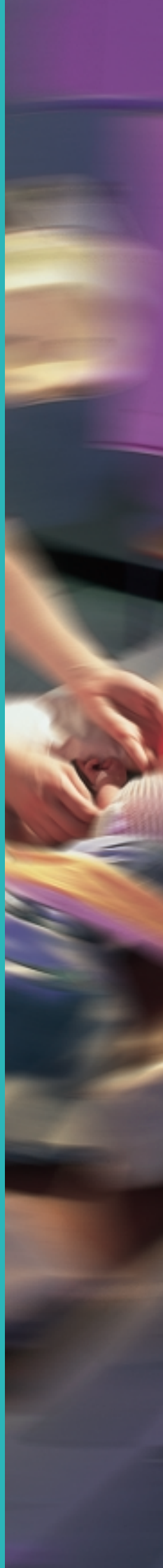


EUROPEAN COMMISSION

EUROPEAN GUIDELINES ON QUALITY CRITERIA FOR DIAGNOSTIC RADIOGRAPHIC IMAGES IN PAEDIATRICS



EUR 16261



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July 1996

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Directorate-General XII: Science, Research and Development

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EUROPEAN GUIDELINES ON QUALITY CRITERIA FOR DIAGNOSTIC RADIOGRAPHIC IMAGES IN PAEDIATRICS

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 IN PAEDIATRICS

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 ionising radiation, and has been integrated into the various branches of diagnosis and treatment.

The Commission of the European Communities contributes to this evolution by the establishment of legal requirements for the radiation protection of persons undergoing medical examination or treatment,¹ of safety requirements for medical devices² 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 also the first Directive on Radiation Protection of the Patient was adopted by the Member States of the European Union. Following the development of Quality Criteria for adult radiology³ it was **recognised that Quality Criteria needed to be specifically adapted to paediatric radiology.**

This is supported by the fact that, because of their longer life expectancy, the risk of late manifestations of detrimental radiation effects is greater in children than in adults. Radiation exposure in the first ten years of life is estimated, for certain detrimental effects, to have an attributable lifetime risk three to four times greater than after exposures between the ages of 30 and 40 years, and five to seven times greater when compared to exposures after the age of 50 years.⁴

This impressively higher individual somatic radiation risk in the younger age groups has been only inadequately considered in radiation protection so far. It is therefore essential to develop appropriate radiation protection measures also in the field of diagnostic radiology for paediatric patients.

¹ Council Directive 84/466 EURATOM, Official Journal L 265/1, 5.10.1994.

² Council Directive 93/42 EEC, Official Journal L 169/1, 12.7.1993.

³ Report EUR 16260, 1996.

⁴ UNSCEAR Report "Sources, Effects and Risks of Ionizing Radiation", p. 433, 1988.

The Quality Criteria for paediatric radiology have been elaborated in a common effort by a European Group of paediatric radiologists, (the Lake Starnberg Group), together with radiographers, physicists, radiation protection experts, health authorities and professional national and international organisations.

The aim of the Quality Criteria is to characterize a level of acceptability of normal basic radiographs which could address any clinical indication. They have first been set up for conventional radiography, concentrating on examinations of high frequency or with relatively high doses to the patient.

The following frequent paediatric radiographic examinations were selected as a first step: chest, skull, pelvis, full and segmental spine, abdomen and urinary tract. The age groups and X-ray examinations using fixed X-ray installations were limited to 10 month old infants for chest AP/PA, skull AP/PA, spine, lateral view, abdomen, AP supine position; and 4 month old babies for pelvis AP. The corresponding criteria for mobile X-ray equipment were for 10 month old infants, and premature babies with weight approximately 1 kg undergoing a chest AP examination in supine position. In a second and third step the age groups of 5 and 10 year old children were added.

The applicability of the Quality Criteria has been checked in European wide Trials involving about 160 paediatric X-ray departments in 14 Member States and other European countries, and roughly 1600 radiographic films and dose measurements.

The results have been discussed at Workshops, by working parties and dedicated study groups, as well as by independent experts all over the world. The conclusions have been integrated in the present Guidelines and provided elements for the improvement of the lists of Quality Criteria.

The **European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics** contain four chapters:

The first chapter concerns the updated lists of the Quality Criteria for conventional paediatric examinations of chest, skull, pelvis, full and segmental spine, abdomen and urinary tract for different projections and, where necessary, specific criteria for newborns. This first chapter defines Diagnostic Requirements for a normal, basic radiograph, specifying anatomical Image Criteria; indicates Criteria for the Radiation Dose to the Patient, as far as available, and gives an Example for Good Radiographic Technique by which the Diagnostic Requirements and the dose criteria can be achieved.

The second chapter summarises the analysis of the findings of the European wide Trials 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 model of the scoring tables, and adapted questionnaires that have been developed during the evaluation of the Trials, are reproduced and can become tools for self-learning and performance checking.

The fourth chapter presents all those to whom the European Commission's services wish to express their sincere thanks for co-operation and creative criticism, which encouraged the EC's Radiation Protection Actions 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 updating 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 in Paediatrics". The Guidelines do not pretend to give strict instructions for the 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 optimisation 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 the 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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QUALITY CRITERIA FOR DIAGNOSTIC RADIOGRAPHIC IMAGES IN PAEDIATRICS

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INTRODUCTION

The two basic principles of radiation protection of the patient as recommended by ICRP are justification of practice and optimisation 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, particularly in paediatric patients. 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.⁵

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 optimised. The optimal use of ionising 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, pelvis, full and segmental spine, abdomen and urinary tract on fixed X-ray installations and chest employing mobile equipment. No attempt has been made to define the procedure for complete examinations. These are often a matter of personal preference of the radiologist and will be determined by local conditions and particular clinical situations. Instead, quality criteria have been drawn up for representative radiographs from the 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 the adult (8) and for computed tomography (9). The need for a comparable effort for fluoroscopy employing image intensification is recognised.

⁵ H. Fendel et al. "Efficacy of Diagnostic Use of X-Rays in Paediatrics", 2nd Report for the Federal Ministry of Environment, Protection of Nature and Reactor Safety, Bonn, 1987, in German.

OBJECTIVES

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

- adequate image quality, comparable throughout Europe;
- accurate radiological interpretation of the image; and
- reasonably low radiation dose per radiograph.

The Guidelines are primarily directed at the technical and clinical staff involved in taking the radiographs and in reporting on them. The Quality Criteria may provide the standard for quality assurance programmes and also serve as a basis for self-education and training in good imaging practice. 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 **Image Criteria** for paediatric patients presented 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 listed image criteria allow an immediate evaluation of the image quality of the respective radiograph. They are appropriate for the most frequent requirements of radiographic imaging of paediatric patients. Where necessary, specific clinical questions and situations are taken into account.

The anatomical features and body proportions vary due to the developmental process in infancy, childhood and adolescence. They are different in the respective age groups and are distinct from those of a mature patient. The Guidelines presuppose knowledge of the changing radiographic anatomy of the developing child. The term "consistent with age" indicates that the respective image criteria essentially depend on the age of the patient.

The smaller body size, the age dependent body composition, the lack of co-operation and many functional differences (e.g. higher heart rate, faster respiration, inability to stop breathing on command, increased intestinal gas etc.) prevent the production of radiographic images in paediatric patients to which standard adult image criteria can be applied. This, however, does not imply that all quality criteria are inappropriate; they must be adapted to paediatric imaging.

Correct positioning of paediatric patients may be much more difficult than in co-operative adult patients. Effective immobilisation often necessitates the use of auxiliary devices. Sufficient skill and experience of the imaging staff and ample time for the particular investigation are the imperative prerequisites to fulfil this quality criterion in infants and younger children. No diagnostic radiation exposure should be allowed unless there is a high probability that the exact positioning will be maintained. Incorrect positioning is the most frequent cause of inadequate image quality in paediatric radiographs. Image criteria for the assessment of adequate positioning (symmetry and absence of tilting etc.) are much more important in paediatric imaging than in adults.

The reasons for diagnostic imaging in paediatrics are often essentially different from those in adult medicine. They vary in the different paediatric age groups. Image quality must be adapted to the particular clinical problem.

In paediatric diagnostic imaging, image quality must be a constant preoccupation; nevertheless, more often than in adults, a lower level of image quality may be acceptable for certain clinical indications. An inferior image quality, however, cannot be justified unless this has been intentionally designed and must then be associated with a lower radiation dose. The fact that the X-ray was taken from a non-cooperative paediatric patient (anxious, crying, heavily resisting) is not an excuse for producing an inferior quality film which is often associated with an excessive dose.





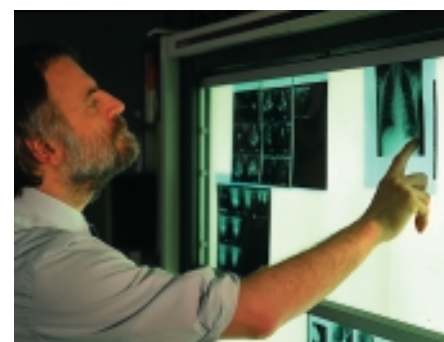
Important Image Details

In contrast to the European Guidelines on Quality Criteria for Diagnostic Radiographic Images for adult patients (8), minimum dimensions of important image details as a means to recognise specific normal or abnormal anatomical details are not indicated in these Guidelines, since in paediatric radiology such image details essentially depend on the particular clinical situation. The fulfilment of the appropriate Image Criteria and the adherence to the example of good radiographic technique will ensure that important pathological image details will not be missed.

The Criteria for Radiation Dose to the Patient included in these Guidelines are expressed in terms of a reference value for the entrance surface dose for a “standardized” paediatric patient. However, reference dose values are available only for the most frequently performed types of radiographs for which sufficient data were acquired in a series of European Trials on infants, 5 year old and 10 year old patients. An overview of the derivation of the reference dose values from the Trial data is given in Chapter 2: Summary of the Evaluations of the European Trials of the Quality Criteria, Part 2: Patient Dose. For reasons indicated there, the reference dose values given under the Criteria for Radiation Dose to the Patient are those for the standard 5 year old patient. The purpose of these reference doses and methods for checking compliance with them are discussed in Appendix I to this Chapter.

The Examples of Good Radiographic Technique included in these Guidelines have evolved from the results of a European Trials of the Quality Criteria. Compliance with the image and patient dose criteria, where available, 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 X-ray examinations 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 organisations, some of which are listed in reference (1) to (17) (see page 15).

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 further useful information on this subject.

3. Low Attenuation Materials

Recent developments in materials for cassettes, grids, tabletops and front plates of film-changers using carbon fibre and some new plastics enable significant reduction in patient doses. This reduction is most significant in the radiographic-voltage range recommended in paediatric patients and may reach 40%. Use of these materials should be encouraged.

4. Patient Positioning and Immobilisation

Patient positioning must be exact whether or not the patient co-operates. In infants, toddlers and younger children immobilisation devices, properly applied, must ensure that;

- the patient does not move
- the beam can be centred correctly
- the film is obtained in the proper projection
- accurate collimation limits the field size exclusively to the required area
- shielding of the remainder of the body is possible.

Immobilisation devices must be easy to use, and their application atraumatic to the patient. Their usefulness should be explained to the accompanying parent(s).

Radiological staff members should only hold a patient under exceptional circumstances. Where physical restraint by parents or another accompanying person is unavoidable, they must know exactly what is required of them. They must be provided with protection from scattered radiation and be absolutely outside the primary beam of radiation applied to the patient. Pregnant women must not be allowed to assist.

Even in quite young children the time allocation for an examination must include the time to explain the procedure not only to the parents but also to the child. It is essential that

both cooperate, and time taken to explain to a child what will happen is time well spent in achieving an optimised examination fulfilling the necessary quality criteria.

5. Field Size and X-ray Beam Limitation

Inappropriate field size is the most important fault in paediatric radiographic technique. A field which is too small will immediately degrade the respective image criteria. A field which is too large will not only impair image contrast and resolution by increasing the amount of scattered radiation but also — most importantly — result in unnecessary irradiation of the body outside the area of interest.

Consequently, the anatomical areas specified by the respective image criteria define the minimal and the maximal field sizes. Although some degree of latitude is necessary to ensure that the entire field of interest is included, this cannot be accepted as an excuse or repeatedly using too large a field size in paediatric patients.

Correct beam limitation requires proper knowledge of the external anatomical landmarks by the technician. These differ with the age of the patient according to the varying proportions of the developing body. In addition, the size of the field of interest depends much more on the nature of the underlying disease in infants and younger children than in adults (e.g. the lung fields may be extremely large in congestive heart failure and emphysematous pulmonary diseases; the position of the diaphragm may be very high in intestinal meteorism, chronic obstruction or digestive diseases). Therefore, a basic knowledge of paediatric pathology is required for radiographers and other technical assistants to ensure proper beam limitation in these age groups.

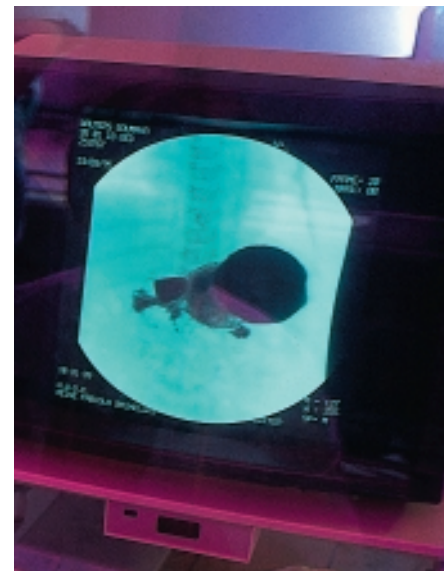
The acceptable minimal field size is set by the listed recognisable anatomical landmarks or specific examinations. Beyond the neonatal period, the tolerance for maximal field size should be less than 2 cm greater than the minimal. In the neonatal period, the tolerance level should be reduced to 1.0 cm at each edge.

In paediatric patients, evidence of the field limits should be apparent by clear rims of unexposed film. This is of particular importance; beam-limiting devices automatically adjusting the field to the full size of the cassette are inappropriate for paediatric patients. Discrepancies between the radiation beam and the light beam must be avoided by regular assessment. Even minimal deviations may have a large effect in relation to the usually small field of interest.

6. Protective Shielding

In all examinations of paediatric patients, the Example for Good Radiographic Technique includes standard equipment of lead-rubber shielding of the body in the immediate proximity of the diagnostic field; special shielding has to be added for certain examinations to protect against external scattered and extra-focal radiation. For exposures of 60 - 80 kV, maximum gonadal dose reduction of about 30 to 40% can be obtained by shielding with 0.25 mm lead equivalent rubber immediately at the field edge. However, this is only true when the protection is placed correctly at the field edge. Lead-rubber covering further away is less effective, and at a distance of more than 4 cm is completely ineffective. This may have a psychological effect but provides no radiation protection at all.

The gonads in "hot examinations", i.e. when they lie within or close (nearer than 5 cm) to the primary beam, should be protected whenever this is possible without impairing necessary diagnostic information. It is best to make one's own lead contact shields for girls and lead capsules for boys. They must be available in varied sizes. The testes must be protected by securing them within the scrotum to avoid upward movement caused by the cremasteric reflex. By properly adjusted capsules, the absorbed dose in the testes can be reduced by up to 95%. In girls, shadow masks within the diaphragm of the collimator are as efficient as direct shields. They can be more exactly positioned and do not slip as easily as contact shields. When shielding of the female gonads is effective, the reduction of the absorbed dose in the ovaries can be about 50%.



There is no reason to include the male gonads in the scrotum within the primary radiation field for radiographs of the abdomen. The same applies, usually, for films of the pelvis and micturating cystourethrographies. The tests should be protected with a lead capsule, but kept outside the field. In abdominal examinations gonad protection for girls is not possible. In practice, the great majority of pelvic films show that female gonad protection is completely ineffective. The position of all sorts of lead material is often ludicrous. There are justifiable reasons for omitting gonad protection for pelvic films in girls, e.g. trauma, incontinence, abdominal pain, etc.

The eyes should be shielded for X-ray examinations involving high absorbed doses in the eyes, e.g. for conventional tomography of the petrous bone, when patient co-operation permits. The absorbed dose in the eyes can be reduced by 50% - 70%. In any radiography of the skull the use of PA-projection rather than the AP-projection can reduce the absorbed dose in the eyes by 95%. PA-projection, therefore, should be preferred as soon as patient age and co-operation permit prone or erect positioning.

As developing breast tissue is particularly sensitive to radiation, exposure must be limited. The most effective method is by using the PA-projection, rather than the AP. While this is well accepted for chest examinations, the greatest risk is during spinal examinations, and here PA-examinations must replace AP.

It should also be remembered that thyroid tissue should be protected, whenever possible, e.g. during dental and facial examinations.

7. Radiographic Exposure Conditions

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

(a) Nominal focal spot value

Usually a nominal focal spot value between 0.6 and 1.3 is suitable for paediatric patients. When bifocal tubes are available, the nominal focal spot value which allows the most appropriate setting of exposure time and radiographic voltage at the chosen focus film distance should be used. This may not always be the smaller one.

(b) Additional filtration

The soft part of the radiation spectrum which is completely absorbed in the patient is useless for the production of the radiographic image and contributes unnecessarily to the patient dose. Part of it is eliminated by the inherent filtration of the tube, tube housing, collimator etc., but this is insufficient. Most tubes have a minimum inherent filtration of 2.5 mm Al. Additional filtration can further reduce unproductive radiation and thus patient dose.

For paediatric patients, total radiation dose must be kept low, particularly when high speed screen film systems or image intensifying techniques are used. Not all generators allow the short exposure times that are required for higher kV technique. Consequently, low radiographic voltage is frequently used for paediatric patients. This results in comparatively higher patient doses.

Adequate additional filtration allows the use of higher radiographic voltage with the shortest available exposure times, thus overcoming the limited capability of such equipment for short exposures. This makes the use of high speed screen film systems and image intensifier photography possible.

filter materials (molybdenum, holmium, erbium, gadolinium or other rare-earth material) with absorption edges at specific wavelengths have no advantages compared to simple and inexpensive aluminium-copper (or aluminium-iron) filters, which can easily be home-made. All tubes used for paediatric patients in stationary, mobile or fluoroscopic equipment should have the facility for adding additional filtration and for changing it easily, when appropriate. Usually, additional filtration of up to 1 mm aluminium plus 0.1 mm or 0.2 mm copper can be appropriate. For standard diagnostic radiographic-voltages, every 0.1 mm copper equals about 3 mm aluminium.

c) Anti-scatter grid

In infants and younger children the use of a grid or other anti-scatter measures is often unnecessary. The examples for good radiographic technique specify when grids are superfluous. Not using grids will then avoid excessive patient dose. Where anti-scatter measures are necessary, grid ratios of 8 and line numbers of 40/cm (moving grid) are usually sufficient even at higher radiographic-voltages. Grids incorporating low attenuation materials such as carbon fibre or other nonmetallic material are preferable. Moving grids may present problems in very short exposure times (< 10 ms); in these cases stationary grids with high strip densities ($\geq 60/\text{cm}$) should be used. Quality control of moving grid devices for paediatric patients must take this into consideration. The accurate alignment of grid, patient and X-ray beam, as well as careful attention to the correct focus-grid distance is of particular importance.

In the supplementary fluoroscopic examinations of the urinary tract, a grid is rarely necessary. Only fluoroscopic equipment with the potential for quick and easy removal of the grid should be used in these age groups. Removable grids are not only desirable for fluoroscopic work; ideally, all equipment used for paediatric patients should have this facility.

d) Focus-film distance (FFD)

Regarding this item there are no differences from adult patients. The FFD is usually approximately 115 cm for over-couch tubes with grid tables and 150 cm for vertical stands. The correct adjustment of the grid to FFD must be observed. When no grid is used and the cassette is placed upon the table, an FFD of about 100 cm should be chosen (so that the same tube-table distance as with a grid is obtained). Longer distances of FFD — indicated in parentheses — may be used for special reasons.

In all fluoroscopic examinations, patient to film and patient to image intensifier distances should be kept as short as possible to reduce patient dose. This has particular significance when using automatic brightness control.

e) Radiographic voltage

As already mentioned, in spite of recommended high voltage techniques lower radiographic voltage is still often used in paediatric patients. Lower settings than the voltages specified in these Guidelines should be avoided wherever possible.

It must be remembered that the effective radiographic voltage depends on the type and age of the generator. Considering the very short exposure times, a nearly rectangular radiation waveform and a minimal amount of ripple are desirable for paediatric patients. 1-, 2- and 6-pulse generators cannot provide this. 12-pulse or high frequency multi-pulse (so-called converter) generators are required. This means — and this is often misunderstood — that the smallest patients need the most powerful machines.

For mobile equipment converter generators are preferable. The disadvantage of capacitor discharge generators is that radiographic voltage decreases over the exposure time (for common exposure times, approximately 1 kV/mAs). One and two-pulse generators should no longer be used. For a 10 month old infant, a chest X-ray with identical film blackening



requires an exposure nearly 20-times longer and gives 2.15-times higher entrance surface dose, when a 1-pulse generator is used instead of a converter generator.

The preset radiographic voltage and effective radiographic voltage may not be identical. In very short exposure times even small discrepancies may have an impact on image quality. When short exposure settings are inconstant, they will effectively influence film blackening and patient dose. Quality control programmes should be meticulous in this regard when assessing equipment for paediatric patients. Generators which do not fulfil requirements for proper and stable calibration (within a tolerance range of about $\pm 10\%$) should not be used for paediatric patients and should be replaced as soon as possible.

The radiation emitted by the tube requires a certain time to reach its peak voltage. With the longer exposures used in adult patients, this pre-peak time radiation is insignificant. With the very short exposure times in paediatric radiography, pre-peak times must be taken into consideration. Some old generators have pre-contact phases in which soft radiation may be emitted. Added filtration eliminates this which is another reason for advocating its use.

(f) Automatic exposure control

Adult patients vary in size, but their variation is minimal compared to the range in paediatric patients: premature infants, weighing considerably less than a thousand grammes, to adolescents approaching 70 kg. Those investigating paediatric patients must be able to adapt to this range. One would expect that a device for automatic exposure control (AEC) would be helpful. However, many of the systems commonly available are not satisfactory. They have relatively large and fixed ionisation chambers. Neither their size nor their shape nor their position is able to compensate for the many variations of body size and body proportion in paediatric patients. In addition, the usual ionisation chambers of AECs are built in behind a grid. Consequently, AEC-use may be associated with the use of the grid (where the grid is not removable) which — as previously mentioned — is frequently unnecessary.

The optimal adaptation of the radiographic technique to the clinical needs requires the use of screen film systems of different speeds and different switch-off doses at the image receptor. Screens and AEC chambers are wavelength dependant, particularly in the lower range of radiographic voltage, but these dependencies do not correspond with each other. AECs lengthen the minimal exposure times. All these factors must be considered when AECs are used in paediatric patients. They are complicated to use and result in many unsatisfactory examinations.

Specially designed paediatric AECs have a small mobile detector for use behind a lead-free cassette. Its position can be selected with respect to the most important region of interest. This must be done extremely carefully, as even minor patient movement may be disastrous. The high speed of modern screens allows a minute dose at the cassette front. Consequently, the detector behind the cassette has to work in the range of a fraction of 1 mGy. It is nearly impossible to provide constancy and reproducibility in this range.

Much safer, easy-to-use and less expensive are exposure charts corresponding to radiographic technique and patient's weight — the so-called body index — when X-raying the trunk, or patient's age for the extremities. In the future, small and simple computers may incorporate multifactorial parameters for this purpose. A learning "intelligent" unit would be ideal for paediatric patients.

The EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE indicates when the AEC may be used and which chamber should be selected.

(g) Automatic brightness control

Automatic brightness control has to be switched off during fluoroscopic examinations where there are relatively large areas of positive contrast material to avoid excessive dose rates, e.g. full bladders.

h) Exposure time

In paediatric imaging, exposure times must be short because young patients do not co-operate and are difficult to restrain. These short times are only possible with powerful generators and tubes, as well as optimal rectification and accurate time switches. The equipment must work and provide constancy in the shortest time range. For old generation generators, exposure time settings lower than 4 ms — although desired — should not be used: the pre-peak times (> 2 ms) interfere, to a relatively greater degree, with short preset exposures; therefore, under the Example of Good Radiographic Technique, exposure times are indicated for the more recent generation of generators such as 12-pulse and converter generators.

For these extremely short exposure times, the cable length between the transformer and the tube is important. The cable works as a capacitor and may — depending on its length — produce a significant surge of radiation after the generator has been switched off. This post-peak radiation may last for 2 ms or more.

Accurately reproducible exposure times around 1 ms with a rectangular configuration of dose rate and wavelength of radiation — practically without pre- and post-radiation — may be achieved with grid controlled tubes.

There are problems associated with the lower limits of the exposure time. For most equipment used for paediatric patients, however, the difficulty is in obtaining optimal short exposure times. Unless it is possible to adapt the available equipment to use the recommended range of exposure times, the equipment should not be used for paediatric patients.

8. Screen Film Systems

Among the technical parameters, the selection of higher speed classes of the screen film system has the greatest impact on dose reduction. In addition, it allows shorter exposure times that minimise motion unsharpness, which is the most important cause of blurring in paediatric imaging. The reduced resolution of higher speed screens is comparatively insignificant for the majority of clinical indications. For special purposes (e.g. bone detail) speed classes of 200 - 400 are preferable. When different sets of cassettes are available, the one — for special indications — with screens of the lower speed and higher resolution, the other for general use, they should be clearly marked.

The relationship between the speed class of the screen film system, the dose requirement at the image receptor (μGy), and the lower limit of visual resolution, is described in the norms of ISO and DIN (see ISO 9236 - 1; DIN 6867 - section 1, 1995, see also (18)).

It must be emphasised, that similar screen film systems vary between manufacturers and that intermediate values of the speed classes are common. Therefore, the indicated nominal speed classes in this Document can only give approximate guidance.

The variation in speed which can occur with changes in X-ray beam energy, especially below 70 kV, for individual screen film systems [BIR Report 18 (12)], is recognised. 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 systems since this varies with any speed class.

9. 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 $D = 1.4$ 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 base and fog 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 judgement on subjective and global impressions 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 the 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 too dark should be viewed with a bright spot light before a decision is made to repeat the examination.

10. 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.

11. 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, e.g. the developer temperature may well be set too low.

12. 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 2000 and 4000 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.

13. 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 paediatric patients 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.

Consequently, the decision to repeat an exposure must be made by a physician responsible for that imaging procedure after critically viewing the film and, if necessary, consulting the referring colleague. All rejected films should be retained so they can be used for the planning of appropriate optimisation.

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 co-operation of the patient whereas others reflect technical performance of the imaging system. 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: (See Chapter 3: Quality Criteria Implementation and Audit Guidelines).

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Reference values of the Entrance Surface Dose (ESD) are provided, as far as available, for a standard five year old child, for the most frequently performed examinations in these Guidelines. The dose data collected during the Trials have shown that, because of the similarity of Entrance Surface Dose values between infants, 5 year and 10 year old children, the values derived for the 5 year old child can tentatively be used as a reference dose value for all age groups until more representative dose values will become available. A more detailed description on the derivation of the reference dose values is given in Chapter 2: Summary of the Evaluations of the European Trials of the Quality Criteria.

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. Information is also given on 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. One possibility might also be the use of equipment that fulfils as closely as possible basic requirements to radiographic equipment in paediatric radiology. Guidelines on such basic requirements are presented in Chapter 3.

1. DIAGNOSTIC REQUIREMENTS

Image Criteria

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

Visualisation:

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.

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

The reference value for the entrance surface dose for a patient is expressed as the absorbed dose to air (μGy) at the point of intersection of the X-ray beam axis with the surface of a paediatric patient, backscatter radiation included. For further information see Appendix 1.

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- 3.0. **Patient position** — upright, supine, prone or lateral.
- 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 filtration.
- 3.4. **Anti-scatter grid** — described 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 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. For convenience in these Guidelines only broad speed categories — nominal speed classes — are indicated.
- 3.6. **FFD — Focus-to-film distance** (cm). If a focused grid is used, FFD must be within the range indicated by the manufacturers.
- 3.7. **Radiographic 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) generators.
- 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** — protection devices additional to existing standard equipment, in order to further reduce exposure of sensitive organs and tissues.

Values in parentheses indicate options which are less desirable but acceptable for special conditions and indications.

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, (Pergamon Press, Oxford), 1991.
- 2) ICRP Publication 34, Protection of the Patient in Diagnostic Radiology, (Pergamon Press, Oxford), 1982.
- 3) ICRP Publication 73, "Radiological Protection and Safety in Medicine", in press.
- 4) Council Directive of 3 September 1984 laying down basic measures for the radiation protection of persons under going medical examination or treatment (84/466 EURATOM) O.J. Nr L 265, p. 1, 05.10.1984, under revision: COM 95-560 final, 1995.
- 5) WHO Technical Report 689 "A Rational Approach to Radiographic Investigations", (World Health Organisation, Geneva), 1986.
- 6) WHO Technical Report 757 "Rational use of Diagnostic Imaging in Paediatrics", (World Health Organisation, Geneva), 1987.
- 7) Booklet on "Making the Best Use of a Department of Radiology", (Royal College of Radiologists, London), 3rd Edition, 1995.
- 8) Quality Criteria for Diagnostic Radiographic Images, (Office for Official Publications of the European Communities, Luxembourg), Report EUR 16260, 1996.
- 9) Quality Criteria for Computed Tomography, (Office for Official Publications of the European Communities, Luxembourg), Report EUR 16263, in press.
- 10) WHO Report "Quality Assurance in Diagnostic Radiology", (World Health Organisation, 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) "Optimisation of Image Quality and Patient Exposure in Diagnostic Radiology", BIR Report 20, 1989.
- 14) Test Phantoms and Optimisation 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.
- 16) National Council on Radiation Protection and Measurements (NCRP). Radiation Protection in Pediatric Radiology. Report No 68. Bethesda: NCRP Publications 1981.
- 17) United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR): Sources, Effects and Risks of Ionising Radiation, Report 1988.
- 18) BÄK, Bundesärztekammer. Leitlinien der Bundesärztekammer zur Qualitätssicherung in der Röntgendiagnostik. Dt. Ärztebl. 92. Heft 34-35, 1995.
- 19) Schneider K, Fendel H, Bakowski C, Stein E, Kellner M, Kohn MM, Schweighofer K & Cartagena G. Results of a Europe-wide Dosimetry Study on Frequent X-ray Examinations in Paediatric Populations. Radiation Protection Dosimetry VOL.43, pp 31-36 (1992).

LIST OF QUALITY CRITERIA FOR DIAGNOSTIC RADIOGRAPHIC IMAGES IN PAEDIATRICS

PA/AP PROJECTION

(Beyond the newborn period)

For co-operative patients PA projection;
AP projection for non-co-operative patients.

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1. Performed at peak of inspiration, except for suspected foreign body aspiration
- 1.2. Reproduction of the thorax without rotation and tilting
- 1.3. Reproduction of the chest must extend from just above the apices of the lungs to T12/L1
- 1.4. Reproduction of the vascular pattern in central 2/3 of the lungs
- 1.5. Reproduction of the trachea and the proximal bronchi
- 1.6. Visually sharp reproduction of the diaphragm and costo-phrenic angles
- 1.7. Reproduction of the spine and paraspinal structures and visualisation of the retrocardiac lung and the mediastinum

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for standard five year old patient: 100 μ Gy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- | | | |
|--------------------------------------|---|---|
| 3.0. Patient position | : | upright, supine position possible |
| 3.1. Radiographic device | : | table or vertical stand, depending on age |
| 3.2. Nominal focal spot value | : | 0.6 (\leq 1.3) |
| 3.3. Additional filtration | : | up to 1 mm Al + 0.1 or 0.2 mm Cu (or equivalent) |
| 3.4. Anti-scatter grid: r = 8; 40/cm | : | only for special indications and in adolescents |
| 3.5. Screen film system | : | nominal speed class 400 - 800
3.6 FFD 100 - 150 cm |
| 3.7. Radiographic voltage | : | 60 - 80 kV (100 - 150 kV with grid for older children) |
| 3.8. Automatic exposure control | : | chamber selected - lateral; preferably none in infants and young children |
| 3.9. Exposure time | : | <10 ms |
| 3.10. Protective shielding | : | lead-rubber coverage of the abdomen in the immediate proximity of the beam edge |

REMARKS There are circumstances where the cervical trachea should be included (e.g. foreign body aspiration, tube position, etc.).

LATERAL PROJECTION

Beyond the newborn period)

This projection must not be done routinely,
and usually only when indicated after evaluation of the PA/AP film

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1. Performed at the peak of inspiration
- 1.2. True lateral projection
- 1.3. Visualisation of the trachea from the apices of the lungs down to and including the main bronchi
- 1.4. Visually sharp reproduction of the whole of both domes of the diaphragm
- 1.5. Reproduction of the hilar vessels
- 1.6. Reproduction of the sternum and the thoracic spine

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for standard five year old patient: 200 μ Gy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- | | |
|---------------------------------|---|
| 3.0. Patient position | : upright, supine position possible |
| 3.1. Radiographic device | : table or vertical stand depending on age |
| 3.2. Nominal focal spot value | : 0.6 (\leq 1.3) |
| 3.3. Additional filtration | : up to 1 mm Al + 0.1 or 0.2 mm Cu
(or equivalent) |
| 3.4. Anti-scatter grid | : r = 8; 40/cm; only for special indications and in adolescents |
| 3.5. Screen film system | : nominal speed class 400 - 800 |
| 3.6. FFD | : 100 - 150 cm |
| 3.7. Radiographic voltage | : 60 - 80 kV (100 - 150 kV with grid for older children) |
| 3.8. Automatic exposure control | : chamber selected - lateral; preferably none in infants and young children |
| 3.9. Exposure time | : < 20 ms |
| 3.10. Protective shielding | : lead-rubber coverage of the abdomen in the immediate proximity of the beam edge |

REMARKS: There are circumstances where the cervical trachea should be included (e.g. foreign body aspiration, tube position, etc.).

AP PROJECTION

(Newborns)

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1. Performed at peak of inspiration
- 1.2. Reproduction of the thorax without rotation and tilting
- 1.3. Reproduction of the chest must extend from the cervical trachea to T12/L1 (part of the abdomen may be included for special purposes)
- 1.4. Reproduction of the vascular pattern in central half of the lungs
- 1.5. Visually sharp reproduction of the trachea and the proximal bronchi
- 1.6. Visually sharp reproduction of the diaphragm and costo-phrenic angles
- 1.7. Reproduction of the spine and paraspinal structures and visualisation of the retrocardiac lung and the mediastinum

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for newborns: 80 μ Gy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- | | |
|---------------------------------|---|
| 3.0. Patient position | : supine |
| 3.1. Radiographic device | : bedside (table), depending on clinical condition |
| 3.2. Nominal focal spot value | : 0.6 (\leq 1.3) |
| 3.3. Additional filtration | : up to 1 mm Al + 0.1 or 0.2 mm Cu (or equivalent) |
| 3.4. Anti-scatter grid | : none |
| 3.5. Screen film system | : nominal speed class 200 - 400 |
| 3.6. FFD | : 80 - 100 (150) cm |
| 3.7. Radiographic voltage | : 60 - 65 kV |
| 3.8. Automatic exposure control | : none |
| 3.9. Exposure time | : < 4 ms |
| 3.10. Protective shielding | : lead-rubber masking of the abdomen in the immediate proximity of the beam edge; if direct placement not possible, then masking on the incubator lid |

PA/AP PROJECTION

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1. Symmetrical reproduction of the skull, particularly cranium, orbits and petrous bones
- 1.2. Projection of the upper margins of the petrous temporal bones into the lower half of the orbits in AP projection
- 1.3. Reproduction of the paranasal sinuses and structure of the temporal bones consistent with age
- 1.4. Visually sharp reproduction of the outer and inner tables of the entire cranial vault consistent with age
- 1.5. Visualisation of the lambdoid and sagittal sutures

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for standard five year old patient: 1500 μ Gy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- 3.0. Patient position : supine, upright position possible
- 3.1. Radiographic device : table, grid table, special skull unit or vertical stand with stationary or moving grid
- 3.2. Nominal focal spot value : 0.6 (\leq 1.3)
- 3.3. Additional filtration : up to 1 mm Al + 0.1 or 0.2 mm Cu (or equivalent)
- 3.4. Anti-scatter grid : r = 8; 40/cm, only for special indications and in adolescents
- 3.5. Screen film system : nominal speed class 400 - 800 (200)
- 3.6. FFD : 115 (100 - 150) cm
- 3.7. Radiographic voltage : 65 - 85 kV
- 3.8. Automatic exposure control : chamber selected - central
- 3.9. Exposure time : < 50 ms
- 3.10. Protective shielding : lead-rubber coverage of the body in the immediate proximity of the beam edge

LATERAL PROJECTION

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1. Visually sharp reproduction of the outer and inner tables of the entire cranial vault and the floor of the sella consistent with age
- 1.2. Superimposition of the orbital roofs and the anterior part of the greater wings of the sphenoid bones
- 1.3. Visually sharp reproduction of the vascular channels and the trabecular structure consistent with age
- 1.4. Reproduction of the sutures and fontanelles consistent with age

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for standard five year old patient: 1000 μ Gy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- | | |
|---------------------------------|--|
| 3.0. Patient position | : supine, upright position possible |
| 3.1. Radiographic device | : table, grid table, special skull unit or vertical stand with stationary or moving grid |
| 3.2. Nominal focal spot value | : 0.6 (\leq 1.3) |
| 3.3. Additional filtration | : up to 1 mm Al + 0.1 or 0.2 mm Cu (or equivalent) |
| 3.4. Anti-scatter grid | : $r = 8$; 40/cm; only for special indications and in adolescents |
| 3.5. Screen film system | : nominal speed class 400 - 800 (200) |
| 3.6. FFD | : 115 (100 - 150) cm |
| 3.7. Radiographic voltage | : 65 - 85 kV |
| 3.8. Automatic exposure control | : chamber selected - central |
| 3.9. Exposure time | : < 20 ms |
| 3.10. Protective shielding | : lead-rubber coverage of the body in the immediate proximity of the beam edge |

AP PROJECTION

Infants)

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1. No tilting: reproduction of the tri-radiate cartilages is in the same horizontal line as the 5th sacral segment or the upper margins of the ischial and pubic ossification centres superimposed
- 1.2. No rotation: a vertical line passing through the middle of the sacrum must pass through the middle of the pubic symphysis or the iliac wings and obturator foramina must be perfectly symmetrical
- 1.3. Reproduction of the necks of the femora in a standard position which should not be distorted by foreshortening or external rotation (patellae parallel to the table top). If a functional study for instability is required, it should be taken in full internal rotation and 45° abduction of the thighs
- 1.4. Visualisation of the peri-articular soft tissue planes

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for infants: 200 μ Gy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- | | |
|---------------------------------|--|
| 3.0. Patient position | : supine |
| 3.1. Radiographic device | : table |
| 3.2. Nominal focal spot value | : 0.6 (\leq 1.3) |
| 3.3. Additional filtration | : up to 1 mm Al + 0.1 or 0.2 mm Cu (or equivalent) |
| 3.4. Anti-scatter grid | : r = 8;40/cm; only for special indications and in adolescents |
| 3.5. Screen film system | : nominal speed class 400 - 800 |
| 3.6. FFD | : 100 cm |
| 3.7. Radiographic voltage | : 60 - 70 kV |
| 3.8. Automatic exposure control | : none |
| 3.9. Exposure time | : < 10 ms |
| 3.10. Protective shielding | : gonad capsules should be employed for male patients and gonad masks or shields for female patients, when diagnostically possible |

AP PROJECTION

(Older children)

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1 Symmetrical reproduction of the pelvis
- 1.2 Visualisation of the sacrum and its intervertebral foramina depending on bowel content (not to be considered in presence of female gonad shielding)
- 1.3 Reproduction of the lower part of the sacroiliac joints (not to be considered in presence of female gonad shielding)
- 1.4 Reproduction of the necks of the femora which should not be distorted by foreshortening or external rotation
- 1.5 Reproduction of spongiosa and cortex
- 1.6 Visualisation of the trochanters consistent with age
- 1.7 Visualisation of the peri-articular soft tissue planes

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for standard five year old patient: 900 μ Gy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- | | | |
|------|----------------------------|--|
| 3.0 | Patient position | : supine |
| 3.1 | Radiographic device | : grid table |
| 3.2 | Nominal focal spot value | : 0.6 (≤ 1.3) |
| 3.3 | Additional filtration | : up to 1 mm Al + 0.1 or 0.2 mm Cu (or equivalent) |
| 3.4 | Anti-scatter grid | : $r = 8$; 40/cm |
| 3.5 | Screen film system | : nominal speed class 400 - 800 |
| 3.6 | FFD | : 115 (100 - 150) cm |
| 3.7 | Radiographic voltage | : 70 - 80 kV |
| 3.8 | Automatic exposure control | : chamber selected - central or both laterals |
| 3.9 | Exposure time | : < 50 ms |
| 3.10 | Protective shielding | : gonad capsules should be employed for male patients and gonad masks or shields for female patients, when diagnostically possible |

PA/AP PROJECTION

Only performed for strict clinical indications.)

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1. Must include the base of the skull and the coccyx, and also the iliac crests
- 1.2. Reproduction of vertebral bodies and pedicles
- 1.3. Visualisation of the posterior articular processes
- 1.4. Reproduction of the spinous and transverse processes consistent with age

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for standard five year old patient: no values as yet available

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- | | |
|---------------------------------|---|
| 3.0. Patient position | : supine or upright |
| 3.1. Radiographic device | : table, grid table or vertical stand with stationary or moving grid, or vertical stand with special cassettes or special devices |
| 3.2. Nominal focal spot value | : ≤ 1.3 |
| 3.3. Additional filtration | : up to 1 mm Al + 0.1 or 0.2 mm Cu (or equivalent) |
| 3.4. Anti-scatter grid | : $r = 8$; 40/cm or special cassettes; no grid for infants < 6 months of age |
| 3.5. Screen film system | : nominal speed class 600 - 800 |
| 3.6. FFD | : 150 - 200 cm |
| 3.7. Radiographic voltage | : 65 - 90 kV |
| 3.8. Automatic exposure control | : none |
| 3.9. Exposure time | : < 800 ms |
| 3.10. Protective shielding | : gonad capsules should be employed for male patients. (see also remarks) |

REMARKS: PA Projection is recommended in order to reduce radiation exposure to the radio-sensitive breast tissue. Edge filters should be used when possible and are preferable to graded screens. Follow-up examinations on scoliotic patients can often be limited to C7 to iliac crests.

PA/AP PROJECTION

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1. Reproduction as a single line of the upper and lower plate surfaces in the centre of the beam
- 1.2. Visualisation of the intervertebral spaces in the centre of the beam area
- 1.3. Visually sharp reproduction of the pedicles, dependent on the anatomical segment
- 1.4. Visualisation of the posterior articular processes (for lumbar spine examinations)
- 1.5. Reproduction of the spinous and transverse processes consistent with age
- 1.6. Visually sharp reproduction of the cortex and trabecular structures consistent with age
- 1.7. Reproduction of the adjacent soft tissues

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for standard five year old patient: no values as yet available

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- | | |
|---------------------------------|--|
| 3.0. Patient position | : supine or upright |
| 3.1. Radiographic device | : table, grid table or vertical stand with stationary or moving grid, depending on age |
| 3.2. Nominal focal spot value | : 0.6 (≤ 1.3) |
| 3.3. Additional filtration | : up to 1 mm Al + 0.1 or 0.2 mm Cu (or equivalent) |
| 3.4. Anti-scatter grid | : $r = 8$; 40/cm or special cassettes, no grid for infants < 6 months of age |
| 3.5. Screen film system | : nominal speed class 400 - 800 |
| 3.6. FFD | : 115 (100 - 150) cm |
| 3.7. Radiographic voltage | : 60 - 85 kV |
| 3.8. Automatic exposure control | : chamber selected - central |
| 3.9. Exposure time | : < 50 ms |
| 3.10. Protective shielding | : gonad capsules should be employed for male patients |

REMARKS: Dispersion of overlying bowel gas can be obtained in examinations of lumbar spine and sacrum by compression of the abdomen. This will also reduce movement blurring and radiation exposure.

LATERAL PROJECTION

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1. Reproduction as a single line of the upper and lower plate surfaces in the centre of the beam
- 1.2. Full superimposition of the posterior margins of the vertebral bodies
- 1.3. Reproduction of the pedicles and the intervertebral foramina
- 1.4. Visualisation of the posterior articular processes
- 1.5. Reproduction of the spinous processes consistent with age
- 1.6. Visually sharp reproduction of the cortex and trabecular structures consistent with age
- 1.7. Reproduction of the adjacent soft tissues

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for standard five year old patient: no values as yet available

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- 3.0. Patient position : supine or upright
- 3.1. Radiographic device : table, grid table or vertical stand with stationary or moving grid, depending on age
- 3.2. Nominal focal spot value : 0.6 (≤ 1.3)
- 3.3. Additional filtration : up to 1 mm Al + 0.1 or 0.2 mm Cu (or equivalent)
- 3.4. Anti-scatter grid : $r = 8$; 40/cm no grid for infants <6 months of age
- 3.5. Screen film system : nominal speed class 400 - 800
- 3.6. FFD : 115 (100 - 150) cm
- 3.7. Radiographic voltage : 65 - 90 kV
- 3.8. Automatic exposure control : chamber selected - central
- 3.9. Exposure time : < 100 ms
- 3.10. Protective shielding : gonad capsules should be employed for male patients

AP/PA PROJECTION WITH VERTICAL/HORIZONTAL BEAM

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1. Reproduction of the abdomen, from the diaphragm to the ischial tuberosities, including the lateral abdominal walls
- 1.2. Reproduction of the properitoneal fat lines consistent with age
- 1.3. Visualisation of the kidney outlines consistent with age and depending on bowel content
- 1.4. Visualisation of the psoas outline consistent with age and depending on bowel content
- 1.5. Visually sharp reproduction of the bones

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for standard five year old patient: 1000 μ Gy

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- | | |
|---------------------------------|---|
| 3.0. Patient position | : supine, prone or decubitus |
| 3.1. Radiographic device | : table, grid table |
| 3.2. Nominal focal spot value | : 0.6 (≤ 1.3) |
| 3.3. Additional filtration | : up to 1 mm Al + 0.1 or 0.2 mm Cu (or equivalent) |
| 3.4. Anti-scatter grid | : $r = 8$; 40/cm, no grid for infants < 6 months of age; grid cassettes for decubitus views |
| 3.5. Screen film system | : nominal speed class 400 - 800 |
| 3.6. FFD | : 100 - 115 cm |
| 3.7. Radiographic voltage | : 65 - 85 kV (100 - 120 kV for older children) |
| 3.8. Automatic exposure control | : chamber selected - central or both lateral; preferably none in infants and young children |
| 3.9. Exposure time | : < 20 ms |
| 3.10. Protective shielding | : gonad capsules should be employed for male patients. Lead-rubber coverage of the thorax in the immediate proximity of the beam edge will reduce radiation exposure to radiosensitive breast tissue and the bone marrow in sternum and ribs. |

REMARKS: Depending on the stature of the child, it is not always possible to satisfy image criteria No 1.1 on a single film. PA projection is recommended for decubitus views.

AP/PA PROJECTION

(Without or before administration of contrast medium)

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1. Reproduction of the area of the whole urinary tract from the upper pole of the kidney to the base of the bladder and the proximal urethra
- 1.2. Visualisation of the kidney outlines consistent with age and depending on bowel content
- 1.3. Visualisation of the psoas outline consistent with age and depending on bowel content
- 1.4. Visually sharp reproduction of the bones

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for standard five year old patient: no values as yet available

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- | | |
|---------------------------------|---|
| 3.0. Patient position | : supine or prone |
| 3.1. Radiographic device | : table, grid table |
| 3.2. Nominal focal spot value | : 0.6 (≤ 1.3) |
| 3.3. Additional filtration | : up to 1 mm Al + 0.1 or 0.2 mm Cu (or equivalent) |
| 3.4. Anti-scatter grid | : r = 8; 40/cm, no grid for infants < 6 months of age |
| 3.5. Screen film system | : nominal speed class 400 - 800 |
| 3.6. FFD | : 100 - 115 cm |
| 3.7. Radiographic voltage | : 65 - 85 kV (100 - 120 kV for older children) |
| 3.8. Automatic exposure control | : chamber selected - central or both lateral |
| 3.9. Exposure time | : < 20 ms |
| 3.10. Protective shielding | : gonad capsules should be employed for male patients. Lead-rubber coverage of the thorax in the immediate proximity of the beam edge will reduce radiation exposure to radiosensitive breast tissue and the bone marrow in sternum and ribs. |

REMARKS: Bowel preparation is recommended for patients over one year of age. Displacement of overlying bowel gas and faeces is essential for adequate urinary tract reproduction and can be obtained by compression of the whole abdomen and by oblique or prone views, or by tube angulation, making tomography unnecessary. Compression of the abdomen will also reduce movement blurring and radiation exposure; no compression in suspected tumours, trauma or acute obstruction.

AP/PA PROJECTION

(After administration of contrast medium)

Contrast medium should rarely be administered without a preceding evaluation by a sonographic examination. Image criteria refer to a sequence of radiographs determined by an experienced qualified physician who will restrict their number to the minimum necessary for solving the clinical problem. There is no need for conventional tomography.

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1. Visualisation of the outline of the kidneys by the increase in parenchymal density (nephrographic effect) in the early film(s) which should be collimated to include the whole of both renal areas
- 1.2. Visually sharp reproduction of the renal pelvis and calyces (pyelographic effect)
- 1.3. Reproduction of the pelvi-ureteric junction
- 1.4. Visualisation of the area normally traversed by the ureter
- 1.5. Reproduction of the whole bladder and the proximal urethra

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for standard five year old patient: no values as yet available

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- | | |
|---------------------------------|--|
| 3.0. Patient position | : supine or prone |
| 3.1. Radiographic device | : table, grid table |
| 3.2. Nominal focal spot value | : 0.6 (≤ 1.3) |
| 3.3. Additional filtration | : up to 1 mm Al + 0.1 or 0.2 mm (or equivalent) |
| 3.4. Anti-scatter grid | : $r = 8$; 40/cm; no grid for infants < 6 months of age |
| 3.5. Screen film system | : nominal speed class 400 - 800 |
| 3.6. FFD | : 100 - 115 cm |
| 3.7. Radiographic voltage | : 65 - 80 kV |
| 3.8. Automatic exposure control | : chamber selected - central or both lateral |
| 3.9. Exposure time | : < 20 ms |
| 3.10. Protective shielding | : gonad capsules should be employed for male patients. Lead-rubber coverage of the thorax in the immediate proximity of the beam edge will reduce radiation exposure to radiosensitive breast tissue and the bone marrow in sternum and ribs. Coverage of the lower abdomen for the nephrographic film |

REMARKS: Bowel preparation is recommended for patients over one year of age. Displacement of overlying bowel gas and faeces is essential for adequate urinary tract reproduction and can be obtained by compression of the whole abdomen and by oblique or prone views, or by tube angulation, making tomography unnecessary. Compression of the abdomen will also reduce movement blurring and radiation exposure; no compression in suspected tumours, trauma or acute obstruction.

MICTURATING CYSTOURETHROGRAPHY (MCU)

Fluoroscopic control is recommended. Fluoroscopy should be intermittent and brief using small fields. Spot films of the base of the bladder should be taken at the end of the filling phase, except in cases of filling defects, when they should be taken early.

1. DIAGNOSTIC REQUIREMENTS

Image criteria

- 1.1. True lateral or steep oblique projection is recommended for bladder outlet and urethra
- 1.2. Reproduction at the peak of voiding of the bladder outlet and proximal urethra and of the entire male urethra in cases of flow disturbances or other penile pathology
- 1.3. Visualisation of any vesico-ureteric reflux for grading
- 1.4. Visualisation of any intrarenal reflux
- 1.5. Reproduction of the refluxing uretero-vesical junction in appropriate oblique projections
- 1.6. Visualisation of the ureter for evaluation of ureteric function after voiding
- 1.7. Reproduction of the whole extent of any duplication

2. CRITERIA FOR RADIATION DOSE TO THE PATIENT

Entrance surface dose for standard five year old patient: no values as yet available

3. EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

- | | |
|---|--|
| 3.0. Patient position | : filling phase in supine position, voiding phase in supine, lateral or upright position |
| 3.1. Radiographic device | : tilting fluoroscopic table |
| 3.2. Nominal focal spot value | : 0.6 (≤ 1.3) |
| 3.3. Additional filtration | : up to 1 mm Al + 0.1 or 0.2 mm Cu (or equivalent) |
| 3.4. Anti-scatter grid | : $r = 8$, 40/cm; no grid for infants < 6 months of age |
| 3.5. Screen film system | : nominal speed class 400 - 800 or image intensifying fluorography |
| 3.6. Object-to-film/-image intensifier distance | : as short as possible |
| 3.7. Radiographic voltage | : 65 - 90 kV (120 kV for older children) |
| 3.8. Automatic exposure control | : measuring chamber should not be covered by the contrast filled urinary bladder |
| 3.9. Exposure time | : < 20 ms |
| 3.10. Protective shielding | : testicle capsules for boys |

REMARKS: Slow dilute contrast medium instillation ($\leq 30\%$) using drip infusion.

GUIDELINES ON RADIATION DOSE TO THE PATIENT

Objective

The Criteria for Radiation Dose to the Patient which are given for some of the more common radiographic projections in these Guidelines are expressed in terms of a reference value of the Entrance Surface Dose for a standard five year old patient. It is intended that this reference dose value is used as an aid to the optimisation of radiation protection of the patient by identifying those situations in most urgent need of investigation and possible corrective action. 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 level 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 (1) that consideration should be given to the use of 'dose constraints or investigation levels' for application in some common diagnostic procedures.

The reference dose values have been derived from the observed distributions of paediatric patient doses in European Trials of the Quality Criteria conducted over the past six years which are described in Chapter 2. They have been set at approximately the level of the third quartile in the dose distributions seen for five year old patients. The reasons for choosing patients of this age are described in Chapter 2, Part 2. The third quartile value was chosen as an appropriate investigation level on the grounds 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 any dose reduction.

Methods of Dose Measurement to Check Compliance with the Criteria

To check compliance with the Criteria for Radiation Dose to the Patient it is necessary to obtain a reliable indication of the Entrance Surface Dose that would be delivered to a standard five year old patient using the radiographic techniques and equipment that are being tested against the Quality Criteria. For the chest examinations the entrance surface doses will often be below 100 μGy and will require particularly sensitive dosimeters for accurate measurement. Special thermoluminescent dosimeters or ionisation chamber dosimeters can be used.

Thermoluminescent dosimeters (TLDs) have the advantage of measuring the required entrance surface dose directly (including backscattered radiation) when attached to the patient's skin at a point coincident with the centre of the incident X-ray beam. For chest examinations in particular they probably need to be of higher sensitivity than the commonly available lithium fluoride or lithium borate material. $\text{CaF}_2:\text{Dy}$ TLDs were successfully used during the European Trials of the Quality Criteria. Uncertainties in the measurements due to the pronounced energy dependence of this material were not found to be

excessive for the range of X-ray spectra used in paediatric radiology if the dosimeters were calibrated at a suitable energy midway through the range.

To obtain a reliable measurement of the entrance surface dose associated with typical practice on the equipment and techniques being tested, it is recommended that measurements are made on a representative sample of patients of close to the standard size. About 10 patients aged between 4 and 6 years old and weighing between 15 and 25 kg would be suitable for this purpose. The mean value of these dose measurements can be taken as an estimate of the dose to a standard five year old patient for comparison with the reference dose value in the Quality Criteria.

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 ionisation 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 depend critically on the beam area and the X-ray spectrum. Backscatter factors calculated using Monte Carlo techniques in a mathematical phantom representing a 5 year old patient vary between about 1.2 and 1.4 for the projections and X-ray qualities included in these Guidelines. A single average value of 1.3 can therefore be used in most situations without appreciable error.

Dose-area product meters are becoming increasingly available and provide a convenient and accurate method for monitoring patient doses from paediatric X-ray examinations. In the future, reference doses for paediatric radiology might be expressed in terms of dose-area product but in the meantime, measurements with these instruments can be converted to entrance surface dose for comparison with the current reference doses. The dose-area product value should be divided by the area of the X-ray beam at the entrance surface of the patient and multiplied by the backscatter factor.

CHAPTER 2

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

Introduction

The Quality Criteria for Diagnostic Radiographic Images presented in Chapter 1 have been developed over a period of about ten years during which a number of local, national and 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. [Fendel et al (1985), Fendel et al (1989), Schneider et al (1992), Schneider et al (1993), Schneider et al (1995)]. In this chapter the results of these Trials are summarised to form a supplementary scientific background to the Quality Criteria Document.

Between 1989 and 1991 a European Union (EU) wide study involving frequent X-ray examinations of infants was undertaken. The age groups and X-ray examinations using fixed X-ray installations were limited to a 10 month old infant for chest PA/AP; skull PA/AP; spine, lateral projection; abdomen AP, supine position; and a 4 month old baby for pelvis AP, in cases of suspected hip dysplasia. The corresponding criteria for mobile equipment were for both a 10 month old infant and a premature baby (weight of approximately 1 kg) chest AP, supine position. Out of 121 invited X-ray departments in 11 member states of the European Union 89 participated in the study. In 1992 this preliminary study was extended to the 5 year old child and 105 X-ray departments in 16 European countries participated. A more recent Trial was undertaken in the period 1994-1995 concerning the 10 year old child. In this case 115 X-ray departments in 17 European countries participated.

TLDs were used to measure the entrance surface dose and technique factors were collected by questionnaires (see Chapter 3: Quality Criteria Implementation and Audit Guidelines). In all Trials the original X-ray films were rated by panels of seven to nine radiologists for assessment against a set Quality Criteria as listed in the Draft Working Document (CEC 1992).

A summary of the results of these three Trials is presented in this chapter, divided into three parts: Part 1 deals with the radiographic technique, Part 2 the patient dose and Part 3 the image quality.

It must be pointed out that the discussion presented in this chapter is based upon results obtained when using the earlier version of the Quality Criteria [CEC (1992)] which do differ in a number of respects from the revised version presented in Chapter 1 of these Guidelines. The revision has been based on the results of the Trials and comments received from competent individuals and professional bodies (see Chapter 4: List of All Those Who Contributed to the Establishment, Testing and Evaluation of the Quality Criteria of this Report).

Part 1 - Radiographic Technique

The following information on radiographic technique was collected:

- Type and make of X-ray equipment
- Tube filtration and nominal focal spot value
- Automatic or manual exposure control
- Exposure time and tube current
- Grid, moving or stationary
- Focus-to-film distance (FFD)
- Manufacturer/type of screen film system
- Speed class of screen film system
- Patient age, weight and height
- Radiographic voltage
- Film size

Results and Discussion

General Aspects of Survey Data

The response rate by the X-ray departments for a number of technical parameters employed is shown in Figure 1. In particular the tube filtration and nominal focal spot value were generally less frequently reported. In general the filtration was reported by less than 30% of departments with a less than 20% response rate for both the chest examinations of the 1 kg neonate and for mobile X-ray examinations. This is surprising given that both European and International Standards [IEC (1979)] 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 (filtration) or image quality (nominal focal spot value) this lack of information is a serious omission.

The response rate for information on the speed class of screen film systems also showed a general lack of awareness by the user. In particular for the infant chest examination performed on a mobile X-ray unit a response rate of only 36% was noted and even for the chest PA/AP, with the highest response rate, a figure of 82% was noted. 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.**

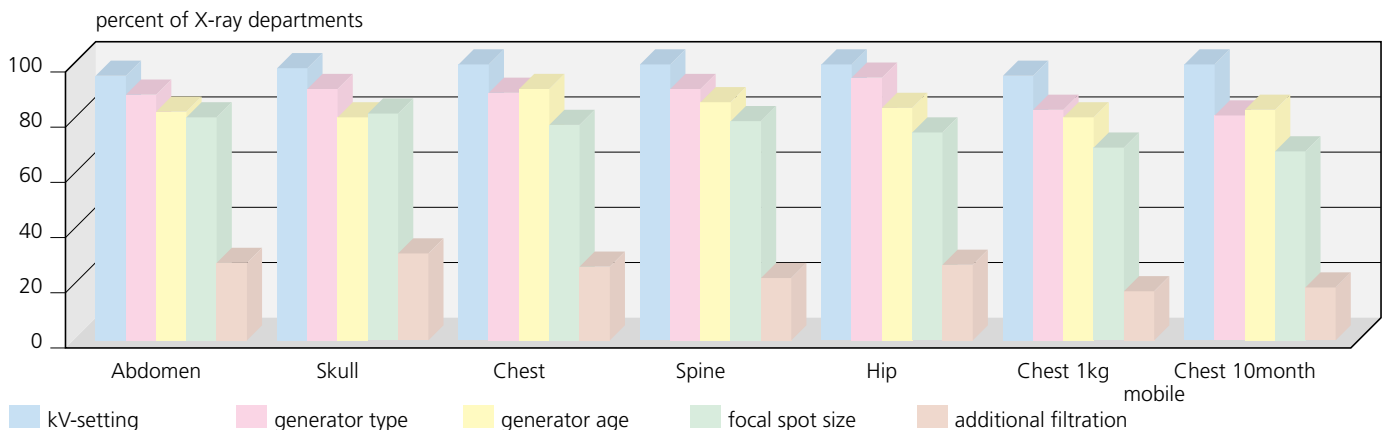


Figure 1 Question-response rates for technical parameters in the first European Trial 1989

Information provided on the type of X-ray generator presently in use indicates that 12-pulse generators are the most common type of generator with over 50% of respondents utilising this type of equipment. However, it would appear that the use of high frequency multi-pulse (converter) generators is increasing with roughly 25% employing this technology. This factor is of significant importance given the extremely short exposure times often needed in paediatric X-ray examinations.

Radiographic Technique for Specific Examinations

The distribution of generator types employed in different radiographic examinations and observed in the 1989/91 and 1994/95 Trials is presented in Figure 2. Although the most frequently employed generator types for all examinations were of the 12-pulse or multi-pulse type, 1-, 2- and 6-pulse generators were still employed. Also, although roughly 50% of installations were of the 12-pulse variety approximately 50% of fixed installations were 10 or more years old. The mobile X-ray units were generally newer, especially those in neonatal intensive care units.

The distribution of types of X-ray generators observed in the later Trial and also shown in Figure 2, indicates that there has been a general move towards the use of more modern X-ray generators in paediatric examinations.

The distributed kV settings employed for the different examinations are shown in Table 1.

The majority of kV settings for the 10 month old infant employed were above 60 kV for most types of examination on fixed installations except those of the pelvis and those on mobile equipment.

The general movement to higher kilovoltage settings for 5 year and 10 year old children is indicated in Figures 3a and 3b for both the chest and pelvis examinations. However, in the case of the pelvis almost 40% of examinations on 5 year old children employed kV settings < 60 and similarly, 17% of this type of low kV examination on 10 year old children.

The distribution of speed class of screen film systems observed in the 1989/91 Trial shows that over 50% of departments employed speed classes of 200 or less for all examinations. Surprisingly screen film systems with speed class < 100 are still employed and only 10% employ high speed systems (≥ 600). Similar results were observed in the later Trials. It must be pointed out that the results for speed class of screen film systems employed cannot be interpreted in isolation from the results presented in Table 1 for kV-settings when attempting to investigate the role of speed class on patient dose. Speed class of screen film systems are kV dependent, particularly at the lower settings observed in Table 1.

Similarly the high proportion of low kV settings observed in the paediatric studies may rise from limitations in other aspects of equipment performance. For example, if the X-ray generator is unable to reproduce the low mAs values often required in paediatric examinations, when utilising high speed class screen film systems, the operator may be forced to lower the kV setting in order to reproduce an acceptable film density.

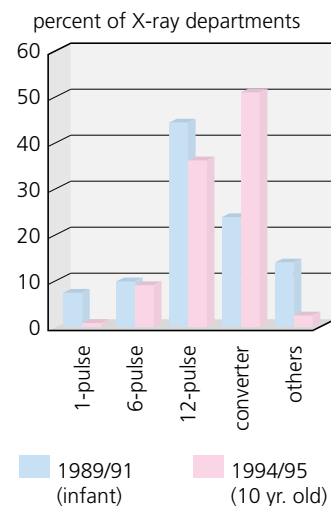


Figure 2 Distribution of generator types observed in the 1989/91 and 1994/95 Trials

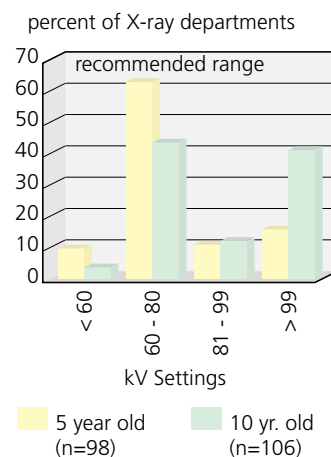


Figure 3a Distribution of kV values employed with 5 and 10 year old children: Chest PA/AP examination; n = number of X-ray departments

Table 1 Frequency of kV-settings used in different X-ray examinations of infants

	kV-setting				total
	< 60	60 - 69	70 - 79	≥ 80	
Chest PA/AP	21.8%	43.6%	15.4%	19.2%	78/100%
Chest AP (10 month) mobile	42.5%	42.5%	15.0%	-	40/100%
Chest, AP (1 000 g newborn)	71.2%	24.7%	2.7%	1.4%	73/100%
Skull PA/AP	16.7%	51.5%	28.8%	3.0%	66/100%
Elvis AP	57.2%	37.4%	5.4%	-	56/100%
Pelvis PA/AP	27.3%	52.3%	18.2%	3.2%	44/100%
Abdomen AP/PA	33.4%	49.0%	15.6%	2.0%	51/100%

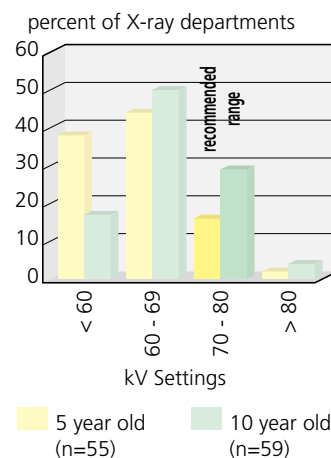


Figure 3b Distribution of kV values employed with 5 and 10 year old children: Pelvis AP examination; n = number of X-ray departments

The use of additional tube filtration has been recommended in the 1992 Quality Criteria Working Document for paediatric X-ray examinations. The distribution of responses to the question "do you employ additional filtration?" is shown in Figure 4. Results indicate that the majority do not employ additional filtration. However, here also the origin of additional filtration in paediatric examinations may have come about in past by the need to artificially increase the mAs value employed in order to permit its selection on the generator control, without the need to lower the kV setting.

Conclusions

The results of the EC Trials of the CEC Quality Criteria for Paediatrics 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. For example 50% of departments did not know the speed class of screen film systems employed in abdomen 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. All 1979 IEC guidelines concerning presentation of nominal focal spot value and total tube filtration on the tube housing should be fully implemented.
2. An extremely high proportion of departments employ lower than recommended kV values even for the 5 year old child. Settings of appropriate kV to make full use of the speed of more modern rare earth screen film systems is imperative.
3. The use of X-ray generators which permit the use of the low mAs values often required in paediatric examinations is crucial if — in order to control X-ray output — the possible lowering of the kV settings is to be eliminated.
4. A significant proportion (54%) of examinations employed screen film systems with a nominal speed class of 200 or below. The prevalent recommended range is 400 - 800 so that further consideration should be given to this fact.

Part 2 - Patient Dose

In this section the results of measurements of the entrance surface dose (ESD) values encountered during the three EC Trials are presented. These results indicate the factors which play an important role in determining the patient dose and highlight some of the problems encountered when trying to define meaningful reference dose values for paediatric X-ray examinations.

Distribution of Individual Doses

In all three of the EC Trials, information was collected and dose measurements made on only one patient at each hospital for each type of examination studies. The total numbers of dosimetric measurements undertaken during the three Trials are shown in Table 2. A summary of the entrance surface dose measurements performed during the 1989/91 and

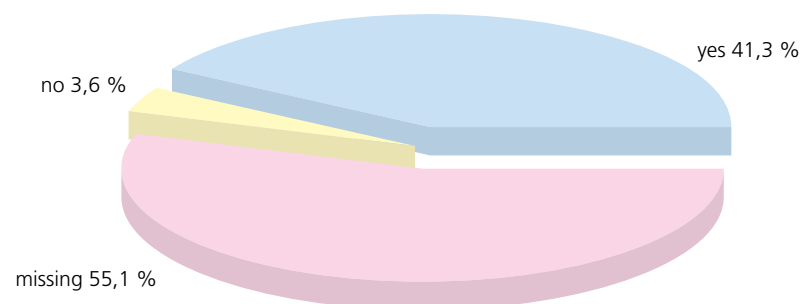


Figure 4 Response rates to the question "do you employ additional filtration?" All X-ray examinations of the 5 year old child

1992 Trials is presented in Tables 3a and 3b for the age groups and examinations shown. These measurements indicate wide variation in measured entrance surface dose values with minimum to maximum dose ratios in the region of 1:40 with the pelvis reaching 1:76.

Variations found in the 1992/1995 Trials are similar, however, patient size — a major factor influencing radiation dose — was limited by age/weight to a narrowly defined range. These wide dose variations are, therefore, cause for concern.

The entrance surface dose distributions shown in Figure 5 for the chest examinations for each age group are skewed towards the low dose end. However the dose distribution for the skull examinations was much wider and irregular.

An overall summary of the entrance surface dose measurements observed during the three EC Trials is shown in Table 4. For the chest and skull examinations there is a remarkable similarity between the median values for the three age groups with no distinct trend or an increase with age. As the chest is mostly composed of air and the skull does not change in size as much as the rest of the body throughout childhood, this result is perhaps not too surprising. A comparison of the results from the three Trials as summarised in Tables 3a, 3b and 4 and in Figure 5 indicates that the dose distributions for all three age groups are very wide and quite similar for all examinations. Many of the infants studied in the first Trial were receiving doses as high or higher than the 5 and 10 year old patients in the other two Trials. However, such comparisons are complicated by the fact that the Trials were separated by a few years in time and were carried out on different samples of hospitals from throughout Europe with often quite different radiographic techniques, as seen in Part 1 of this Chapter.

Table 2 Number of examinations surveyed in three dosimetric Trials on frequent X-ray examinations in paediatrics patients

	Infant	5 year	10 year	Total
Chest PA/AP	77	98	107	282
Chest AP (1 000 g newborn)	72	—	—	72
Chest AP (10 month) mobile	42	46	34	122
Chest Lateral	—	74	75	149
Skull PA/AP	66	67	56	189
Skull Lateral	—	68	61	129
Wrist AP	56	55	59	170
Wrist spine PA/AP	44	—	—	44
Thoracic Spine PA/AP	—	—	42	42
Thoracic Spine Lateral	—	—	42	42
Lumbar Spine PA/AP	—	—	53	53
Lumbar Spine Lateral	—	—	55	55
Abdomen AP/PA	53	63	64	180

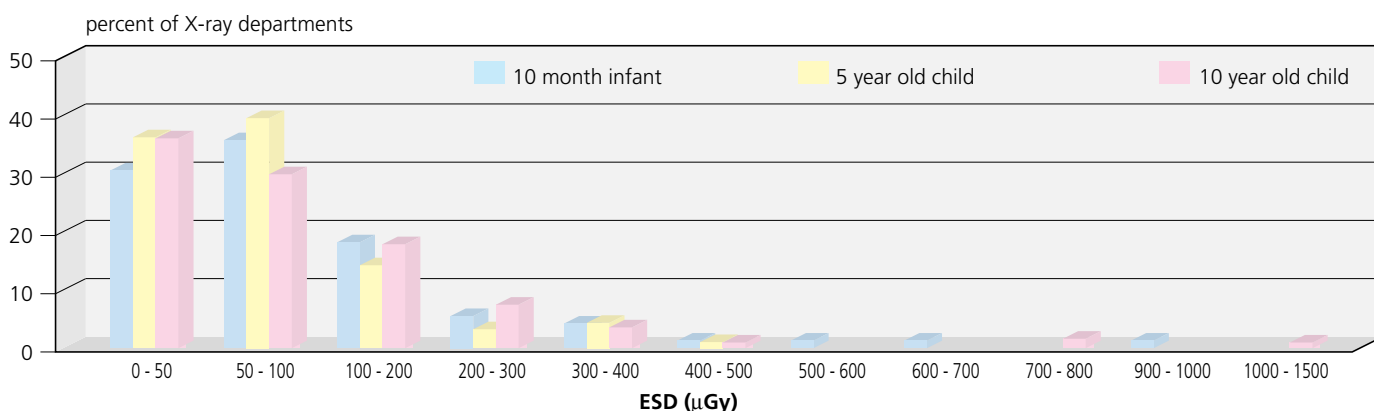


Figure 5 Entrance surface dose distributions (ESD) for 10 month old infant, 5 year old and 10 year old children for chest PA/AP examination

Derivation of the reference dose values

The derivation of reference dose values for paediatric patients is not as straightforward as for adult patients. Patient doses for the same type of examination are expected to vary significantly throughout the paediatric age range because of the wide variation in patient size and composition and the corresponding image requirements. However, it is important

Table 3a Entrance surface doses measured in the 1989/91 CEC Trial of infants for a number of frequent X-ray examinations

	Entrance Surface Dose (µGy)						
	min	1st quartile	median	mean	3rd quartile	max	ratio
Chest AP (1 000 g newborn)	11	25	45	68	80	386	1:35
Chest PA/AP (10 month)	21	45	75	132	135	979	1:47
Chest AP (10 month) mobile	34	55	90	129	150	718	1:21
Skull PA/AP (10 month)	152	600	930	1260	1690	4514	1:30
Pelvis AP (4 month)	18	100	260	398	640	1369	1:76
Spine Lateral (10 month)	107	450	880	1128	1500	4351	1:41
Abdomen AP/PA (10 month)	77	260	440	651	700	3210	1:42

Table 3b Entrance surface doses measured in the 1992 CEC Trial of 5 year old children for a number of frequent X-ray examinations

	Entrance Surface Dose (µGy)						
	min	1st quartile	median	mean	3rd quartile	max	ratio
Chest PA/AP	18	45	67	102	100	1347	1:71
Chest AP, mobile	29	49	68	89	86	333	1:11
Chest Lateral	37	102	140	170	213	554	1:15
Skull PA/AP	242	691	967	1248	1540	4626	1:19
Skull Lateral	138	396	703	827	1078	2358	1:17
Pelvis AP	86	282	485	707	924	2785	1:32
Abdomen AP/PA	56	340	588	796	1000	2917	1:52

Table 4 Variation of entrance surface dose (µGy) observed in the three CEC paediatric Trials (1989/91, 1992, 1994/95): median, minimum-maximum values and corresponding ratio (min:max) of frequent X-ray examinations in paediatric patients

type of X-ray examination		Infant			5 year			10 year	
Chest AP (1000 g newborn)	45	11 - 386	1:35	—	—	—	—	—	—
Chest PA/AP	75	21 - 979	1:47	67	19 - 1347	1:71	71	17 - 1157	1:68
Chest AP (mobile)	90	34 - 718	1:21	68	29 - 333	1:11	91	29 - 760	1:26
Chest Lateral	—	—	—	140	37 - 554	1:15	153	39 - 1976	1:51
Skull PA/AP	930	152 - 4514	1:30	967	242 - 4626	1:19	1036	130 - 5210	1:40
Skull Lateral	—	—	—	703	138 - 2358	1:17	577	113 - 3787	1:33
Pelvis AP	260	18 - 1369	1:76	485	86 - 2785	1:32	812	89 - 4167	1:47
Skull Spine PA/AP	867	107 - 4351	1:41	—	—	—	—	—	—
Thoracic Spine AP	—	—	—	—	—	—	887	204 - 4312	1:21
Thoracic Spine Lateral	—	—	—	—	—	—	1629	303 - 6660	1:22
Lumbar Spine AP	—	—	—	—	—	—	1146	131 - 5685	1:43
Lumbar Spine Lateral	—	—	—	—	—	—	2427	249 - 23465	1:94
Abdomen AP/PA	440	77 - 3210	1:42	588	56 - 2917	1:52	729	148 - 3981	1:27

hat a system is developed for estimating or measuring paediatric doses and for comparing them to some reference dose values so that X-ray department staff can identify when investigation and corrective action is most urgently required.

Because of the general similarity observed between the entrance surface dose distributions during the three Trials on the infant, 5 year old and 10 year old child, it has not been possible to use these data to derive specific reference dose levels for each age group. **Instead, as a first step, it was decided to employ the third quartile dose values for the 5 year old as the Criteria for Radiation Dose to the Patient presented in Chapter 1.** However, in presenting these values it is clearly understood that:

Every effort should be made by staff undertaking paediatric X-ray examinations to ensure that entrance dose values for infants and children less than 5 years old are lower than these values.

Entrance surface dose values for children older than 5 years of age are, if possible, no higher than the values indicated in this document, allowing for variations in weight and patient thickness.

Further work is undertaken to develop a rational and consistent framework for comparing entrance surface doses employed in paediatric X-ray examinations on children of different stages of development.

Relation Between Patient Dose and Radiographic Technique

Considering the relatively standard age/size of the patients encountered in each of the three Trials, the observed variations in radiographic technique were extremely large. The frequency of X-ray departments which fulfilled the CEC Criteria for Good Radiographic technique for X-rays of the newborn chest are presented in Table 5. The extremely low adherence to specific technique factors which can directly affect patient dose must play a major role in determining the wide variations observed.

For example Figure 6 shows the mean ESD encountered both with and without a grid for the three age groups covered by the Trials. Clearly if it is possible to perform an examination without a grid, a large dose saving is possible. There is, generally, no need for anti-scatter grids in chest X-ray examinations of children under 8 years of age. However, 25% of departments use a grid for chest X-ray examinations of infants and nearly 50% do this unnecessarily for 5 year old children.

Similarly Figure 7 shows the distribution of ESD for the PA/AP skull examinations performed on 5 year old children when screen film systems of different speed classes are used.

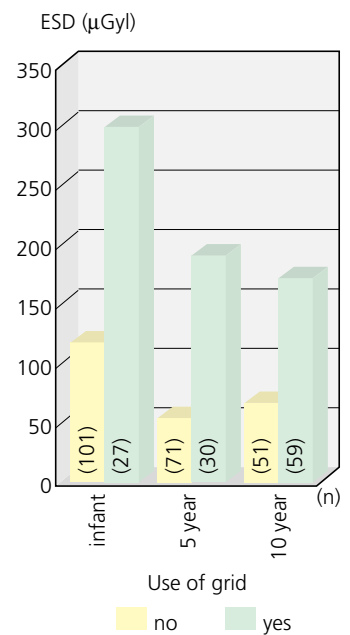


Figure 6 Mean entrance surface dose (ESD) with and without a grid for the chest PA/AP examinations on 10 month infant, 5 year and 10 year old children; n = number of X-ray departments

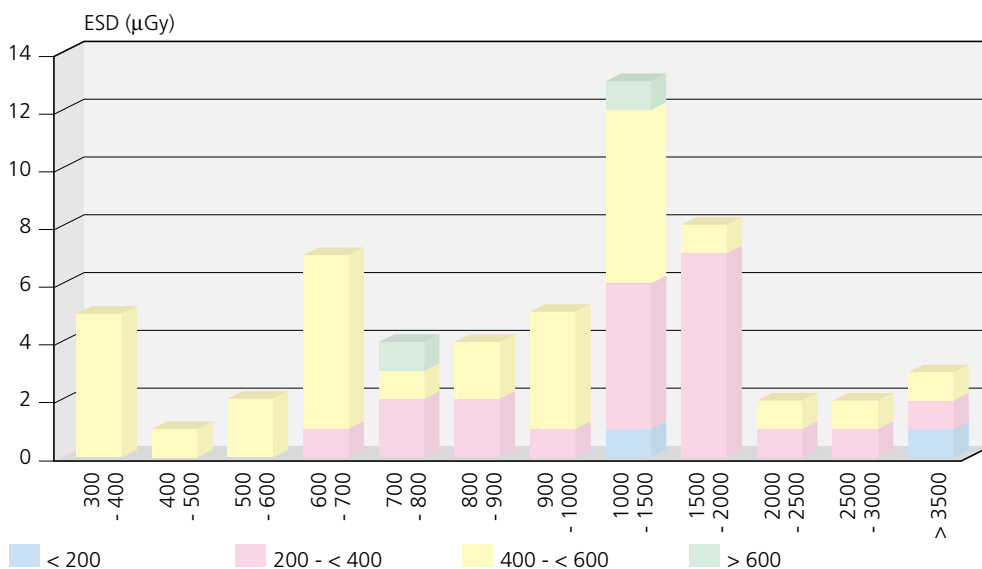


Figure 7 Distribution of entrance surface dose with screen film system nominal speed classes for the skull PA/AP examination undertaken on the 5 year old child; n = number of X-ray departments

Table 5 Percentage of children's hospitals in Germany fulfilling the CEC Criteria for Good Radiographic Technique for chest X-ray examinations in newborns

Exposure time	12%	13/94
kV-setting	21%	21/100
Additional filtration	30%	26/106
Focus-film distance	67%	71/106
Screen film system speed	66%	66/100

employed. Clearly demonstrated is the fact that practically only nominal speed classes of > 400 were used for those examinations with an ESD below 700 μGy . Examinations with higher dose had a speed class of mostly 200 — some even less. Two departments had higher ESD despite the use of high nominal speed classes (≥ 600). However, this may be due to the fact that speed class decreases at lower kV settings and/or lower kV values are employed in order to compensate for the inability of the generator to provide a low enough mAs value.

In order to explore the role of radiographic technique on patient dose the number of individual radiographic technique factors, e.g. kV, filtration, speed class, recommended in the Quality Criteria Document which were fulfilled was investigated together with the corresponding ESD values. Table 6 presents results for the 5 year old child for different examinations and clearly demonstrates that the greater the number of recommended radiographic technique factors which are met the lower the mean ESD value for all examinations. As shown in Part 3 of this Chapter, this lower dose does not lead to loss of image quality.

Conclusions

1. The rounded third quartile dose values presented in Table 3b for the 5 year old child should be taken as reference dose values for paediatric patients.
2. Every effort should be made to reduce doses for children less than 5 years of age to below the values presented.
3. Strict adherence to all the radiographic technique factors recommended can lead to significant dose reduction.
4. X-ray generators employed in paediatric examinations should be capable of selecting the low mAs values required to ensure that the recommended kV values can be employed.
5. Screen film systems with nominal speed classes > 400 should always be employed together with the appropriate kV settings.

Table 6 Frequency of fulfilment of the criteria for Good Radiographic Technique in the 5 year old child (number of X-ray departments [n] and corresponding mean ESD values [μGy] — only criteria directly affecting dose are considered)

	Fulfilment of Criteria of an Example of Good Radiographic Technique													
	zero criteria		one criterion		two criteria		three criteria		four criteria		five criteria		six criteria	
	n	μGy	n	μGy	n	μGy	n	μGy	n	μGy	n	μGy	n	μGy
Chest PA/AP	—	—	—	—	8	143	13	193	40	80	18	54	6	25
Chest AP (mobile)	—	—	—	—	—	—	9	131	19	88	13	88	—	—
Chest Lateral	—	—	1	120	3	273	14	246	30	214	17	103	4	53
kull PA/AP	—	—	—	—	2	1422	7	1358	24	1637	19	881	4	654
kull Lateral	—	—	—	—	1	435	10	1149	26	865	19	771	6	464
elvis AP	—	—	1	1085	9	1307	24	533	11	851	5	302	—	—
Abdomen AP/PA	—	—	—	—	2	386	10	1171	25	769	9	470	5	270

Part 3 — Image Quality

For each Trial the X-ray films (approximately 350) were assessed by a group of expert paediatric radiologists from five EU countries. The first 1989/91 Trial involved 8 radiologists, the second 1992 Trial 9 radiologists and the third 1994/95 Trial 7 radiologists. Generally, each evaluated the original radiographs twice using a preliminary Draft Working Document in the 1989/91 Trial and subsequently the revised Working Document [CEC 1992]. The image quality score for an individual image was defined as the mean score of all raters in each Trial. Following the first Trial the Image Criteria were modified since it was noted that in some instances, images which were obviously of poor quality, were receiving maximum scores for the criteria then defined. Consequently more selective criteria needed to be added to ensure that inferior images could not receive a maximum score.

Inter-rater agreement on fulfilment of Image Criteria for each film was generally high (approximately 80%). This is obviously important since criteria which have a great deal of subjectivity will receive widely different scores for different viewers. This is undesirable. In general the robustness and overall applicability of the Image Criteria was extremely good.

In order to evaluate the possible relationship between both image quality, patient dose and radiographic technique the basic set of radiographic technique criteria were defined. Thus, for the skull these were:

Local spot size	: ≤ 1.3 mm
Additional filtration	: ≤ 4 mm Al equivalent
Anti-scatter grid	: Used
Screen film system	: nominal speed class ≥ 400
Focus-to-film distance	: ≥ 100 cm
Radiographic voltage	: ≥ 65 kV

The mean entrance surface dose value and image quality scores are shown in Figure 8 as a function of the number of radiographic technique factors fulfilled for the chest lateral examination of the 5 year old child. Clearly the more technique factors fulfilled the lower the mean dose which is achieved without any sacrifice in image quality. This trend was highly significant ($p \leq 0.001$ based upon the Kruskal-Wallis test).

A similar conclusion was noted in the chest PA/AP examination of the 10 year old child (see Figure 9), consequently departments which consistently fulfil a higher proportion of the recommended radiographic technique factors for paediatric X-ray examinations employ on average lower entrance surface dose values with high levels of image quality.

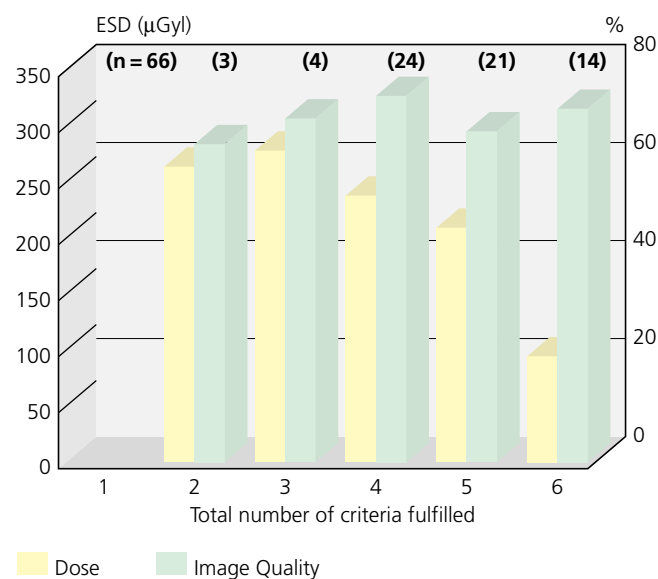


Figure 8 Impact of good radiographic technique on entrance surface dose and image quality: Chest lateral examination for 5 year old child; n = number of X-ray departments

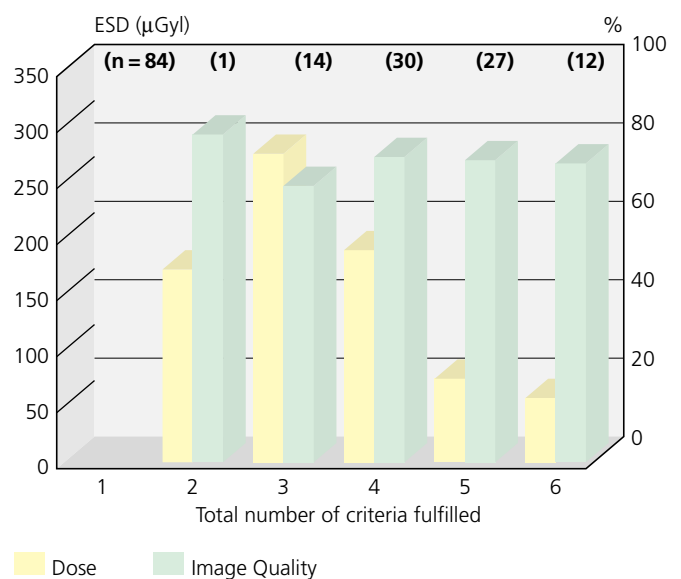


Figure 9 Impact of good radiographic technique on entrance surface dose and image quality: Chest AP/PA examination for 10 year old child; n = number of X-ray departments

LIST OF REFERENCES FOR CHAPTER 2

1. Fendel H., Schneider K., Schofer H., Bakowski C. and Kohn M.M. (1985). Optimization in paediatric radiology: are there specific problems for quality assurance in paediatric radiology? *BJR (Suppl.)* 18:159-165.
2. Fendel H., Schneider K., Kohn M.M. and Bakowski C. (1989). Specific principles for optimization of image quality and patient exposure in paediatric diagnostic imaging. *BIR Report* 20:91-101.
3. Schneider K., Fendel H., Bakowski C., Stein E., Kohn M.M., Kellner M., Schweighofer K., Cartagena G., Padovani R., Panzer W., Scheurer C., Wall B. (1992). Results of a dosimetric study in the European Community on frequent X-ray examinations in infants. *Radiation Protection Dosimetry* 43: 31-36.
4. Schneider K., Kohn M.M., Bakowski C., Stein E., Freidhof C., Horwitz A.E., Padovani R., Wall B., Panzer W., Fendel H. (1993) Impact of radiographic imaging criteria on dose and image quality in infants in an EC-wide survey. *Radiation Protection Dosimetry* 49:73-76.
5. Schneider K., Kohn M.M., Endemann B., Ernst G., Panzer W., Padovani R. and Wall B. (1995). Variation in radiation dose and image quality of common X-rays of the five year old child. A European wide survey in children's clinics. Supplement to Vol. 5. *European Radiology*, p. 192 (abstract, detailed publication in preparation).
6. CEC 1992: Quality Criteria for Diagnostic Radiographic Images in Paediatrics, Draft Working Document, CEC XII/307/91, June 1992.
7. IEC 1979, Marking of accompanying documents for X-ray tubes and X-ray tube assemblies for medical use, International Electrotechnical Commission, Publication 637, 1979.

Chapter 3

QUALITY CRITERIA IMPLEMENTATION AND AUDIT GUIDELINES

The Quality Criteria are designed to be easily applied in practice in any X-ray department, with equipment that ideally should be able to meet the basic requirements listed on the next page but one, and 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 a 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 summarised 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 type of radiograph frequently taken on 4-6 year old patients in the X-ray facility to be audited.
2. Take a random sample of at least 10 patients aged 4-6 years, weight 15-25 kg.
3. Take 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 average sized patients with the corresponding reference dose in the Quality Criteria.
6. At least two observers check compliance of each radiograph with the Image Criteria independently. Appendix II to this chapter contains a copy of the Image Quality Assessment form similar to those used by the panel radiologists for scoring films in the Trials of Quality Criteria. Observers taking part in this audit process might find this form useful. The form can be adopted 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 these forms also include a system for scoring more general aspects of the image such as film blackening, field size and diagnostic acceptability; other aspects such as contrast and sharpness may also be considered.

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 optimised 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) is not being met.
8. Investigate the cause(s) of any consistent noncompliance 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 noncompliance.
10. After a short period of using the revised techniques or equipment, repeat steps 2-7.
11. If no improvement, repeats steps 7-10.
12. If initial standards (criteria) are now being met in full, consider improving standards, for example, by setting lower reference doses in line with the ALARA principle.

To 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.

Optimisation of radiographic techniques in paediatric radiology is often restricted by the fact that the equipment is not designed specifically for use on small children. A list of basic requirements for radiographic equipment suitable for paediatric radiology may be deduced from discussions which took place within the European Study Group under contract No 91/ET005, DG XI-C-1/1992.

For further guidance this list is presented below:

Guidelines on basic requirements for radiographic equipment in paediatric radiology as an aid to fulfilment of the quality criteria for diagnostic radiographic images in paediatrics

1. Generators

Waveform:	preferably 12-pulse or high frequency multi-pulse converter
Power:	≥ 30 kW (fixed generator equipment) ≥ 10 kW (mobile equipment)
Tube voltage:	45 to 120 kV (150 kV for special conditions and indications) (constancy of tube voltage (kV) < 5%)
mA settings:	adjustable, lowest possible mAs value ≤ 0.5
Exposure time:	shortest exposure time nominal 1 ms separate display of exposure time (ms) and mAs

2. Tube

Nominal focal spot value:	≤ 1.3 (according to IEC 336, 1993)
Extra-focal radiation:	minimise by use of focusing lead strips

3. Filtration

Minimum inherent filtration:	beam quality of first half value layer equal to 2.7 mm Al at 100 kV (according to EN 60601-1-3, 1994)
Additional filtration:	1 mm Al and 0.1 mm Cu or more (selected settings should be visually displayed)

4. Anti-scatter Grid

General requirements: removable (automatically or manually, visual display)
high primary beam transmission (carbon fibre covers and inter-space material or better)
moving grids with strip density ≥ 36 lines/cm and grid ratio 8;
multi-line grids with strip density ≥ 60 lines/cm (according to IEC 627, 1978)

5. Automatic Exposure Control System

General requirements: particularly adaptable for infants

6. Screen Film System

Nominal speed class: 400 - 800 (200 for special conditions)

7. Dose-Area Product Device

General requirements: Measurement and display of dose area product, dose, and, optionally, dose area product rate and dose rate

8. Ancillary Equipment

General requirements: table top with low attenuation material
immobilisation board or chair
immobilisation devices
compression bands
lead contact shields or shadow masks for girls
shaped lead gonadal capsules for boys
special organ shaped filters and shadow shields
lead rubber contact shields
organ shaped sponges

9. Image Intensifier (25 cm diameter)

Resolution limit: ≥ 1.4 lp/mm

Other requirements: digital spot imaging 1024² matrix
adaption of field size to the size of the image intensifier system

10. Digital Image processing (storage phosphor screens)

General requirements: 1576 x 1976 pixels with 24 cm x 30 cm cassette (≥ 3 lp/mm)
1770 x 2370 pixels with 18 cm x 24 cm cassette (≥ 4 lp/mm)
reading grey scale ≥ 8 bit

11. Fluoroscopy

ntensifier input dose rate: For standard 25 cm diameter image intensifier field size

Low dose fluoroscopy:	infants	0.1 mGys ⁻¹
	children	0.2 mGys ⁻¹
	maximum	0.6 mGys ⁻¹

'High Level Control'
Fluoroscopy: maximum 1.0 mGys⁻¹
(not needed if other options provided)

ube voltage: ≥ 70 kV (with override available to allow setting for infant studies)

Nominal focal spot value: 0.6 (according to IEC 336)

Other requirements: automatic brightness control
preferably pulsed fluoroscopy
last image hold
fluoroscopy only with an additional filtration of 0.2 mm Cu or more
multi leaf diaphragm and/or iris diaphragm
minimum field size at the image recording system ≤ 4 cm x 4 cm

LIST OF REFERENCES OF CHAPTER 3

1. EN 60601-1-3, 1994 = IEC 601-1-3, 1994, part 1: General requirements for safety
3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
2. IEC 627, 1978; Characteristics of anti-scatter grids used in X-ray equipment.
3. IEC 336, 1993; X-ray tube assemblies for medical diagnosis — Characteristics of focal spots.

CHAPTER 3

APPENDIX I

SAMPLE QUESTIONNAIRE FOR RECORDING PATIENT INFORMATION, EQUIPMENT, RADIOGRAPHIC TECHNIQUE, AND DOSE DATA

Chest examination

Questionnaire sheets for the other examinations were identical with exception of the title box (upper left corner) and diagrams for TLD-placement. Diagrams for the other examinations are given in the sheet following the **Chest PA/AP** questionnaire.

Chest PA/AP

stationary unit - 5 year old child

Clinical Diagnosis: _____

Clinical Question: _____

Dosemeter N°: _____

IMPORTANT! Please fill in the dosemeter N° used for this examination and the clinical information in the left box.

Name of the study center: _____

. Information on the patient

Exposure Date	Sex	Date of Birth	Weight	Height
/ /	<input type="checkbox"/> female	/ /		
D M Y	<input type="checkbox"/> male	D M Y	kg	cm



TLD placement
(always place the TLD
on the **beam entrance**
side of the patient)

I. Information on equipment

	Generator	Generator Type	Automatic exposure control used?	X-ray device
Manufacturer		<input type="checkbox"/> 1 or 2-Pulse	<input type="checkbox"/> no	<input type="checkbox"/> table
Model/Type		<input type="checkbox"/> 6-Pulse	<input type="checkbox"/> yes	<input type="checkbox"/> stand
Construct. Year		<input type="checkbox"/> 12-Pulse		<input type="checkbox"/> in front of cassette
Power	kW	<input type="checkbox"/> converter, multipulse	<input type="checkbox"/> behind cassette	<input type="checkbox"/> other
		<input type="checkbox"/> condensator discharge		specify: _____
		<input type="checkbox"/> direct-current generator		

Filtration: what is the inherent filtration of the X-ray tube used for this examination?: _____ mm Al-equivalent
was additional filtration used for this exposure?

no

yes, please specify material (Cu, Mo, Fe, etc.) and thickness _____ mm Al + _____ mm _____ (e.g. 1 mmAl + 0.1 mm Cu)

II. Information on radiographic technique

kV : _____ mAs : _____

Anti-scatter grid used?: no yes

mA : _____ nominal focal spot val.: _____ mm

stationary grid

ms : _____ focus-film-dist. : _____ cm

moving grid

dose area product : _____ R cm² or Gy cm²

grid cassettes

Were radiation protection measures taken? no yes

ovarian shields

testicular capsules

others, specify

ovarian masks

testicular shields

	Film	Screen	Material of cassette front
Manufacturer			<input type="checkbox"/> aluminium
Model/Type			<input type="checkbox"/> plastic
Light emission	<input type="checkbox"/> green <input type="checkbox"/> blue	<input type="checkbox"/> green <input type="checkbox"/> blue	<input type="checkbox"/> carbon fibre
			<input type="checkbox"/> kevlar

Nominal speed class of screen film system:

Base optical density (fog) of the film:

(e.g. 0.20)

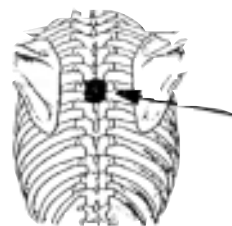
(e.g. 100, 200, 400, 600, 800, etc.)

**Diagrams for TLD-placement
for the respective examination**

accompanying instruction:
(always place the TLD on the
beam entrance side of the patient)

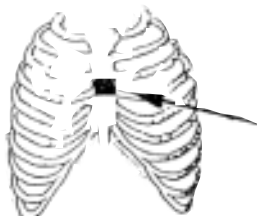
CHEST PA/AP

stationary unit
5 year old child



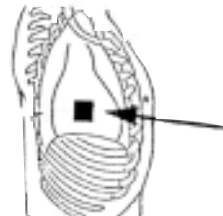
CHEST AP

mobile unit
5 year old child



CHEST Lateral

stationary unit
5 year old child



SKULL PA/AP

5 year old child



SKULL Lateral

5 year old child



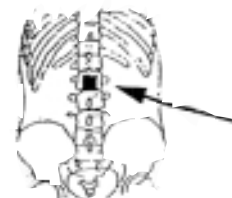
PELVIS AP

5 year old child



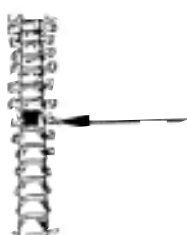
ABDOMEN PA/AP

5 year old child



THORACIC SPINE PA/AP

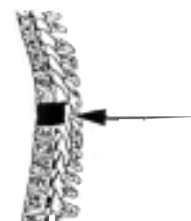
5 year old child



TLD-position = T6-T7

THORACIC SPINE Lateral

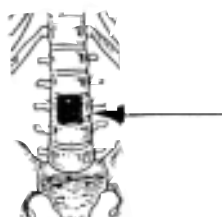
5 year old child



TLD-position = T6-T7

LUMBAR SPINE PA/AP

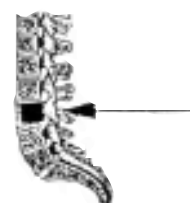
5 year old child



TLD-position = L3

LUMBAR SPINE Lateral

5 year old child



TLD-position = L3

CHAPTER 3

APPENDIX II

IMAGE QUALITY ASSESSMENT FORM

This appendix contains a sample of the image quality assessment form similar to those used by the panel of radiologists for scoring films in the Trials of the Quality Criteria discussed in Chapter 2. In the course of these Trials considerable experience was gained and many problems came to light which could have been avoided with the benefit of hindsight. A few examples are listed below which may prove useful for people attempting this audit procedure for the first time.

1. The TLDs were not always visible on the films. To confirm correct positioning it is useful to ask the radiographer who placed the TLD to indicate its position on the diagram in the questionnaire.
2. All edges of the beam must be visible on the film so that correct positioning can be checked. Sometimes the patient identification details had been removed by cutting off a complete edge of the film together with the corresponding edge of the beam. Patient details should be masked rather than cut off.
3. Numbered stickers should be supplied to indicate the order of the films taken in the IVP series, for example.
4. A processed but unexposed film is useful for assessing fog level.
5. The patient position (supine, prone, upright, etc.) is not always apparent from the film and should be indicated on the questionnaire.
6. Useful if the name of the person (and telephone or fax number) who took films and completed the questionnaire is indicated so that they can be easily contacted if details are not clear.
7. All light boxes used for viewing the films should be from the same manufacturer and of the same colour and brightness.
8. Each observer (film reader) should have their own light box and work independently of other observers.
9. Experience should be gained in observing films and filling in the assessment forms before starting on the real trial. Judgements have been seen to change during the early stages of the learning process.

The sample assessment form for **Chest PA/AP** follows on the next page. Assessment forms for other examinations are similar; the respective Image Criteria listed in Chapter 1 should then replace the Image Criteria, rows 1 to 7 on the sample scoring sheet for Chest A/AP.

An example of the individual feedback sheet used in the Trial of the 5 year old child follows the scoring sheet.

Assessment of Image Quality

CHEST PA/AP

Image criteria assessment	Film - No.									
1. Performed at peak of inspiration, except for foreign body aspiration										
2. Reproduction of the thorax a: without rotation b: and without tilting										
3. Reproduction of the chest must extend from just above the apices of the lungs to T12/L1										
4. Reproduction of the vascular pattern in central 2/3 of the lungs										
5. Reproduction of a: the trachea b: and the proximal bronchi										
6. Visually sharp reproduction of a: the diaphragm b: and costo-phrenic angles										
7. Reproduction of a: the spine b: and paraspinal structures and visualisation of c: the retrocardiac lung d: and the mediastinum										
Total score										
General assessment										
Appropriate film-blackening *										
Contrast *										
Sharpness **										
Appropriate field size **										
Correctly centred over the region of interest **										
Film acceptable for the given clinical question ***										

Name of radiologist and hospital code

Scoring

image criteria	1 = yes	0 = no	
*	+ = optimum	↑ = too much / too high	↓ = too little / too low
**	+ = optimum	↓ = sub-optimum	0 = unacceptable
***	1 = fully acceptable	2 = only acceptable under special conditions	3 = unacceptable (give reasons)

Individual Feed Back Sheet

EC-Wide TLD III Survey: ESPR Lake Starnberg Group

The graph on the right is similar to the previous feedback you had received in the past. The dose values and image quality scores measured in your department are shown as a profile in relation to the median of all the other values measured for the respective examination (the statistical ranking procedure yields values slightly below the median values for the extreme scores).

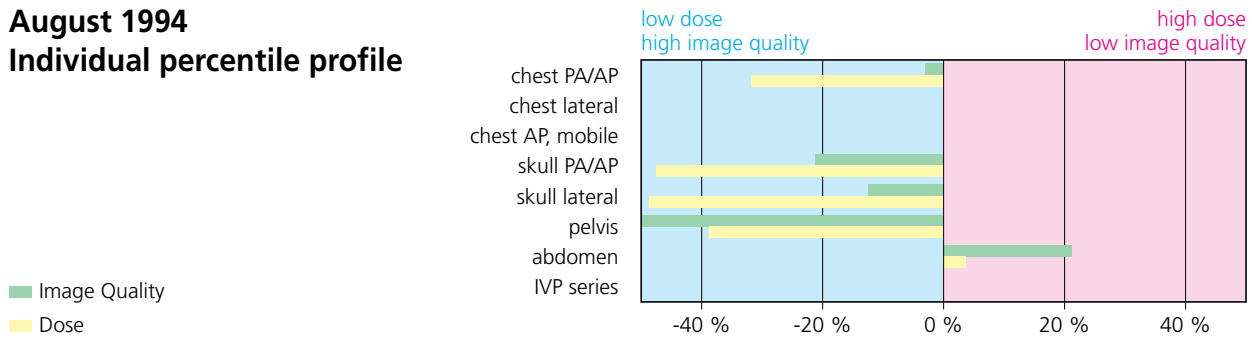
For example: A chest PA/AP dose value extremely close to 0% (e.g. 4 µGy for chest PA/AP) means that your dose value lies near to or exactly at the median of all values; a value extremely near to or at -100% (-50%) means, your value equalled the minimum (maximum) or, i.e. reached the lowest (highest) percentile of all dose measurements. The bars for image quality can be interpreted similarly. All values are indicated as deviations from the median; optimal values should be as far left as possible (minimum dose or maximum image quality). The median, minimum and maximum and your individual scores for the respective examinations are given in the Table below.

The image quality score is a very rough indicator of the image quality based on the definitions in the Document "Quality criteria for diagnostic radiographic images in paediatrics". A panel of nine paediatric

radiologists rated each film in respect to fulfilment of the criteria defined in this document and, in addition, to three general image criteria, i.e. appropriate film-blackening and field size and whether the film is acceptable for the given clinical question. For comparisons and to simplify the analysis, the score for the IVP-series is an average score for all all X-ray films during the contrast phase of the IVP; the score for the plain film alone is given under "abdomen". A score (mean score of all nine raters) of 100% means that all of the criteria were rated as fulfilled. You may find some, and in a few cases all values missing on the profile. There was then either no X-ray made for the respective examination or the dose measurements were not possible or misleading (occasionally the TLDs were placed on the beam exit side of the patient yielding a low exit dose). When patient age/weight was not within the requested range, we have still listed your dose values and image quality scores and the corresponding percentile graphs (highlighted in yellow) showing your percentiles for a data analysis where no exclusions for age and weight were made.

As we have stated at the start of the Trial, all statistics remain anonymous and the individual results are being disclosed only to you.

August 1994 Individual percentile profile



survey statistics for clinic N° C1			X-ray examination							
			chest PA/AP	chest lateral	chest AP, mobile	skull AP	skull lateral	pelvis	abdomen plain film	IVP series
DOSE	total survey	median	64	141	67	1006	713	460	518	552
		minimum	19	37	29	242	138	86	56	136
		maximum	1347	666	481	5186	3720	2785	2679	3600
	individual dose	36			242	138	134	558		
	percentile (%)	- 0.32			- 0.48	- 0.49	- 0.39	0.04		
IMAGE QUALITY	total survey	median	76.67	72.09	70.00	68.06	70.64	80.36	69.88	82.47
		minimum	37.78	35.71	8.73	11.71	8.47	33.33	16.14	46.25
		maximum	96.42	92.06	88.89	95.83	98.41	96.83	96.83	90.54
	individual image quality score	77.18			77.18	75.66	96.83	58.33		
	percentile (%)	- 0.03			- 0.21	- 0.13		- 0,21		



CHAPTER 4

LIST OF ALL THOSE WHO CONTRIBUTED TO THE ESTABLISHMENT, TESTING AND EVALUATION OF THE QUALITY CRITERIA OF THIS REPORT

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

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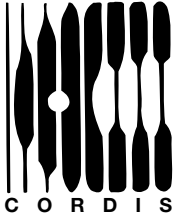
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European Commission

EUR 16261 – European Guidelines on Quality Criteria for Diagnostic Radiographic Images in Paediatrics

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Considerable efforts are made at the European Union level for introducing optimization principles in the radiation protection of the patient. Whilst radiological examinations are indispensable throughout people's lives, their justification and optimization, which provide the basis for radiation protection are even of far greater importance for children than for adults. In the younger age-group there is an impressively higher individual somatic and future genetic radiation risk due to the more sensitive organs and tissues and longer life expectancy. These facts must be taken into consideration urgently.

The anatomical features and body proportions vary due to the developmental process in infancy, childhood and adolescence. The present document on Quality Criteria for Diagnostic Radiographic Images in Paediatrics presupposes knowledge of the changing radiographic anatomy of the developing child and defines specific Quality Criteria for different age-groups (newborns, infants, five and 10 year-old children).

Particular attention must be given to adapt image quality to the particular clinical problem; image quality must be a constant preoccupation in paediatric radiology.

Therefore the Working Document on Quality Criteria for Diagnostic Radiographic Images in Paediatrics has been tested repeatedly under various conditions. The result of trials in Europe and the comments received from experts worldwide have been integrated into the present revision of the June 1992 version.

The selected x-ray examinations are: chest, skull, pelvis, full spine, segmental spine, abdomen, and urinary tract. Contrary to the quality criteria for adult patients, reference values for doses to the patient are indicated only tentatively. They should help to make the medical staff aware of the great variations in doses in day-to-day practice. The use of the Quality Criteria contributes to making the dose values more consistent since they can be linked to recommended radiographic techniques and the appropriate quality of the required diagnostic information.

In Chapter 2, a brief history is given of the development of the actuality criteria in paediatric radiology. In Chapter 3, guidelines are established for the implementation of the Quality Criteria and for their use in quality assurance audits. The achievements may stimulate the medical staff to try to do better and continue the improvement of the quality and safety situation in paediatric radiology.

The report will be published first in English, the other former eight official languages will follow soon, as their versions are already partly completed; the new languages will follow if appropriate. Number of pages 61, possible date of publication autumn 1996.

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