is obscured by a pathological condition, then 'P' should be placed in the appropriate box.

Maximum total score : 6.

** +: yes; if 'no' indicate minimum visible detail (in mm).

Name of radiologist:

Hospital code:

Patient No:

Image criteria *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Visually sharp reproduction of:															
(a) the outer and inner lamina of the cranial vault															
(b) the floor of the sella															
(c) the apex of the petrous temporal bone															
Superimposition respectively of the contours of:															
(a) the frontal cranial fossa															
(b) the lesser wing of the sphenoid bone															
(c) the clinoid processes															
(d) the external auditory canals															
Visually sharp reproduction of:															
(a) the vascular channels															
(b) the vertex of the skull															
(c) the trabecular structure of the cranium															
Superimposition of the mandibular angles and ascending rami															
Total:															

Important image details **

0.3-0.5 mm															
------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Scoring: * 1: yes; 0: no; where any area is obscured by a pathological condition, then 'P' should be placed in the appropriate box.

Maximum total score : 11.

** +: yes; if 'no' indicate minimum visible detail (in mm).

Name:

Hospital code:

Complete image annotation (see p.4) must be available on each film

Patient No:

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Appropriate film density (blackening) *															
Contrast **															
Sharpness ***															
Appropriate beam limitation ****															
Film acceptability *****															

Scoring:

- * Film density: +: optimum; ↑: too much; ↓: too little
- ** Contrast: +: optimum; ↑ : too high; ↓ : too low
- *** Sharpness: +: optimum; ↓: sub-optimum; 0: unacceptable
- **** Beam limitation: +: optimum; ↑: field size too large; ↓: field size too small
- ***** Film acceptability: 1 = fully acceptable; 2 = probably acceptable; 3 = only acceptable under limited clinical conditions; 4 = unacceptable (give reasons)

Film No	Not accepted because of:

1. Comments specific to an individual film: _____

2. General comments on a group of films from one source: _____

Name of radiologist:

Hospital code:

Patient No:

Image criteria *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Visually sharp reproduction of the upper and lower-plate surfaces, represented as lines in the centred beam area															
Visually sharp reproduction of the pedicles															
Reproduction of the intervertebral joints															
Reproduction of the spinous and transverse processes															
Visually sharp reproduction of the cortex and trabecular structures															
Reproduction of the adjacent soft tissues, particularly the psoas shadows															
Reproduction of the sacro-iliac joints															
Total:															

Important image details **

Image detail at 3rd lumbar vertebral body: 0.3-0.5 mm in width															
--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Scoring: * 1: yes; 0: no; where any area is obscured by a pathological condition, then 'P' should be placed in the appropriate box.

Maximum total score: 7.

** +: yes; if 'no' indicate minimum visible detail (in mm).

Name of radiologist:

Hospital code:

Patient No:

Image criteria *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Visually sharp reproduction of the upper and lower-plate surfaces, represented as lines with the resultant visualization of the intervertebral spaces															
Full superimposition of the posterior vertebral edges															
Reproduction of the pedicles and intervertebral foramina															
Visualization of the spinous processes															
Visually sharp reproduction of the cortex and trabecular structures															
Total:															

Important image details **

Image details at 3rd lumbar vertebral body, ventral edge: 0.5 mm in width															
---	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Scoring: * 1: yes; 0: no; where any area is obscured by a pathological condition, then 'P' should be placed in the appropriate box.

Maximum total score: 5.

** +: yes; if 'no' indicate minimum visible detail (in mm).

Name of radiologist:

Hospital code:

Patient No:

Image criteria *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Reproduction by tangential projection of the inferior end plate of L5 and the superior end plate of S1															
Visualization of the spinous process of L5															
Visualization of the anterior border of the upper sacrum															
Reproduction of vertebral pieces of the upper sacrum															
Total:															

Important image details **

Linear and reticular details: 0.5 mm in width															
---	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Scoring: * 1: yes; 0: no; where any area is obscured by a pathological condition, then 'P' should be placed in the appropriate box.

Maximum total score: 4.

** +: yes; if 'no' indicate minimum visible detail (in mm).

Name

Hospital code:

Complete image annotation (see p.4) must be available on each film

Patient No:

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Appropriate film density (blackening): vertebral bone *															
Appropriate film density (blackening): soft tissue *															
Contrast **															
Sharpness ***															
Appropriate beam limitation ****															
Film acceptability *****															

Scoring:

- * Film density: +: optimum; ↑: too much; ↓: too little
- ** Contrast: +: optimum; ↑ : too high; ↓ : too low
- *** Sharpness: +: optimum; ↓: sub-optimum; 0: unacceptable
- **** Beam limitation: +: optimum; ↑: field size too large; ↓: field size too small
- ***** Film acceptability: 1 = fully acceptable; 2 = probably acceptable; 3 = only acceptable under limited clinical conditions; 4 = unacceptable (give reasons)

Film No	Not accepted because of:

1. Comments specific to an individual film: _____

2. General comments on a group of films from one source: _____

Name of radiologist:

Hospital code:

Patient No:

Image criteria *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Symmetrical reproduction of the pelvis as judged by the imposition of the symphysis pubis over the midline of the sacrum															
Visually sharp reproduction of the sacrum and its intervertebral foramina															
Visually sharp reproduction of the pubic and ischial rami															
Visually sharp reproduction of the sacroiliac joints															
Visually sharp reproduction of the necks of the femora which should not be distorted by foreshortening or rotation															
Visually sharp reproduction of the: (a) spongiosa and corticalis															
(b) trochanters															
Total:															

Important image details **

0.5 mm															
--------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Scoring: * 1: yes; 0: no; where any area is obscured by a pathological condition, then 'P' should be placed in the appropriate box.

Maximum total score: 7.

** +: yes; if 'no' indicate minimum visible detail (in mm).

Name:

Hospital code:

Complete image annotation (see p.3) must be available on each film

Patient No:

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Appropriate film density (blackening) *															
Contrast **															
Sharpness ***															
Appropriate beam limitation ****															
Film acceptability *****															

Scoring:

* Film density: +: optimum; ↑: too much; ↓: too little

** Contrast: +: optimum; ↑ : too high; ↓ : too low

*** Sharpness: +: optimum; ↓: sub-optimum; 0: unacceptable

**** Beam limitation: +: optimum; ↑: field size too large; ↓: field size too small

***** Film acceptability: 1 = fully acceptable; 2 = probably acceptable; 3 = only acceptable under limited clinical conditions; 4 = unacceptable (give reasons)

Film No	Not accepted because of :

1. Comments specific to an individual film: _____

2. General comments on a group of films from one source: _____

Name of radiologist:

Hospital code:

Patient No:

Image criteria *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Reproduction of the area of the whole urinary tract from the upper pole of the kidney to the base of the bladder															
Reproduction of the kidneys outlines															
Visualization of the psoas outlines															
Visually sharp reproduction of the bones															
Total:															

Important image details **

Calcifications: 1.0 mm															
------------------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Scoring: * 1: yes; 0: no; where any area is obscured by a pathological condition, then 'P' should be placed in the appropriate box.

Maximum total score: 4.

** +: yes; if 'no' indicate minimum visible detail (in mm).

Name of radiologist:

Hospital code:

Patient No:

Image criteria *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Increase in parenchymal density (nephrographic effect)															
Visually sharp reproduction of the renal pelvis and calyces (pyelographic effect)															
Reproduction of the pelvi-ureteric junction															
Visualization of the area normally traversed by the ureter															
Reproduction of the whole bladder area															
Total:															

Important image details **

Calyceal details : 0.3 mm															
Calcifications : 1.0 mm															

Scoring : * 1: yes; 0: no; where any area is obscured by a pathological condition, then 'P' should be placed in the appropriate box.

Maximum total score: 5.

** +: yes; if 'no' indicate minimum visible detail (in mm).

Name:

Hospital code:

Complete image annotation (see p.4) must be available on each film

Patient No:

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Appropriate film density (blackening)*															
Contrast **															
Sharpness ***															
Appropriate beam limitation ****															
Film acceptability *****															

Scoring:

- * Film density: +: optimum; ↑: too much; ↓: too little
- ** Contrast: +: optimum; ↑ : too high; ↓ : too low
- *** Sharpness, noise, latitude: +: optimum; ↓: sub-optimum; 0: unacceptable
- **** Beam limitation: +: optimum; ↑: field size too large; ↓: field size too small
- ***** Film acceptability: 1 = fully acceptable; 2 = probably acceptable; 3 = only acceptable under limited clinical conditions; 4 = unacceptable (give reasons)

Film No	Not accepted because of:

1. Comments specific to an individual film: _____

2. General comments on a group of films from one source: _____

Name of radiologist:

Hospital code:

Patient No:

Image criteria related to positioning *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Pectoral muscle at correct angle															
Inframammary angle visualized															
Visually sharp reproduction of craniolateral glandular tissue															
Visually sharp reproduction of retroglandular fat tissue															
Nipple in full profile, clear of overlying breast tissue and/or indicated by marker															
No skinfolds seen															
Symmetrical images of left and right breast															

Image criteria related to exposure parameters *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Visualization of skin outline with bright light (but barely without it)															
Reproduction of vascular structures seen through most dense parenchyma (optical density of no less than 0.5 in most dense parenchyma)															
Visually sharp reproduction of all vessels and fibrous strands and pectoral muscle margin (absence of movement)															
Visually sharp reproduction of skin structure (rosettes from pores) along the pectoralis muscle															
Total:															

Important image details **

Microcalcifications: 0.2 mm															
-----------------------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Scoring: * 1: yes; 0: no; where any area is obscured by a pathological condition, then 'P' should be placed in the appropriate box.

Maximum total score: 11.

** +: yes; if 'no' indicate minimum visible detail (in mm).

Name of radiologist:

Hospital code:

Patient No:

Image criteria related to positioning *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Visually sharp reproduction of pectoral muscle at image margin															
Visually sharp reproduction of retroglandular fat tissue															
Visually sharp reproduction of medial breast tissue															
Visually sharp reproduction of lateral glandular tissue															
No skinfolds seen															
Symmetrical images of left and right breast															

Image criteria related to exposure parameters *

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Visualization of skin outline with bright light (but barely without it)															
Reproduction of vascular structures seen through most dense parenchyma (optical density of no less than 0.5 in most dense parenchyma)															
Visually sharp reproduction of all vessels and fibrous strands and pectoral muscle margin (absence of movement)															
Visually sharp reproduction of skin structure (rosettes from pores) along the pectoralis muscle															
Total:															

Important image details **

Microcalcifications: 0.2 mm															
-----------------------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Scoring: * 1: yes; 0: no; where any area is obscured by a pathological condition, then 'P' should be placed in the appropriate box.

Maximum total score: 10.

** +: yes; if 'no' indicate minimum visible detail (in mm).

Name:

Hospital code:

Complete image annotation (see p.4) must be available on each film

Patient No:

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Appropriate film density (blackening) *															
Contrast **															
Sharpness ***															
Noise level ***															
Latitude (whole tissue density range of breast documented) ***															
Maintenance and handling characteristics ****															
(a) absence of artefacts in cassette (dust etc.)															
(b) absence of processing artefacts															
(c) absence of handling artefacts															
(d) no visible gridlines															
Film acceptability *****															

Scoring:

- * Film density: +: optimum; ↑: too much; ↓: too little
- ** Contrast: +: optimum; ↑ : too high; ↓ : too low
- *** Sharpness, noise, latitude: +: optimum; ↓: sub-optimum; 0: unacceptable
- **** Maintenance and handling characteristics: +: fulfilled; 0: not fulfilled
- ***** Film acceptability: 1 = fully acceptable; 2 = probably acceptable; 3 = only acceptable under limited clinical conditions; 4 = unacceptable (give reasons).

Film No	Not accepted because of:

1. Comments specific to an individual film: _____

2. General comments on a group of films from one source: _____

CHAPTER 4

LIST OF ALL THOSE WHO CONTRIBUTED TO THE ESTABLISHMENT, TESTING AND EVALUATION OF THE QUALITY CRITERIA PRESENTED IN THESE GUIDELINES

These European Guidelines on Quality Criteria for Radiographic Images result from a European-wide cooperation between the various professionals and authorities involved in Diagnostic Radiology.

The services of the European Commission (EC) would like to express their sincere thanks to all those mentioned hereafter for their efforts and encouraging support to the development of the Quality Criteria concept:

First CEC Study Group on Quality Criteria for Radiographic Images (1986-90)

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Independent Experts who evaluated the films collected during the 1991 Trial

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 OLIETE, S. International Ruber Hospital — Madrid (E)
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 Institut für Strahlenschutz, GSF — Neuherberg (D)
 National Radiological Protection Board, NRPB — Chilton (UK)

Hospitals that participated in the 1987 Trial

BELGIUM

C.H.U. de Bavière — Liège

DENMARK

Rigshospitalet — Copenhagen

FRANCE

Hôpital Saint Louis — Paris

GERMANY

Klinik für Frauenheilkunde Universität Erlangen-Nürnberg — Erlangen

Klinikum der Johann Wolfgang Goethe Universität — Frankfurt/M

Klinikum der Stadt Nürnberg — Nuremberg

Krankenhaus Martha Maria — Nuremberg

Medizinische Klinik der Universität, Erlangen-Nürnberg — Erlangen

TALY

Ospedale Civile — Brescia

Ospedale di Gattinara — Trieste

Ospedale Santa Maria della Misericordia — Udine

UXEMBOURG

Clinique Sainte Thérèse — Luxembourg

SPAIN

Hospital Clinico de San Car — Madrid

Hospital de la Princesa — Madrid

Hospital Gomez Ulla — Madrid

Hospital Primero de Octubre — Madrid

stituto Catalan de la Salud — Girona

SWEDEN

National Institute of Radiation Protection — Stockholm

Regional Hospital — Halmstat

University Clinics — Lund

THE NETHERLANDS

Hogeschool Haarlem — Haarlem

UNITED KINGDOM

Broadgreen Hospital — Liverpool

Central Middlesex Hospital — London

Queen Elizabeth Hospital — Birmingham

Victoria Hospital — Blackpool

Hospitals that participated in the 1991 Trial

BELGIUM

Academisch Ziekenhuis U.V.B. — Brussels

Centre de Sénologie SPRL — Liège

Centre Hospitalier Molière — Brussels

aint-Elisabets Hospital — Anvers

DENMARK

Aalborg Sygehus Syd. — Aalborg
Arhus Kommun Hospital — Arhus
Bispebjerg Hospital — Copenhagen
Herning Central Sygehus — Herning
Odense Sygehus — Odense
Sonderborg Sygehus — Sonderborg
Vejle Sygehus — Vejle

FINLAND

Helsinki University Central Hospital — Helsinki
Surgical Hospital Kaserngatan — Helsinki

FRANCE

Centre Alexis Vautrin — Vandoeuvre-les-Nancy
Centre Antoine Lacassagne — Nice
Centre René Gauducheau — Nantes
C.H.R. d'Annecy — Annecy
C.H.U. de Tours — Tours
C.H.R. Hôtel-Dieu Saint-Jacques — Toulouse
Clinique du Mail — Grenoble
Institut Curie — Paris

GERMANY

Charité Hospital — Berlin
Freidrichshain — Berlin
Magdeburg Hospital — Magdeburg
Mannheim Hospital — Mannheim
Martin Luther Universität — Halle-Wittenberg
Medizin. Hochschule — Hannover
Münster Hospital — Münster
Praxis Dr Rottkay — Landshut
Universität Erlangen — Nuremberg

GREECE

Araeteion Hospital — Athens
Evangelismos Hospital — Athens
General Hospital of Nikea — Piraeus
Geniko Kratiko Hospital — Athens
Ippokrateio General Hospital, Kostantinoupoleos — Thessaloniki
Medical Physics Department, Univ. of Patras — Patras
St Savas Hospital — Athens

IRELAND

Beaumont Hospital — Dublin

Mater Misericordiae Hospital — Dublin

Saint James's Hospital — Dublin

ITALY

Istituto di Radiologia, Ospedale Cremonese — Cremona

Ospedale Generale Regionale di Bolzano — Bolzano

Ospedale Santa Maria della Misericordia — Udine

NORWAY

Region sykehuset — Trondheim

PORTUGAL

Centro de Senologia — Lisbon

Hospital de Universidade — Coimbra

Hospital de Santa Maria — Lisbon

Instituto Portugues de Oncologia — Lisbon

SPAIN

Hospital General 'Gregorio Maranon' — Madrid

Hospital Internacional — Madrid

Hospital La Santa Creu y San Pau — Barcelona

Instituto Nacional de la Salud — Madrid

SWEDEN

Central Sygehuset — Holstebro

Danderyd Hospital — Danderyd

Karolinska Sygehuset — Stockholm

Söders Kronna Hospital — Lund

Linköping Hospital — Linköping

University Hospital — Lund

University Hospital — Uppsala

THE NETHERLANDS

Academic Hospital, Vrije Universiteit — Amsterdam

Academisch Ziekenhuis — Maastricht

Academisch Ziekenhuis — Leiden

Deventer Ziekenhuis — Almelo

Erasmus Ziekenhuis — Rotterdam

UNITED KINGDOM

Birmingham Hospital — Birmingham
Hairmyres Hospital — East Kilbride, Glasgow
Ipswich Hospital — Ipswich
Middlesex Hospital — London
Newcastle Hospital — Newcastle
RAF Hospital — Wroughton, Swindon
Romsey Breast Screening Unit — Romsey
Royal London Hospital — White Chapel
Southampton General Hospital (Breast screening unit) — Southampton
Southampton General Hospital (X-ray department) — Southampton
University Hospital of Wales — Cardiff
Western General Hospital — Edinburgh
York District Hospital — York

YUGOSLAVIA

Zavod Republike Slovenije — Ljubljana

The CAATS group (Bourg-la-Reine) that collected and analysed the Trials' data

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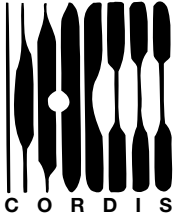
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European Commission

**EUR 16260 – European Guidelines on Quality Criteria
for Diagnostic Radiographic Images**

*edited by J.H.E. Carmichael, C. Maccia, B.M. Moores, J. W. Oestmann, H. Schibilla,
D. Teunen, R. Van Tiggelen and B. Wall*

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The Quality Criteria concept has proven to be an efficient means for optimizing the use of ionizing radiation in medical imaging procedures. Radiation protection measures based on the definition and introduction of Quality Criteria for the medical information content as well as for the equipment performance should give guidance in day-to-day practice for the implementation of Council Directive 84/466/EURATOM laying down basic measures for the radiation protection of persons undergoing medical examination or treatment.

Several research projects and trials with the Quality Criteria have been carried out at the European Union level. The results and the comments collected from experts all around the world have been analysed with a view to completing the concept of the possible reduction of patient exposure while providing the required clinical information in its optimum form.

The report presents as an introduction an overview on European actions, cooperative efforts, perspectives on the revision of the Council Directive and on new research priorities in the field of Optimization of Radiation Protection of the Patient.

Chapter 1 presents the revised Quality Criteria for Diagnostic Radiographic Images in the form of tables for six of the most common conventional X-ray examinations chest, skull, lumbar spine, pelvis, urinary tract and breast.

Chapter 2 summarizes the evaluation of two European trials with the Quality Criteria, covering the three aspects: radiographic technique and its practice in Europe, radiographic technique and patient dose, and radiographic technique and image quality in Europe; the evaluation has been summarized by the recommendations for an optimized procedure on how to get the most pertinent and instructive information from a trial.

Chapter 3 gives Quality Criteria Implementation and Audit Guidelines and a model checklist of the Quality Criteria as used by the radiologists for ranking the image quality of the trial's radiographs.

Chapter 4 contains the lists of the radiological departments in Europe and the national coordinators participating in the trial, the dosimetry laboratories involved, the radiologists who evaluated the trial's radiographs and the members of the Study Group on Quality Criteria Development.

The report will be published first in English, the eight official languages will follow shortly afterwards as they are already partly completed. It will also be published in the new languages if appropriate (possible number of pages 50, possible date of publication autumn 1996).

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