CODE OF SAFE PRACTICE FOR THE USE OF
X-RAYS IN MEDICAL DIAGNOSIS

National Radiation Laboratory
Ministry of Health
P O Box 25-099
Christchurch
New Zealand

January 1994

Information Centre
Ministry of Health
Wellington
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National Radiation Laboratory

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1 INTRODUCTION

1.1 This Code of Safe Practice sets out requirements and recommendations for radiation safety associated with the use of x-rays for medical diagnosis and for research on humans. The Code does not cover the use of x-rays for chiropractic, dental, podiatric or veterinary diagnosis.

1.2 Requirements from the Radiation Protection Act 1965 and the Radiation Protection Regulations 1982 are incorporated in this Code. Further requirements and recommendations are taken from source material listed in the section of References and Bibliography, or from advice received from experts in the field. Their assistance is gratefully acknowledged.

1.3 Whenever compliance with this document is required as a condition to a licence under the Radiation Protection Act 1965 for the purpose of medical diagnosis or research on humans (see paragraph 2.5), the word shall is used. The word should indicates a practice that is recommended but not mandatory. Whenever a requirement is not specified explicitly, but uses the term suitable or suitably qualified, the judgement as to whether these terms are satisfied rests with the National Radiation Laboratory (NRL).

1.4 Where a given x-ray technology or practice is not specifically covered by this Code, guidance in matters of radiation protection shall be sought from the National Radiation Laboratory.

1.5 In instances where a requirement is not complied with, but the radiation protection purpose behind the requirement may be met by alternative means, then compliance with that requirement may not be needed. The alternative means shall be assessed as being acceptable or not by the Director of the National Radiation Laboratory.

1.6 Radiation protection surveys* of the x-ray facilities of persons licensed for the use of x-rays for medical diagnosis or research on humans shall be performed by a qualified health physicist for auditing compliance with this Code. The interval between surveys should not exceed 2 years, and shall not exceed the following:

* All items in italics in this Code are defined in Annex 1.
radiography only facilities - 4 years;
fluoroscopy facilities - 2 years;
CT facilities - 2 years;
mammography facilities - 2 years.

1.7 All new facilities or facilities with new equipment shall undergo a radiation protection survey for compliance with this Code performed by a qualified health physicist as soon as possible after commissioning.

1.8 Radiation protection surveys for testing for compliance with this Code shall be performed to a protocol approved by NRL and with instruments whose suitability and calibration have been approved by NRL.

1.9 The licensee shall be responsible for ensuring that corrective action takes place as soon as practicable on items of non-compliance with this Code. Where the owner of the equipment is not the licensee, the owner shall not act to oppose this corrective action.

1.10 The owner of x-ray equipment used for medical exposures shall ensure that there is a programme for the progressive replacement of equipment whose performance has deteriorated and will soon fail to comply with the requirements of this Code.
2 PRINCIPLES AND ADMINISTRATION OF RADIATION PROTECTION

Basic radiation protection principles

2.1 Radiation protection shall be based on the three principles of justification, optimisation, and limitation (ICRP, 1991), as follows:

(a) No practice shall be adopted unless its introduction produces a positive net benefit to the exposed individuals or to society. (The justification of the practice.)

(b) In relation to a particular practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposure shall be kept as low as reasonably achievable, economic and social factors being taken into account. (The optimisation of protection.)

(c) The risk either from a dose or potential dose to a class of individuals shall not exceed the limits set for that class. (Limitation of individual dose and risk.)

New Zealand radiation protection legislation

2.2 The Radiation Protection Act 1965 and amendments, and the Radiation Protection Regulations 1982, govern the safe use of irradiating apparatus and radioactive materials in New Zealand. The Act is administered in the Ministry of Health by the National Radiation Laboratory. The Act establishes the Radiation Protection Advisory Council whose functions are to advise and make recommendations to the Director-General of Health and the Minister on matters relating to the Act and the Regulations. The term Director-General includes persons to whom his powers are delegated under the Radiation Protection Act. Irradiating apparatus is defined in the Act as any apparatus that can be used for the production of x-rays or gamma rays or for the acceleration of atomic particles in such a way that it produces a dose equivalent rate of or exceeding 2.5 microsieverts per hour at a point which could be reached by a human being.

2.3 The Radiation Protection Act 1965 does not permit any person to use irradiating apparatus for any purpose unless he or she holds a licence under the
Act for that purpose, or is acting on the instructions or under the supervision of a person holding such a licence.

2.4 This Code applies to licences granted under the Radiation Protection Act to use x-rays for the purpose of medical diagnosis or research on humans. Licences to use x-rays for medical diagnosis are granted to radiologists. Limited licences to use x-rays for medical diagnosis may be granted to medical practitioners under certain circumstances approved by the Director-General of Health (See para 2.6). A limited licence to use an x-ray bone densitometer for medical diagnosis may be granted to an appropriate medical specialist. Licences to use x-rays for research on humans are issued only to persons who qualify for a licence to use x-rays for medical diagnosis.

2.5 Licences issued under the Act may be subject to special conditions. Compliance with this Code shall be a condition on a licence to use x-rays for medical diagnosis or research on humans.

2.6 An application for a licence to use x-rays for medical diagnosis is assessed on the basis of the qualifications and experience of the applicant, taking into account the advice of the Radiation Protection Advisory Council when appropriate. General guidelines for considering applications from non-radiologist medical practitioners for a licence to use x-rays for medical diagnosis shall be:

(a) Service to a community and the management of patients in conjunction with the isolation of the community from specialist radiology services, and the likelihood and nature of potential trauma.

(b) Training in appropriate areas of radiation protection, radiographic technique, and film processing and darkroom practice.

(c) Employment of a medical radiation technologist, if available, to perform the radiography.

(d) Reporting of films by a radiologist.

A licence to a non-radiologist medical practitioner, if granted, shall be limited to specific types of radiographic examination, usually extremities only, and this limited radiography shall be performed at a specific x-ray facility only.
2.7 Whenever more than one licensee is employed in a given area, Regulation 9(3) of the Radiation Protection Regulations, 1982, requires that the owner of the irradiating apparatus either appoints one as principal licensee, or clearly defines the respective areas of responsibility of the individual licensees.

2.8 The licensee shall notify the Director-General of any case of overexposure or suspected overexposure to radiation as soon as possible after becoming aware of it.
3 PROTECTION OF RADIATION PERSONNEL, NON-RADIATION PERSONNEL AND MEMBERS OF THE PUBLIC

Introduction

3.1 Protection of radiation personnel and members of the public shall be assured by adherence to the 3 basic radiation protection principles of justification, optimisation and dose limitation (See para 2.1).

3.2 Doses for radiation personnel and members of the public shall be below their respective individual dose limits (see paras 3.4 - 3.6 below). The individual dose limits represent the boundary between unacceptable doses and doses that are tolerable. Doses should be well below these limits, and efforts shall be made to keep doses to individuals as low as reasonably achievable (ALARA), economic and social factors being taken into account.

3.3 In many circumstances it is feasible to maintain dose rates in areas occupied by radiation personnel at levels that would not lead to doses in excess of the dose limits for the public — namely 20 μSv per week summed over the period normally occupied. In accordance with ALARA (para 3.2) this should be done. There shall be an investigation of the working practice of radiation personnel receiving an effective dose in excess of 5 mSv per year, or one quarter of any of the relevant dose limits for the skin, extremities, or lens of the eye.

Individual dose limits

3.4 The individual dose limits are prescribed by the Radiation Protection Regulations 1982. At the time of this Code going to print, new draft legislation for radiation protection in New Zealand has been prepared, and includes adoption of the dose limits in the 1990 recommendations of the ICRP (ICRP 1991). These dose limits have been adopted in this Code. Doses received as a patient from medical uses of radiation (diagnosis, therapy, or research) are exempted from these dose limits. The dose limits are:
3.5 Radiation personnel

(a) An effective dose of 20 mSv per year averaged over any five year period and 50 mSv in any one year.

(b) An equivalent dose of 500 mSv to the skin (at the nominal depth of 7 mg/cm²) averaged over 1 cm², regardless of the total area exposed, in any one year.

(c) An equivalent dose of 150 mSv to the lens of either eye in any one year.

(d) An equivalent dose of 500 mSv to the hands and feet in any one year.

(e) For women who declare themselves pregnant, a dose of 2 mSv at the surface of the abdomen over the remainder of the pregnancy.

3.6 Non-radiation personnel and members of the public

(a) An effective dose of 1 mSv in any one year.

(b) An equivalent dose to the skin of 50 mSv over any 1 cm², regardless of the total area exposed, in any one year.

(c) An equivalent dose of 15 mSv to the lens of either eye in any one year.

Protection of non-radiation personnel and members of the public

3.7 Non-radiation personnel or members of the public shall not remain in the x-ray room during any x-ray procedure unless they are required to be in attendance.

3.8 The occasional use of non-radiation personnel to give assistance, particularly in ward or theatre radiography, is acceptable but shall involve the full use of protective materials and techniques to minimise personnel dose. Care shall be taken to ensure that the same non-radiation personnel are not always involved. Women who are pregnant shall not be used in this role. (See also para 3.23)
Protection of radiation personnel

3.9 Only those persons required to assist, or being in the course of training, shall be present during the performance of x-ray examinations.

3.10 Movable or adjustable protective barriers and shielded doors shall be in their closed or protective positions during the x-ray examination.

Radiography

3.11 Means shall be provided to ensure that the dose rate at the x-ray controls shall be such that occupational doses are significantly below the dose limits for radiation personnel (see paras 3.2, 3.3, 3.4 and 3.5). This will normally require a protective barrier at the x-ray controls. (See para 6.2)

3.12 A protective apron of lead equivalence not less than 0.25 mm shall be used by the operator of a mobile or portable x-ray machine. Additional leaded aprons and leaded gloves shall always be available with mobile and portable x-ray machines in case patients are required to be held in position during radiography, or other persons are required to assist in any way.

Fluoroscopy

3.13 Personnel required to be in close proximity to the patient during fluoroscopy shall as much as is reasonably achievable be protected from exposure to scattered radiation.

3.14 The fluoroscopist or any other person shall not be exposed to the unattenuated primary x-ray beam.

3.15 Fluoroscopy shall be performed only by persons who have had special training in this technique. This shall apply to both fixed fluoroscopic units and mobile image intensifiers.

3.16 Personnel not required to be in attendance shall not remain in the fluoroscopy room.

3.17 (a) The fluoroscopist or any other person who is required to remain close to the patient during the x-ray procedure shall wear a
leaded apron having a lead equivalence of not less than 0.25 mm and preferably of lead equivalence 0.5 mm.

(b) Other persons who are required to remain in the room during fluoroscopy shall wear a leaded apron having a lead equivalence not less than 0.25 mm.

3.18 Personnel required to be present in the room during fluoroscopy shall not remain any closer to the patient than is necessary.

3.19 A double sided leaded apron or coat shall be worn by personnel who may receive scattered radiation posteriorly or laterally as well as anteriorly.

3.20 The fluoroscopist shall wear a leaded glove on a hand used to palpate the patient. The glove shall have a lead equivalence of 0.5 mm.

3.21 In procedures where scattered radiation levels are high (e.g., cardiac and interventional procedures), personnel required to remain close to the patient should wear leaded glasses and thyroid shields if there is no additional protective barrier available.

Protection of persons holding patients or image receptors

3.22 No person shall hold a patient, x-ray film cassette, or other imaging equipment or x-ray tube head in position during exposures unless it is otherwise impossible to obtain a diagnostically useful image and not merely that it is a matter of convenience.

3.23 Holding of patients or x-ray film cassettes during exposures shall be done by persons accompanying the patient in preference to non-radiation personnel; and by non-radiation personnel in preference to radiation personnel. Non-radiation personnel should be chosen on the basis of a roster, i.e., it shall not always be the same person who does the holding. No pregnant women or young persons (under the age of 18) shall do any holding.

3.24 Any persons holding patients or film cassettes in position during an x-ray examination shall wear a leaded apron and wherever practicable, leaded gloves.
No part of the holder's body shall be in the primary beam, even if covered with protective clothing.

**Personnel monitoring**

3.25 Personnel that are required to work in a *controlled area* shall be continuously monitored.

3.26 Individual monitoring shall be provided by a personal monitoring service* authorised by the *Director-General*.

3.27 For persons performing general radiography (where a leaded apron is not or is only occasionally worn), or performing both fluoroscopy and radiography duties, the normal wearing position shall be on the trunk somewhere between waist level and chest level. For the times when an apron is being worn, the dosimeter shall be under the apron.

3.28 In situations where a leaded apron is always worn, the dosimeter shall be worn outside the apron at collar level as a means of assessing doses to the eyes — the likely "critical organ". The personal monitoring service shall be notified of the wearing position.

3.29 It may be preferable in some situations where scattered radiation levels are high and workloads are high, to wear two dosimeters — one under the apron and the other outside the apron. Guidance from the Director, National Radiation Laboratory, shall be sought in these situations.

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* Details on the NRL personal monitoring service are given in a booklet: Radiation monitoring film service. Christchurch: National Radiation Laboratory, 1992.
4 PROTECTION OF THE PATIENT

Justification of a practice

4.1 The justification of the use of x-rays for medical diagnosis shall take into account the merits of other available diagnostic imaging modalities relative to available x-ray based modalities, and the risks entailed in the administration of radiation. Guidance is given in the WHO technical report series 795 (World Health Organization, 1990).

4.2 X-ray examinations shall not be performed unless there are valid clinical indications. Guidelines are given in WHO technical report series 689 and 757 (World Health Organization, 1983, 1987), ICRP publication 34 (International Commission on Radiation Protection, 1982), Documents of the NRPB (National Radiological Protection Board, 1990) and in Making the best use of a department of radiology: guidelines for doctors.

4.3 Examinations on children shall require a higher level of justification, since such patients are at greater risk from radiation than are adults.

4.4 Previous x-ray images shall be readily available across departments or facilities to minimise the taking of repeat films.

4.5 Radiographs to compare the injured with the uninjured limb shall not be routine.

4.6 Screening programmes of asymptomatic persons shall not be instituted unless there is proven evidence based on sound epidemiological study that the programme is of net benefit to the screened population.

Optimisation of protection

4.7 Once radiodiagnosis is chosen as being appropriate, the particular mode of x-ray imaging, the form of the examination, and the technical factors used, shall be optimised. This means obtaining the required diagnostic information for a minimum of radiation dose to the patient.
4.8 Licensees shall be aware of the approximate patient doses associated with x-ray examinations as performed in their x-ray facilities. (See also paras 4.11 and 4.19.)

4.9 Examinations with the potential for high patient doses, such as CT examinations, should be carried out only after there has been proper clinical justification for the examination of each individual patient by a radiologist.

4.10 The need for repeating an x-ray examination due to incorrect patient positioning or equipment malfunction shall be minimised by:

(a) ensuring all radiation personnel are appropriately qualified for their work, and undertake additional training as necessary;

(b) ensuring all x-ray equipment complies at all times with the requirements of this Code;

(c) ensuring all ancillary equipment and facilities (such as x-ray cassettes and intensifying screens, x-ray film processor and darkroom, and grids) that can influence the successful outcome of an examination are part of a quality assurance programme.

4.11 The licensee in all x-ray facilities shall institute, with respect to radiation protection, a quality assurance programme appropriate to the type of x-ray facility to ensure the provision of a high quality service for minimum radiation detriment (see chapter 7). The quality assurance programme shall include periodic assessment of patient doses and these values shall be compared with the reference doses given in this Code.

Radiography

4.12 Values for those radiographic technique factors that can influence patient dose for a given exposure shall be chosen to result in the required diagnostic image quality for the minimum of radiation dose to the patient. In particular:

(a) The x-ray beam shall be collimated strictly to the region of clinical interest and in any case shall not exceed the effective cross-section of the cassette or image receptor.
(b) While the incident primary beam shall comply with para 5.8, additional filtration will result in lower patient dose and should be used where practicable.

(c) The highest kilovoltage compatible with the image quality requirements of the examination shall be selected for each projection.

(d) The fastest film-screen combination compatible with the image quality requirements of the examination shall be selected for each projection.

(e) The longest focus-to-film distance practicable within the limitations of the x-ray equipment and the x-ray room shall be used for each projection. (See also para 5.18.)

(f) Antiscatter grids shall be used only where scattered radiation is likely to degrade the image to unacceptable levels.

(g) Film processors shall be monitored as part of the quality assurance programme to ensure optimum performance, and in particular to avoid under-processing. (See para 7.3)

(h) Where the gonads lie in or very close to the primary beam, and where collimation cannot be used to avoid their irradiation, the gonads shall be shielded unless such shielding would obscure structures whose visualisation is relevant to the examination. Lead shields cut to appropriate shapes and placed on or close to the patient are preferred to the so-called "shadow-shields" placed on the light beam diaphragm. Shields shall have a lead equivalence of not less than 0.5 mm. Shielding shall not be used as an attempt to remedy inadequate collimation.

(i) With digital radiography, because there is no equivalent to film blackening acting as an upper bound to the radiation exposure, special care shall be taken to ensure that settings are used that result in the required diagnostic image quality for the minimum radiation dose to the patient. Typically this process will be limited by quantum mottle considerations.
4.13 The number of films or projections comprising a radiography examination shall be the minimum necessary to provide the required diagnostic information.

4.14 The medical radiation technologist shall observe the patient during the exposure, but in addition shall confirm that the exposure terminated properly.

**Fluoroscopy**

4.15 Values for those fluoroscopic technique factors that can influence patient dose for a given procedure shall be chosen to result in the required diagnostic image quality for the minimum of radiation dose to the patient. In particular:

(a) Screening times shall be kept to a minimum, since patient doses are directly proportional to screening time, all other factors being constant.

(b) Short-periods-of-intermittent-fluoroscopy shall be used, rather than continuous fluoroscopy.

(c) "Last image hold" facilities, where available, shall be used as a means of reducing the screening time.

(d) If pulsed fluoroscopy mode is available, and is clinically compatible with the procedure, then it shall be used in preference to continuous fluoroscopy.

(e) The x-ray beam shall be collimated strictly to the region of interest, and in any case the x-ray beam shall not exceed the actual field of view of the image intensifier as seen on the monitor (or in the mirror viewer). It is good practice to have the collimators visible during fluoroscopy. (See also paras 5.36 - 5.38, and 5.54)

(f) Antiscatter grids on the input face of the image intensifier shall be used only where scattered radiation is likely to degrade the image to unacceptable levels.

(g) As low a screening tube current (mA) as possible shall be used.
(h) During fluoroscopy being performed with a mobile image intensifier unit, or any other unit where the focus-to-skin distance can be varied, the patient shall be positioned as close to the image intensifier as possible.

(i) As large an optical iris as possible for the television camera, consistent with the image quality required, should be used.

Cinefluorography

4.16 Values for those cinefluorographic technique factors that can influence patient dose for a given procedure shall be chosen to result in the required diagnostic image quality for the minimum of radiation dose to the patient. In particular:

(a) The x-ray beam shall be collimated strictly to the region of interest, and in any case shall not exceed the field of view of the image intensifier.

(b) Cine runs of as short a duration as possible consistent with the required diagnostic needs shall be used.

(c) The lowest frame rate compatible with the clinical requirements of the procedure shall be used.

(d) The number of cine runs shall be the minimum that is compatible with obtaining the required diagnostic information.

Computed tomography

4.17 Values for those computed tomography technique factors that can influence patient dose for a given procedure shall be chosen to result in the required diagnostic image quality for the minimum of radiation dose to the patient. In particular:

(a) The number of slices shall be the minimum that is compatible with the clinical purpose.

(b) The mAs per slice shall be the minimum consistent with the required image quality.
(c) The use of pre-contrast scans in addition to post-contrast scans shall not be routine.

(d) The slice width shall be the widest consistent with the size of structure to be imaged.

(e) Couch increment shall be greater than or equal to slice width unless there are specific requirements to the contrary.

(f) Care shall be taken to minimise exposure of the eyes, particularly for patients likely to undergo multiple examinations. Angulation of the gantry should be utilised where consistent with the clinical requirements of the procedure, in order to substantially reduce doses to the lens of the eyes during examinations of the head.

Mammography

4.18 Values for those mammographic technique factors that can influence patient dose for a given procedure shall be chosen to result in the required diagnostic image quality for the minimum of radiation dose to the patient. In particular:

(a) A purpose-designed mammography unit shall be used for screen/film mammography.

(b) A screen/film system specifically designed for mammography shall be used.

(c) A film processor (including choice of processing parameters and the chemistry) optimised for mammographic images shall be used.

(d) Compression shall be used in all mammographic procedures. (See para 5.69)

(e) Exposure times should be minimised by the use of sufficiently high mA values, in order to avoid unnecessary dose increase due to reciprocity law failure.
(f) An antiscatter grid may be necessary for optimum image quality, in which case a grid shall be used. The grid shall be specifically designed for mammography, and should be a moving grid.

Reference doses

4.19 While the International Commission on Radiological Protection excludes exposures of medical patients from the system of dose limitations, it does recommend the introduction of dose constraints or investigation levels for application in common diagnostic x-ray procedures. The term reference dose is used in this Code for the dose that under normal circumstances should not be exceeded in performing an x-ray examination or projection for an average patient (which in this Code is taken to be 70 kg). The primary quantity for the reference dose is effective dose (see annex 1), with entrance surface dose (including backscatter) being a secondary quantity for discrete projections, and dose-area product a secondary quantity for x-ray examinations. The values for the reference doses have been derived from surveys of clinical practice in several countries and are linked to accepted radiographic practice and image quality (see annex 2). Doses typically used at an x-ray facility shall be compared with the reference doses and appropriate measures taken to reduce average doses to below the reference dose levels.

4.20 Based on current technology and x-ray practice the following values of reference dose have been adopted. Other or additional values may be issued by NRL from time to time as required.
(a) Reference doses for radiographic projections

<table>
<thead>
<tr>
<th>Radiograph</th>
<th>Effective dose (mSv)</th>
<th>Entrance surface dose (mGy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skull</td>
<td></td>
<td></td>
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<tr>
<td>AP</td>
<td>0.06</td>
<td>5</td>
</tr>
<tr>
<td>PA</td>
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<td>Lat</td>
<td>0.03</td>
<td>3</td>
</tr>
<tr>
<td>Chest</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PA</td>
<td>0.04</td>
<td>0.3</td>
</tr>
<tr>
<td>Lat</td>
<td>0.1</td>
<td>1.5</td>
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<tr>
<td>Thoracic spine</td>
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<td></td>
</tr>
<tr>
<td>AP</td>
<td>0.8</td>
<td>7</td>
</tr>
<tr>
<td>Lat</td>
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<td>Lumbar spine</td>
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<tr>
<td>Pelvis</td>
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</tr>
<tr>
<td>AP</td>
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(b) Reference doses for x-ray examinations

<table>
<thead>
<tr>
<th>Examination</th>
<th>Effective dose (mSv)</th>
<th>Dose-area product (Gy cm²)</th>
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<tbody>
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<td>Barium enema</td>
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<td>60</td>
</tr>
<tr>
<td>Barium meal</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>IVU</td>
<td>6</td>
<td>40</td>
</tr>
</tbody>
</table>

(c) Reference doses for CT examinations

The National Radiation Laboratory will advise on reference doses for classes of CT examination for individual CT scanners, having regard to the type of CT scanner and other local factors.

(d) Reference doses for mammography

The reference dose for a single view of a 45 mm compressed breast is an entrance surface dose of 7 mGy or a mean glandular dose of 1.5 mGy.
(e) Reference doses for paediatrics

Because of the wide variation in patient size, paediatric reference doses need to be specified for particular age groups. The following table presents reference doses (in terms of entrance surface dose, including backscatter) for a limited selection of examinations and age groups. Further reference doses will be issued by the National Radiation Laboratory as additional data become available.

<table>
<thead>
<tr>
<th>Projection</th>
<th>Age</th>
<th>Reference entrance surface dose (micrograys)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest</td>
<td>AP 1000 g, premature</td>
<td>80</td>
</tr>
<tr>
<td>Skull</td>
<td>AP/PA 10 months</td>
<td>1700</td>
</tr>
<tr>
<td>Chest</td>
<td>AP/PA 10 months</td>
<td>150</td>
</tr>
<tr>
<td>Abdomen</td>
<td>AP 10 months</td>
<td>700</td>
</tr>
<tr>
<td>Pelvis (Hip)</td>
<td>AP 4 months</td>
<td>200</td>
</tr>
</tbody>
</table>

Exposure of women of reproductive capacity

4.21 Diagnostic x-ray procedures involving the exposure of the abdomen of women likely to be pregnant shall be avoided unless there are strong clinical indications for the examination.

4.22 It should be assumed that a woman is pregnant if she has clearly missed her most recent expected menstruation or is overdue, and there is no other relevant information.

4.23 In order to minimise the possibility of unintentional exposure of the embryo/foetus there shall be notices posted at several places within the radiology facility (including in the dressing cubicles) with wording similar to, or having the same meaning as, the following:

If you think you might be pregnant notify the medical radiation technologist (radiographer), or nurse, before your x-ray examination.
4.24 Upon being so informed by a patient, the *medical radiation technologist* shall refer the matter to a radiologist who *shall* decide whether the examination is to proceed, be performed in a modified form or be postponed for further consideration.

**Protection of the embryo/foetus**

4.25 X-ray examinations performed during the course of pregnancy *shall* involve the minimum radiation dose to the foetus consistent with obtaining images of the required diagnostic quality.

4.26 The use of alternative imaging modalities, especially ultrasound for obstetric procedures, *shall* be used where appropriate. No woman *shall* undergo an x-ray examination to assess foetal development where ultrasound facilities are available.

4.27 X-ray pelvimetry *shall not* be performed on a routine basis.

4.28 Irrespective of whether plain film pelvimetry, axial scan CT pelvimetry, scan projection radiography pelvimetry or any combination of these is used, low dose techniques *shall* be used for each modality.

4.29 For examinations where the primary beam unavoidably irradiates the foetus, the methods of minimising dose (paras 4.12 - 4.17) *shall* be used as appropriate, and particular attention *shall* be given to:
- minimising the number of views
- strict beam collimation
- using higher kVps
- using fast image recording media (eg, rare earth screens)
- maximum total filtration in the useful beam; employing wedge filters for lateral views.
- where practicable using PA projections in preference to AP projections; or where it is more desirable to perform the examination AP, then at least a wide (450 mm) compression band *should* be used.

4.30 X-ray examinations performed during the course of pregnancy and not involving the abdominal or pelvic regions *shall* keep the primary x-ray beam
collimated strictly to the region of interest, and hence avoid inadvertent primary beam irradiation of the foetus. Where the primary beam angulation is such that it may incidentally irradiate the abdominal region, that region should be shielded with an apron or similar, with a lead equivalence of not less than 0.5 mm.

4.31 Where the embryo/foetus has been irradiated in the course of an x-ray examination of the mother, and the dose to the foetus may exceed 5 mSv, a qualified health physicist shall estimate the doses involved and shall advise on the ensuing radiation risks.

Protection of paediatric patients

4.32 The longer life expectancy of children results in greater potential for the manifestation of possible harmful effects of radiation. In addition children may be more radiosensitive than adults. Moreover, infants and smaller children are likely to be less cooperative than adults, breathe faster than adults and will often not stay still for the examination, thus increasing the chances of retakes. For these reasons particular attention shall be given in paediatric x-ray examinations to the selection of procedure, equipment, techniques, and patient management. In addition to the requirements made in this Code for patients in general, the following requirements for paediatric x-ray examinations shall be observed.

4.33 Procedures

(a) For a given procedure each view shall be examined, where practicable, before deciding whether to take a further view.

(b) Fluoroscopy in paediatrics shall in general be used only when radiography will not provide the information required.

(c) For girls who have reached puberty, the requirements and recommendations in this Code for x-ray examinations of women of reproductive capacity shall apply (paras 4.21 - 4.24).

(d) There shall be strong justification for x-ray procedures involving high doses, such as CT, DSA and cinefluorography. The use of
cinefluorography in paediatric radiology should be restricted to cardiac studies.

4.34 Equipment

(a) The shortest practicable exposure time shall be used in paediatric radiography.

(b) The x-ray generator shall have sufficient power and the x-ray tube sufficient rating, to allow the selection of high mA values (at least 200 mA), and hence short exposure times.

(c) Where a choice of generator exists, the one with the highest power rating shall be used.

(d) Automatic exposure control (AEC) devices, if available, shall have a fast response time (≤ 10 ms) because of the short exposure times used. The AEC detectors shall be of appropriate size and arranged in a suitable configuration for paediatric patients.

4.35 Techniques

(a) The x-ray beam shall be collimated strictly to the region of clinical interest, bearing in mind that the area of the body examined in infants can often be smaller than the available film, and that inadvertent whole body irradiation must be avoided.

(b) Clothing, gowns, bandages and nappies may produce artefacts on the film, especially with young children. In young children, all clothing should be removed from the body part to be examined whenever possible.

(c) The x-ray beam shall be collimated to exclude the gonads whenever practicable. When the gonads are in the primary beam, gonad shielding shall be used whenever its use will not obscure regions of clinical interest. Care shall be exercised in examinations of the hand/arm, with the child seated at a table, to ensure that the child is so positioned that the gonads are not inadvertently exposed to the primary beam.
(d) In general, the highest kVp **shall** be used that is consistent with the required image quality.

(e) The examination **should** be performed without a grid for small infants since the very small amount of scatter does not necessitate their use. Not using a grid will lead to substantially lower doses.

(f) Materials with low radiation absorption, such as carbon fibre materials, **should** be used in cassette fronts, the front plates of film changers, and table tops.

(g) In cinefluorography (para 4.16(c)), the frame rate selected **shall** be as low as is consistent with obtaining the required image quality.

(h) Automatic exposure control (AEC) devices **shall** be used in preference to manual settings.

### 4.36 Patient management

(a) Devices for immobilisation **shall** be used for small infants whenever practicable, since limiting the motion of the child not only decreases the likelihood of retakes but also permits the use of stricter collimation.

(b) In very young children immobilisation methods may not be successful and hence attempts **shall** be made by the medical radiation technologist and other persons involved in the procedure to establish rapport with the child before an examination is attempted. Although time consuming, such rapport is worthwhile both in decreasing radiation dose and producing a successful examination.

(c) Where persons are required to hold the child in position during an x-ray examination (see para 3.23), they **shall** be provided with and required to use adequate protective garments: apron and gloves.

### Records

**4.37** Every x-ray exposure of a patient **shall** be recorded on his/her medical record, and **should** be recorded also on an independent record of the facility's x-ray procedures.
4.38 Each record should include date, patient identification, sex, date of birth or age, whether pregnant and the type of x-ray procedure. In addition it would be preferable if additional information that would allow retrospective estimation of patient doses were recorded. Such additional data would be kVp, mAs and FFD for x-ray projections; screening time and number of films for fluoroscopic and angiographic procedures; screening and cine times for cardiac procedures; or dose-area product for any procedure.

Research on humans

General principles

4.39 It is expected that in the course of the practice of medical diagnosis new procedures will be tried in the realistic belief that the treatment of the patient will be improved as a result. This is covered by the licence for the purpose Medical Diagnosis, and the practice is constrained by the principles of radiation protection given elsewhere in this Code. For the purpose of this Code, a procedure is only classified as Research on Humans if the subject receives insufficient personal benefit from it to justify its use purely for patient management. This definition includes the use in clinical trials of diagnostic procedures which the patient would not have needed for normal management. (For brevity, Research on Humans is referred to as "Research" in the following.)

4.40 All Research shall be subject to the approval of an Ethics Committee.

4.41 All radiation exposure is deemed to carry some risk of cancer or genetic damage. A diagnostic x-ray procedure shall only be used for Research after the relative risks and benefits of the use of alternative modalities not using radiation have been weighed up.

4.42 The principle of optimisation of radiation protection (see paras 4.7 - 4.18) requires that the desired information or clinical effect be obtained for the minimum total risk to the subjects. This implies that the most efficient procedure shall be used giving the lowest effective dose, and that the subjects are chosen from the lowest possible risk groups (age, sex, state of health). The total number of subjects should be kept to the minimum required to obtain the level of statistical accuracy declared in the Research proposal. This number should be estimated at the outset from the expected statistical spread of results.
Submission of Project Proposals to NRL

4.43 Every new Project Proposal involving Research shall be submitted to the Director, NRL, before submission to the Ethics Committee. A modification of an existing Project is considered to be a "new" Project if there is any material change to the exposure of subjects to radiation.

4.44 The Project Proposal shall state clearly the risks associated with the use of radiation. It shall contain sufficient details about the procedures exposing volunteers to radiation to allow an independent estimation of the effective dose received by each, and hence the level of risk from the study. This should include details such as x-ray fields used, screening times, etc, and also the groups from which the subjects will be recruited and the expected total number.

4.45 The levels of risk have been categorised by the ICRP (ICRP Publication 62) and these are given in the Table below. The levels of benefit that should be expected from the research are also indicated. As a general guide, risks in Category IIa will probably be related to increases in knowledge leading to health benefit, Category IIb will be more directly aimed at the cure or prevention of disease, and Category III at directly saving life.

4.46 A formal ratification will be issued by NRL when it is judged that the radiation risks have been correctly estimated and described for presentation to the Ethics Committee.
Categories of risk and corresponding levels of benefit
(from ICRP Publication 62)

<table>
<thead>
<tr>
<th>Level of risk</th>
<th>Effective dose range (adults) (mSv)</th>
<th>Corresponding risk category (total risk)</th>
<th>Level of societal benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trivial</td>
<td>&lt; 0.1</td>
<td>Category I (~10^{-6} or less)</td>
<td>Minor</td>
</tr>
<tr>
<td>Minor to intermediate</td>
<td>0.1 - 1 1 - 10</td>
<td>Category II IIa (~10^{-5}) IIb (~10^{-4})</td>
<td>Intermediate to moderate</td>
</tr>
<tr>
<td>Moderate</td>
<td>&gt;10</td>
<td>Category III (~10^{-3} or-more)</td>
<td>Substantial</td>
</tr>
</tbody>
</table>

Risk assessment

4.47 The Project Proposal shall contain an estimate of the risk to each subject, including the risk to the conceptus or foetus if the subject may be pregnant, from the procedure to be used. In the case the risk is within Categories II or III this shall be estimated numerically (see below).

4.48 The risk estimate shall be obtained by first calculating effective dose, then applying the procedure given in the Table below.

Estimation of risks from effective dose

<table>
<thead>
<tr>
<th>Age</th>
<th>Risk (normal life expectancy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 20 y</td>
<td>Effective dose (Sv) x 7% x 2</td>
</tr>
<tr>
<td>20 - 65 y</td>
<td>Effective dose (Sv) x 7% x 1</td>
</tr>
<tr>
<td>&gt; 65 y</td>
<td>Effective dose (Sv) x 6% x 0.4</td>
</tr>
</tbody>
</table>

4.49 When the subjects have reduced life expectancy, as is often the case in clinical trials, because of the long latency period for many fatal cancers, the risk
is reduced accordingly. If the subjects to be used have a life expectancy of five years or less and are unlikely to have children the risk is negligible.

4.50 If there is insufficient expertise available, the estimation of risks shall be referred to the Director, National Radiation Laboratory.

Suggestions for subject information

4.51 The risk from radiation exposure may be compared to the risk from the same effective dose received from natural background radiation normally received by all New Zealanders over a specified time. In New Zealand the natural background is approximately 2 mSv per year.

4.52 When the level of risk is in Category I the risk may be described in the information sheet as "negligible" or "trivial". Strictly speaking there is only "no risk" when the subject has a very limited life expectancy and is not going to have children.

4.53 Comparison may be made with the risk from a chest x-ray. However, because the effective dose from a PA chest x-ray is only 0.05 mSv this will probably not convey the intended meaning when the risks are greater than Category I.

4.54 When the level of risk is in Category II or III, this may be described by comparison with similar risks in everyday life, or by a numerical statement such as: "The total lifetime risk of any hazard from the radiation received in this study is no greater than 5 in 10,000." The Table below gives values of typical lifetime risks of fatality from various causes in New Zealand.

**Approximate lifetime risks of fatality from various causes in New Zealand**

<table>
<thead>
<tr>
<th>Cause</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer from all causes</td>
<td>230 per 1000</td>
</tr>
<tr>
<td>Motor vehicle accidents</td>
<td>16 per 1000</td>
</tr>
<tr>
<td>Natural background radiation</td>
<td>7 per 1000</td>
</tr>
<tr>
<td>Accidental falls</td>
<td>5 per 1000</td>
</tr>
<tr>
<td>Homicide</td>
<td>2 per 1000</td>
</tr>
<tr>
<td>Drowning</td>
<td>2 per 1000</td>
</tr>
<tr>
<td>Fire</td>
<td>6 per 10,000</td>
</tr>
<tr>
<td>Accidental poisoning</td>
<td>2 per 10,000</td>
</tr>
</tbody>
</table>
5 X-RAY EQUIPMENT

Appropriate x-ray equipment

5.1 The specification, selection and acquisition of x-ray equipment shall be performed by the licensee in consultation with other radiologists, medical physicists, bio-medical engineers, senior medical radiation technologists or x-ray engineers.

5.2 The x-ray machine and ancillary apparatus shall be that most appropriate for the x-ray examination.

5.3 A special purpose x-ray machine shall be used only for the purpose for which it was designed.

5.4 X-ray machines and ancillary equipment shall be capable of the performance specified in Annex 2 as good practice for relevant techniques.

5.5 Wherever practicable and the patient's condition permitting, radiography shall be performed with fixed x-ray equipment in the x-ray department itself rather than with mobile x-ray equipment on the ward.

5.6 In general, capacitor discharge x-ray machines shall be used for radiography of babies and of chests and extremities of adults only. They shall not be used for radiography of spines or for heavy abdominal exposures. (See also para 5.79)

5.7 No x-ray equipment shall be used where the x-ray output is so low that multiple exposures are required in an attempt to obtain the required diagnostic information.

X-ray machine requirements

Filtration

5.8 The total filtration in the incident primary x-ray beam for all x-ray procedures except mammography shall not be less than 2.5 mm aluminium
equivalence. For mammography see para 5.67. (See also para 4.12(b) on the use of additional filtration).

5.9 Any filters which may be added as required to the primary x-ray beam in addition to the minimum amount of 2.5 mm aluminium should where practicable be permanently labelled in such a manner that the labels may be read when the filter is in the primary x-ray beam. The labels shall state the material of which the filter is composed and its thickness.

5.10 Rare-earth or other special filters may be used in some circumstances. These should be approved by a qualified health physicist.

Leakage radiation

5.11 Every x-ray tube used for diagnostic purposes shall be enclosed in a housing such that the dose to air from the leakage radiation at a distance of 1 m from the focus shall not exceed 1 mGy, and should not exceed 100 μGy, in an hour at every rating specified by the manufacturer for that tube in that housing. Diaphragms, cones and other collimating devices shall be so constructed that, in combination with the x-ray tube housing, the whole assembly (ie, the x-ray tube assembly) conforms with this criterion.

5.12 Compliance shall be determined by measurements averaged over an area of 100 cm² with no linear dimension greater than 20 cm. The significance of narrow leakage beams shall, however, be investigated.

Radiography

X-ray beam limitation

5.13 A device shall be installed on the x-ray tube assembly so that the primary beam may be collimated to the desired cross-section.

5.14 The x-ray cassette shall completely intercept the primary beam.

5.15 A light beam diaphragm shall be used wherever it is practicable. Where it may be inappropriate to use a light beam diaphragm (such as in skull radiography), a fixed or adjustable diaphragm shall be used.
Light beam diaphragms

5.16 Light beam diaphragms (LBDs) shall have the following features:

(a) **Accuracy:** The misalignment of each edge of the visually defined light field with the respective edge of the x-ray field should not exceed 1%, and shall not exceed 1.5%, of the distance from the focus to the centre of the visually defined field when the surface on which it appears is perpendicular to the central axis of the useful x-ray beam.

(b) **Delineation:** The visually defined field (light field) should contain cross wires or other acceptable mode of indicating the centre of the x-ray beam. The centre of the x-ray beam and indicated centre of the light beam should coincide to an accuracy of within 1% and shall coincide to an accuracy of within 1.5% of the distance from the focus to the point on the illuminated surface at which it appears.

(c) **Illumination:** The brightness of the light field shall be sufficiently great that the light field is clearly visible in ambient illumination. The outer edges of the light field shall be clearly shown and sharply defined.

Fixed or adjustable diaphragms

5.17 Fixed or adjustable diaphragms shall have the following features:

(a) The device shall provide an x-ray beam of either a rectangular cross-section congruent with that of the x-ray film being used, or a circular cross-section that inscribes the x-ray film being used.

(b) There shall be affixed to the collimating device a notice stating the x-ray beam dimensions at each focus-film distance for which it is used.

(c) The misalignment of the edges of the x-ray field with the image receptor shall not exceed two percent of the distance from the focus to the image receptor.

(d) There should be some indicator of the central axis of the x-ray beam.
Focus-skin and focus-film distance

5.18 The focus-skin distance (FSD) shall not be less than 400 mm and should not be less than 500 mm.

Exceptions: Those techniques which specifically require short FSD (and angulation) to demonstrate spacing in joints, etc, and some magnification techniques.

5.19 For the majority of x-ray procedures the standard focus-film distance (FFD) shall not be less than 1 metre. Chest radiography should not use an FFD less than 1.5 metres. (See also Annex 2)

5.20 On fixed x-ray equipment, for all orientations, means shall be provided to indicate distances from the focus to the film. The FFD so indicated shall be accurate to ± 10 mm. On mobile and portable x-ray equipment a retractable tape measure shall be mounted on the x-ray tube head assembly so that the distance from the focus to the end of the extended tape is indicated to an accuracy within ± 10 mm.

X-ray exposure device

5.21 A device shall be incorporated in the x-ray equipment to terminate radiographic exposures after the elapse of a preset time (timer), preset exposure to an imaging device (automatic exposure control), or preset mAs.

5.22 Except in special techniques where a sequence of repeated exposures is required, it shall not be possible to make repeat exposures without release of the exposure-initiating control.

5.23 It shall not be possible to make exposures when the exposure device is set to zero, "0", or "off", or equivalent positions if these are provided.

5.24 To prevent accidental exposures, operation of the exposure device shall require continuous firm pressure on the exposure control throughout the exposure. Premature release of this pressure shall cause the x-ray exposure to terminate immediately.
5.25 The exposure device shall determine the exposure accurately and reproducibly. (See para 5.26 for x-ray timers, and paras 5.30 and 5.31 for automatic exposure control devices.)

5.26 Where the exposure device determines the exposure time, the actual time should not differ from the set time by more than 10% when the set time is 0.2 seconds or greater; and successive exposures should not differ by more than 10%.

5.27 A timer shall be capable of short exposure times. Single phase x-ray machines shall be capable of exposure times of 20 milliseconds, and multi-phase x-ray machines shall be capable of exposure times of less than 20 milliseconds.

Automatic exposure control (AEC) device

5.28 The minimum response time of the AEC device with the appropriate chamber selected for the x-ray projection shall be less than 20 milliseconds for single phase x-ray machines, and less than 10 milliseconds for multi-phase, medium and high frequency x-ray machines.

5.29 A device shall be installed which can be set to terminate the exposure after a time no greater than 6 seconds, or after an exposure of no more than 600 mAs, whichever is the lesser.

5.30 The AEC device shall so control exposures that films are produced whose optical density varies by less than ± 20% when the patient thickness, kVp, mA station, and field size, are varied over their normal clinical ranges for which the x-ray machine is used.

5.31 The AEC device during a series of exposures made at the same settings and with the same absorber in the primary beam shall so control exposures that either the variation in film optical density is no more than ± 0.1 at a density around 1.2, or the variation in radiation output measured after the absorber is no more than ± 5%.
Fluoroscopy

5.32  Image intensification shall always be used. Direct viewing fluoroscopes are not permitted.

5.33  The x-ray tube assembly and fluoroscopic imaging assembly shall be ganged together such that there can be no lateral movement of the one with respect to the other. Where the ganging is disconnected it shall no longer be possible to perform fluoroscopy.

Collimation

5.34  Either: An adjustable collimator such as a lead shutter diaphragm shall be provided to define the primary x-ray beam,

Or: A fixed diaphragm shall be provided to ensure that the cross-section of the primary beam at the image intensifier input plane is within the image intensifier, provided that the diameter of the image intensifier is equal to or less than 150 mm and the focus-to-intensifier distance is fixed.

5.35  During spot film radiography the x-ray field should automatically cone to the size of the film, and should automatically return to the size of the image intensifier input face when radiography is completed.

5.36  The equipment should be such that it is not possible to operate the x-ray machine in the fluoroscopy mode with the primary beam cross-section as for the radiography mode.

5.37  Multiple-field image intensifiers should be provided with automatic collimators to ensure that the area of the x-ray beam does not exceed the selected input area of the intensifier during fluoroscopy.

5.38  On a mobile image intensifier the equipment shall be such that it is not possible to operate the x-ray machine in the fluoroscopy mode with the primary beam cross-section as for the radiography mode.
Focus-skin distance

5.39 The focus-skin distance shall not be less than 350 mm and should not be less than 450 mm.

X-ray exposure device

5.40 The fluoroscopy exposure switch shall require continuous pressure to produce x-rays. Release of this pressure shall immediately stop x-rays being produced. The fluoroscopy exposure switch shall be clearly identified and shall be located so that it can be controlled by the fluoroscopist and should be protected against accidental operation.

5.41 (a) A cumulative timing device activated by the control circuit for fluoroscopy shall be provided to display elapsed time in seconds or minutes.

(b) The fluoroscopy timing device shall give a characteristic audible signal at the end of a predetermined time interval not longer than 10 min. The audible signal shall continue until the timer is reset. Or, alternatively, the cumulative timing device may terminate the irradiation when the total exposure time of fluoroscopy exceeds the predetermined time interval. In this case, instead of the characteristic signal at the end of the predetermined time interval, a characteristic continuous and audible signal shall be given at least 30 s before the end of the time interval in order to permit the device to be reset if necessary.

Entrance dose rates

5.42 The entrance surface dose rate to air measured free-in-air in the central axis of the x-ray beam at the position of the patient's skin shall not exceed 50 mGy per minute for any field size of the image intensifier. Means shall be employed to prevent the screening output from exceeding this dose rate for normal use. However, dose rates greater than 50 mGy per minute shall be permitted for special modes of operation provided that:

(a) There shall be a special control to activate and de-activate the high dose rate mode.
(b) The special control shall be clearly labelled as a "high dose rate control", or equivalent statement.

(c) The entrance surface dose rate to air measured free-in-air in the central axis of the x-ray beam at the position of the patient's skin shall not exceed 100 mGy per minute for any field size of the image intensifier.

(d) The high dose rate mode shall be de-activated if the x-ray machine is turned off while the high dose rate mode is still selected.

Image intensifier performance

5.43 The performance requirements for image intensifier systems are greater for units being used for cardiac or angiographic procedures than for units being used for general fluoroscopy. While the following requirements are for all fluoroscopy systems, it would be expected that image intensifiers being used for cardiac or angiographic procedures would have performance greatly exceeding these baseline requirements.

5.44 Wherever practicable, the conversion factor of an image intensifier should be measured at installation. (This measurement may be made with the optics in place.) The image intensifier should be replaced if the conversion factor drops to less than one third of the initial value.

5.45 For systems with automatic brightness control (ABC), the input dose rate to air at the image intensifier input face shall not exceed

- 120 μGy per min for 11 to < 14 cm field size
- 90 μGy per min for 14 to < 23 cm field size
- 60 μGy per min for ≥ 23 cm field size

This measurement shall be made with 2.5 mm Cu added to the x-ray beam and at approximately 90 kVp.

5.46 For manually controlled systems, the dose rates in para 5.45 shall not be exceeded for the normal clinical settings when used with average patients. (2.5 mm Cu may be used to simulate the patient when making this measurement.)
5.47 The fluoroscopy image contrast measured at 70 kVp, 1 mm added copper filtration shall not be worse than 5.0% for a 10 mm diameter detail, and 15.0% for a 1.0 mm diameter detail, at the maximum dose rate permitted in para 5.45. (These correspond to visualisation of at least 6 discs for NRL LC test object, and the fourth disc of the inner-most arc of the fine details (H4) for NRL CD test object. See Poletti and Le Heron, 1987.)

5.48 All components of the optical system (lenses and mirrors) shall be kept clean and in good condition (particularly multi-coatings on lenses).

5.49 The field size viewed on the TV monitor should not differ from the nominal field size by more than 10 mm.

Other requirements

5.50 Where practicable, protective materials shall be affixed to the x-ray equipment or otherwise installed in such a way as to be interposed between sources of scattered radiation and x-ray personnel. These materials shall have a lead equivalence of not less than 0.5 mm over the fluoroscopy range of kilovoltages. Protective materials shall be effective in any position of the image intensifier assembly. They shall not obstruct palpation or other necessary manipulation of the patient. For remote control fluoroscopy systems, a protective barrier shall be provided for the fluoroscopist. This barrier shall provide protection so that the radiation levels at the position of the fluoroscopist are as low as is reasonably achievable, social and economic considerations being taken into account, and in any case these levels shall not lead to exposures of persons to doses in excess of the dose limits for radiation personnel (see para 3.5).

5.51 The side of the x-ray couch nearer the fluoroscopist including the bucky slot should be closed or otherwise shielded to protect the legs and feet of the fluoroscopist. Where the couch is open-sided or lightly covered, a shielded enclosure should extend from the undercouch x-ray tube and collimating device to the underside of the panel of the x-ray couch.

5.52 The fluoroscopy assembly shall have as an integral part a primary barrier of lead equivalence of 2.0 mm. Components of the fluoroscopic imaging assembly may form part of this barrier.
5.53 The central axis of the primary beam shall pass through the geometric centre of the input face of the image intensifier.

5.54 Where an x-ray beam collimating device (eg, shutter diaphragm system) is present to give variable x-ray beams then at all focus-table top and image intensifier-table top distances the primary barrier shall completely intercept the primary beam for all openings of the collimating device. Where a fixed diaphragm is used with a fixed focus to image intensifier distance, as in mobile image intensifier x-ray machines, the cross-section of the x-ray beam shall match the cross-section of the image intensifier at the input plane of the image intensifier.

Digital subtraction imaging systems

5.55 An image intensifier used for digital subtraction imaging (DSI) shall comply with the requirements in paras 5.43 to 5.49 for image intensifiers. In addition, the limiting resolution of the intensifier should be better than 4 mm\(^{-1}\) at the 10% level of the modulation transfer function.

5.56 The dose per frame measured at the image intensifier input face for DSI images shall set to a value appropriate to the type of equipment, as determined by a qualified health physicist. Guideline values for typical systems are up to 10 µGy per frame for slow (less than 10 frames per second) frame acquisition rates and up to 1 µGy per frame for high (greater than 10 frames per second) frame acquisition rates. The dose per frame shall be measured at least annually and should be checked three-monthly.

5.57 The requirements for collimation and focus-skin distance for fluoroscopy shall also apply to DSI (see paras 5.34 and 5.39).

Cinefluorography systems

5.58 An image intensifier used for cinefluorography shall comply with the requirements for image intensifiers in paras 5.43 to 5.49.

5.59 The maximum dose per frame at the image intensifier input face for intensifier field sizes greater than 17 cm should not exceed 0.1 µGy per frame
and shall not exceed 0.2 μGy per frame. The maximum dose per frame at the image intensifier input face for intensifier field sizes less than 17 cm should not exceed 0.2 μGy per frame and shall not exceed 0.4 μGy per frame.

5.60 The cine projector shall be kept clean and in good condition.

Computed tomography

5.61 The Computed Tomography Dose Index (CTDI) shall be measured in air at the iso-centre of the CT scanner by a qualified health physicist, at the time of installation. This measurement shall be repeated annually and following any major servicing which is likely to have affected the x-ray dose.

5.62 The CT number of air determined by the CT scanner shall be as near to -1000 as possible, preferably -1000 ± 10. The CT number of water determined by the scanner shall be 0.0 ± 4.

5.63 The CT number of water and the noise (standard deviation of CT numbers of a uniform phantom in a region of interest) shall be checked weekly.

5.64 The full-width-half-maximum (FWHM) of the sensitivity profile shall be within 1 mm of the FWHM of the dose profile, as determined at the iso-centre using an aluminium ramp of less than 1.0 mm thickness. Post-patient collimation should not be used to reduce the sensitivity profile width without corresponding pre-patient collimation of the dose profile.

5.65 CT scanners should be upgraded or replaced when the number of retakes due to machine faults or breakdowns during a slice or scan series exceeds levels considered acceptable by the licensee or a qualified health physicist. To this end, a log of all scans and all breakdowns that result in repeat irradiations should be kept.

Mammography

5.66 Mammography x-ray machines shall be purpose designed dedicated x-ray machines. The anode material shall be molybdenum. (Other materials may be approved by the Director NRL — see para 1.4.)
5.67 The minimum filtration for mammography machines shall be 0.03 mm Mo for Mo tubes. The actual filtration shall be as close to this lower limit as reasonably achievable, such that the half value layer measures between 0.3 and 0.37 mm Al at 28 kVp, with the compression paddle in the beam.

5.68 The kVp shall be able to be set at least as low as 24 kV and shall be adjustable in 1 kV increments. The true kV shall not differ from the set kV by more than 1 kV.

5.69 A mechanical compression device shall be fitted. The compression device shall be capable of applying a force of 160 newtons but not more than 200 newtons. It shall be possible to release the compression force quickly. The paddle shall be flat with minimal chest wall radius and shall remain parallel to the breast support at maximum compression force.

5.70 The nominal focal spot size shall not be greater than 0.6 mm for contact mammograms and 0.15 mm for magnification mammograms. The measured focal spot sizes determined by the slit camera method shall be within the tolerances specified in IEC 336 Table 5 (see Annex 4).

5.71 The general requirements for radiography in paras 5.13 to 5.31 shall be met.

5.72 The automatic exposure control device shall meet the requirements in paras 5.28 to 5.31.

5.73 The x-ray film and the intensifying screens shall be specially designed for mammography.

5.74 Film illuminators shall meet the requirements in Annex 2 (see Image viewing conditions).

Radiation from components other than the x-ray tube assembly

5.75 The radiation emitted from any component other than the x-ray tube assembly and which is an integral part of the x-ray machine shall not exceed a dose rate of 2.5 μGy per hour at any accessible position.
Special requirements for capacitor discharge x-ray equipment

5.76 Capacitor discharge x-ray equipment shall be fitted with electrically interlocked shutters to prevent emission of radiation before exposure and after termination of the exposure.

5.77 (a) Provision shall be made for preventing initiation of an exposure during the initial charging of the capacitor to the required potential.

(b) Capacitor discharge equipment should be provided with an automatic recharge facility for maintaining the kVp at the selected value after the initial charging. The automatic recharge facility should operate automatically when the potential difference drops below the preset value by more than 3 percent. It shall be possible to initiate the exposure during the automatic re-charge procedure.

5.78 The high voltage capacitor shall be provided with means for the discharging and short-circuiting of the plates whenever the transformer is disconnected from the supply. A control switch shall be provided to allow manual discharge of the capacitor plates when the x-ray equipment is connected to the mains supply. Capacitor discharge equipment shall have provision for discharging the capacitor by energising the x-ray tube with its shutters positioned so as to prevent emission of x-radiation from the x-ray tube enclosure.

5.79 Means shall be provided to prevent the selection of milliampere seconds (mAs) that will result in a kilovoltage value at the end of the exposure of less than 70 percent of the initial kilovoltage. The lowest terminating kilovoltage shall not be less than 45 kV.

5.80 Leakage radiation from the x-ray tube housing assembly when the exposure device is not activated shall not exceed 20 μGy in one hour at 50 mm from any accessible surface of the x-ray tube assembly with the x-ray beam collimating device fully open and with the maximum voltage on the capacitors.
Warning lights at the x-ray controls

5.81 There shall be a prominent light on the x-ray control panel which is illuminated when the x-ray machine is switched on to the electrical mains. Alternatively the meters, indicators, etc, of the x-ray control panel may generally become illuminated when the electrical mains are switched on to the x-ray machine.

5.82 There should be a prominent light on the x-ray control panel which is illuminated when the x-ray exposure is in "preparation" mode and another which shall be illuminated during the period when x-rays are being produced.

5.83 Where there is more than one x-ray tube connected to the generator the tube selector switch at the x-ray control panel shall be clearly and unambiguously labelled and the x-ray tube presently connected shall be indicated by an illuminated sign close to the selector switch or by other clear and unmistakable means.

Warning lights at the x-ray tube

5.84 When more than one patient may be examined at the same time in the same room or in adjacent rooms using more than one x-ray tube connected to the same generator, each tube shall have a prominent warning light which becomes illuminated when that tube is connected to the generator. The light shall indicate that an exposure is likely to be made, or is being made. The warning light should be red.

X-ray tube assemblies

5.85 X-ray tube assemblies should bear the following markings on the outer side of the tube housing in a visible position:

(a) Name or trademark of the supplier and the assembler.

(b) Type number and serial number of x-ray tube insert.

(c) Maximum potential difference of x-ray tube assembly.
(d) Nominal value of the inherent filtration and added filtration of the original tube assembly expressed in thickness of aluminium equivalence.

(e) Size of nominal focal spot(s).

(f) Position of focal spot(s).

Exceptions:

(a) For a double focus x-ray tube, a single indication of mean position of the focal spots is permissible.

(b) Where the type number or the serial number of the tube assembly incorporates in a clear manner any part of the information required in items (c), (d), or (e) above, it is not necessary for this information to be repeated separately on the tube assembly.

Darkroom

5.86 Darkroom fog shall be minimised. In particular, the density increase of the mid-density portion of the film (OD = 1.2 to 1.6) shall not be greater than 0.05, for the fastest film used in the facility, after an exposure on the workbench to the safelights of 1 minute duration.

Efficient performance of x-ray machines

5.87 X-ray equipment shall perform properly and consistently.

5.88 X-ray equipment should be maintained in radiographic calibration such that examinations performed on one machine are capable of reproduction on another of similar characteristics, at the same or closely similar settings.

5.89 Any assessments of the performance of x-ray machines in respect of efficient performance should be made with the x-ray machine connected to an electrical power supply as specified by the manufacturer for that machine. Electrical line volts, during the assessment tests, shall be properly adjusted to the indicated value where such adjustment is available to the operator.
5.90 Any set of measurements assessing one of the factors below should be made within one hour. Measurements shall be made at least at those kV, mA, mAs, and time settings likely to be used on that machine.

Reproducibility of x-ray output

5.91 The x-ray output, as assessed by the coefficient of variation of a series of not less than 5 consecutive exposures at the same settings, shall be reproducible. The coefficient of variation of the x-ray output shall not exceed 0.10 and should not exceed 0.05. Between each exposure the x-ray machine settings should be shifted significantly away from, and then returned to, those being used.

Linearity of x-ray output

5.92 Where a choice of x-ray tube current settings is available the linearity of the output of the x-ray machine with nominal x-ray tube current shall be assessed in terms of the following relationship between any pair of x-ray tube current settings where the larger mA setting is no more than 4 times the smaller mA setting.

\[
\frac{|X_1 - X_2|}{X_1 + X_2}
\]

shall not exceed 0.1.

5.93 Where a choice of mAs settings is available the linearity of the output of the x-ray machine shall be assessed in terms of the following relationship between two mAs settings that do not differ by more than a factor of 4.

If \( X_1 \) = the average x-ray output expressed in terms of dose to air per mAs at mAs setting 1, and

\( X_2 = \) the average x-ray output expressed in terms of dose to air per mAs at mAs setting 2, then

\[
\frac{|X_1 - X_2|}{X_1 + X_2}
\]

shall not exceed 0.1.

43
\[ X_2 = \text{the average x-ray output expressed in terms of dose to air per mAs at mAs setting 2, then} \]
\[
\frac{|X_1 - X_2|}{X_1 + X_2} \]

shall not exceed 0.1.

5.94 Where a choice of time settings is available the linearity of the output of the x-ray machine shall be assessed in terms of the following relationship between two exposure time settings that do not differ by more than a factor of 4.

If \( X_1 \) = the average x-ray output expressed in terms of dose to air per mAs at time setting 1, and

\( X_2 \) = the average x-ray output expressed in terms of dose to air per mAs at time setting 2, then

\[
\frac{|X_1 - X_2|}{X_1 + X_2} \]

shall not exceed 0.1.

Accuracy of kilovoltage settings

5.95 The deviations, whether positive or negative, of actual peak kilovoltages from indicated or preset peak kilovoltage settings during exposure shall not exceed 5% of the indicated or preset value over the range of kV, time, current, and mAs settings for which the x-ray machine is normally used.
6  X-RAY ROOMS AND AUXILIARY PROTECTION REQUIREMENTS

Introduction

6.1 The walls, floors, ceilings and other material constructions of the x-ray room shall have a protective value such that the radiation transmitted through them will not lead to exposures of persons to levels in excess of the requirements for non-radiation personnel and members of the public (see para 3.6). In recognition that it should not be assumed that proximity to an x-ray facility is going to be the only source of radiation exposure to a member of the public, the levels of radiation in areas of public access outside x-ray rooms should not lead to doses in excess of 0.3 mSv to any member of the public in any one year.

6.2 The operator position at the x-ray controls shall be so shielded and located that the radiation levels there are as low as is reasonably achievable, social and economic considerations being taken into account, and in any case these levels shall not lead to exposures of persons to levels in excess of the requirements for radiation personnel (see para 3.5).

6.3 If a mobile x-ray machine is used permanently in one location then the room it is in shall be shielded according to paras 6.1 and 6.2 above.

6.4 Wherever practicable the protective barrier and x-ray controls shall be located so that they are not exposed to the primary x-ray beam for any of its normal orientations. If the barrier or controls are exposed to the primary beam then the shielding shall be individually specified by a qualified health physicist.

Standard barriers

Primary x-ray barriers

6.5 All primary barriers in standard diagnostic x-ray facilities shall have a lead equivalence of 2.0 mm with an allowable tolerance of ± 10%.

6.6 The primary barrier shall extend at least 300 mm beyond each boundary of the area normally exposed to the primary x-ray beam.
The colours of the "trefoil" sign may be black on a yellow ground or magenta on a yellow ground. The relative dimensions of wording and "trefoil" sign may be varied. The "trefoil" sign should have a diameter not less than 200 mm. The wording may be varied to suit each individual situation.

Protective equipment in x-ray rooms

6.21 All x-ray rooms shall be provided with sufficient protective aprons and gloves suitable for the purposes for which the room is intended.

6.22 The aprons and gloves shall be checked at least annually by the licensee for basic integrity of the radiation shielding.

6.23 The aprons and gloves shall be clearly labelled with their lead equivalence.

6.24 In situations where levels of scattered radiation are high, the use of leaded glasses and thyroid shields should be encouraged by making these available.
7 QUALITY ASSURANCE PROGRAMME

General requirements

7.1 The principal licensee for any facility that uses x-rays for medical diagnosis or research on humans shall ensure that a suitable programme of quality assurance (with respect to radiation protection), is instituted and maintained (see para 4.11). This specific quality assurance programme is referred to as the programme, hereafter.

7.2 The programme shall ensure as a primary goal, accurate and timely diagnosis. As secondary goals the programme shall ensure minimisation of radiation exposure and risk and of discomfort and cost to patient and community. These secondary goals shall always be balanced against the primary goal.

7.3 The programme shall comprise such routine checks and procedures as are required to give reasonable confidence in the continuing compliance with this Code of Practice. The programme shall be approved by a qualified health physicist, to ensure that the quality control procedures are sufficient to ensure compliance with this Code. The programme shall include quality control of x-ray film processing facilities (manual or automatic). Note: A programme is not to be confused with a radiation protection survey (see Paras 1.6 - 1.8 and Annex 1).

7.4 There shall be a well defined responsibility and reporting structure, appropriate to the size and scope of the facility. Each staff member shall routinely review the results of checks for which they are responsible and report summary results to their superior. Any anomalous check shall be reported immediately. Each staff member shall be responsible for the maintenance of the programme by any personnel under his/her control.

7.5 Procedures should be standardised and set down in protocols or local rules (a quality assurance manual) wherever possible.

7.6 All equipment shall be checked at suitable regular intervals to ensure it is operating within suitable tolerances of accuracy and consistency. The tests performed and their frequency shall be approved by a qualified health physicist. All measurements and maintenance shall be recorded in an equipment log. As
well as routine tests any faults or breakdowns shall be logged and reported to superiors.

7.7 Acceptance tests shall be performed on all new equipment to

(a) ensure that it meets the manufacturer's specifications;

(b) ensure that it complies with this Code;

(c) establish baseline data for subsequent quality assurance.

7.8 Control charts shall be established for all parameters measured. Control limits shall be established for all parameters. If a measured value of any parameter exceeds a control limit, action shall be taken to correct the parameter.

7.9 A retake analysis shall be performed at regular intervals to monitor the effectiveness of the programme.

7.10 The frequency with which a particular parameter is tested should be determined by both the likelihood and the consequences of an error beyond the acceptable tolerances.

7.11 The programme should conform to the procedures and tolerances given in NCRP report 99 (National Council on Radiation Protection and Measurements, 1988) or Assurance of quality in the diagnostic x-ray department.

7.12 The programme for CT facilities should include the recommendations given in IEC 1223-2-6.
REFERENCES AND BIBLIOGRAPHY


ANNEX 1  DEFINITION OF TERMS AND GLOSSARY

The meanings for the following terms are in the context of this Code.

*ALARA*. An acronym for the *optimisation* principle — As low as reasonably achievable, social and economic factors being taken into account.

*Computed tomography dose index (CTDI)*. A dose descriptor for CT. It is defined as the integral along the axial direction of a single slice dose profile, \( D(z) \), divided by the nominal slice width.

*Controlled area*. A region defined by the licensee, described by either

- (a) specifying part or all of a room, or rooms, or
- (b) rules to define a region

and, either

- (c) specifying a time period or time periods, or
- (d) rules to define time period(s)

where irradiating apparatus is used, in which established procedures are required to control radiation exposure.

X-ray rooms, and other rooms where x-ray procedures are performed, would be considered controlled areas when in use or about to be in use.

*Conversion factor*. The x-ray-to-light conversion efficiency of an image intensifier is often measured by its conversion factor, where

\[
\text{conversion factor} = \frac{\text{luminance of output phosphor (cd m}^{-2})}{\text{input dose rate (mGy s}^{-1})}\n\]

*Director-General*. The Director-General of Health under the Health Act 1956; and includes any person to whom his/her powers are delegated under the Radiation Protection Act and Regulations. For the purpose of this Code the Director, NRL, has the delegated authority of the Director-General of Health.
**Dose-area product.** The dose-area product is the absorbed dose to air averaged over the area of the x-ray beam in a plane perpendicular to the beam axis, multiplied by the area of the beam in the same plane.

**Effective dose.** The effective dose, E, is the sum of the weighted equivalent doses in all the tissues and organs of the body. It represents the uniform whole body dose that would have the same radiation detriment as the actual dose distribution arising from a given irradiation.

**Entrance surface dose (ESD).** The entrance surface dose is the absorbed dose to air at the point of intersection of the x-ray beam axis with the entrance surface of the patient, including backscatter.

**Equivalent dose.** The equivalent dose in tissue T, H_T, is the absorbed dose averaged over that tissue or organ and weighted for the radiation quality of interest. (For diagnostic radiation, the radiation weighted factor for x-rays equals one.)

**Full-width-half-maximum (FWHM).** The width of a pulse at half of its height.

**International Commission on Radiological Protection (ICRP).** Internationally recognised body established to make recommendations on matters of radiation protection.

**Irradiating apparatus.** A term used in the New Zealand Radiation Protection legislation and this Code to mean any apparatus that can be used for the production of x-rays or gamma rays or for the acceleration of atomic particles in such a way that it produces a dose equivalent rate of or exceeding 2.5 microsieverts per hour at a point which could be reached by a living human being.

**Justification.** The justification of a practice is a fundamental principle of the ICRP radiation protection system. No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes.

**Limitation.** A principle of the ICRP approach to radiation protection where a limit is placed on doses and risks that may be received by persons from ionizing radiation. Doses or risks over these limits are not acceptable.
Medical radiation technologist (MRT). A person who has undergone a recognised course of training of duration of several years, including requisite experience, and is registered or certificated to perform radiography occupationally. Previously known as radiographers.

Non-radiation personnel. Any person who is employed at an x-ray facility but whose work does not directly and centrally involve the use of x-rays.

Optimisation. The optimisation of protection is a fundamental principle of the ICRP radiation protection system. In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account.

Overexposure. An overexposure for a patient refers to a situation where the patient receives a radiation dose substantially greater than intended. It does not include the usual small percentage of repeats of projections normally encountered in a radiology facility, but does include situations such as failure of the exposure to terminate correctly. An overexposure for radiation personnel means an exposure to radiation that exceeds the dose limits given in Para 3.5, or exceeds one-tenth of the limits given in Para 3.5 during a period of one month, or exceeds three-tenths of the same limits during a period of three months. An overexposure for non-radiation personnel and members of the public means an exposure to radiation that exceeds the dose limits given in Para 3.6, or exceeds one-tenth of the limits given in Para 3.6 during a period of one month, or exceeds three-tenths of the same limits during a period of three months.

Primary barrier. A barrier sufficient to attenuate the primary x-ray beam to the required level.

Programme. A quality assurance programme in radiation protection which, in addition to its main goals of adequate diagnosis for minimum dose, provides reasonable confidence in an x-ray facility complying with NRL C5 at any time.

Qualified health physicist. Any person who could be expected to qualify for membership of a professional organisation (such as the ACPSEM, IPSM, AAPM) who, in the opinion of the Director of the National Radiation
Laboratory, has special knowledge and experience in the measurement and evaluation of hazards arising from the use of x-rays for medical diagnosis.

* Radiation personnel. * Any persons whose work involves directly and centrally the use of x-rays.

* Radiation protection survey. * A survey performed by a *qualified health physicist*, using a protocol approved by NRL and instruments calibrated to the satisfaction of NRL, to check an x-ray facility's compliance with NRL C5. (See also *programme.*

* Reference dose. * A dose that under normal circumstances *should not* be exceeded when performing a given x-ray procedure on an average patient.

* Secondary barrier. * A barrier sufficient to attenuate secondary radiation to the required level.

* Sensitivity profile. * In CT a measure of the width of the patient seen by the detector system, as opposed to the width irradiated by the x-ray beam.

* Tolerable. * Refers to a level of dose that is below but close to the dose limits. Such a dose is not welcome but can reasonably be tolerated in some circumstances.
ANNEX 2 QUALITY CRITERIA FOR DIAGNOSTIC RADIOPHGRAPHIC IMAGES

Introduction

Requirements relating to the justification and optimisation of the x-ray examination and to reference doses are given in Chapter 4. In this annex additional guidance is given on three important aspects of the x-ray imaging process:

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

This guidance is given for a selection of radiographic projections, and is largely based on the Working Document, Quality criteria for diagnostic radiographic images of the CEC study group. It is primarily directed to the clinical and technical staff involved in taking the radiographs and in reporting on them.

The quality criteria presented apply to adult patients of near average size with the usual presenting symptoms for the type of x-ray examination being considered.

General principles associated with good imaging performance

The following general principles are common to all radiographic x-ray examinations. All persons who either request, carry out, or report on the results of diagnostic x-ray procedures should be aware of them.

Quality control of x-ray imaging equipment

Quality control programmes form an essential part of dose-effective radiological practice. Such programmes shall be implemented in every medical x-ray facility and shall cover a selection of the most important physical and technical parameters associated with the types of x-ray examination being carried out. (See Chapter 7.)
Technical innovations

Technical innovations can sometimes lead to dose reductions. The use of the following may result in reduced doses, which also may be accompanied by improvement in image quality.

- rare earth screens,
- carbon fibre products in table tops, grid facing and interleaving, and cassette fronts,
- digital radiography,
- advanced film emulsions.

Patient positioning

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

X-ray beam limitation

Image quality is improved and the radiation dose to the patient is reduced by limiting the x-ray beam to the smallest field giving the required diagnostic information. Limitation of the radiation beam should also consider the need to exclude radiosensitive organs from the primary irradiation whenever possible. On no occasion shall the x-ray beam fall outside the image receptor area. The use of an automated limitation device is of help. A requirement to visualise beam limitation on the radiograph is an alternative.

Protective shielding

For radiation protection purposes radiosensitive tissues or organs should be shielded wherever possible. In particular, for patients of high reproductive capacity, testes or ovary shields should be used in examinations which are likely to give a high radiation dose to the gonads.
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. This requires that those factors which can lead to high reject or retake rates are subject to reject analysis. This will help to delineate the areas of concern in each medical x-ray facility.

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

Image viewing conditions

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

(a) The person viewing the radiographs requires a brightness through the film of about 100 cd/m². To achieve this, the film illuminator needs to have a uniform brightness of at least 2000 cd/m².

(b) The colour of the illuminator 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 of the radiograph to avoid dazzling, and shall be provided for mammography viewers.

(d) Means for magnifying details in the displayed radiographic image shall be available for mammography, and should be available generally. 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 generally, and shall be available for mammography.

(f) A low level of ambient light in the viewing room is essential.

Quality criteria

The criteria are divided into 3 parts:

Diagnostic requirements

These list image criteria which in most cases specify important anatomical structures and details that should be visible in a radiograph to enable accurate diagnosis. These criteria can be used by radiologists, in the course of reporting films, to make a personal visual assessment of the image quality.

The degree of visibility of features are graded using the following:

- visualisation: an anatomical feature is detectable but details are not fully reproduced.
- reproduction: the details of anatomical features are visible but not necessarily clearly defined.
- visually sharp reproduction: the anatomical details are clearly defined.

Criteria for good imaging performance

Important image details provide minimum dimensions at which important anatomical details should be recognised in the image. Reference values are also provided for the entrance surface dose to a standard-sized patient.

These criteria can be used by radiologists, MRTs and medical physicists as a check on the performance of the entire imaging process and as an aid in identifying desirable technical specifications of x-ray equipment.
Example of good radiographic technique

This provides a set of values for various radiographic technique parameters that has been found to result in good imaging performance that will meet all the above quality criteria. This example of good technique can act as a guide to improving techniques that do not meet the quality criteria.

Note:

1) The anti-scatter grid is specified in terms of the grid ratio, r, and the number of absorbing strips per cm.

2) The sensitivity of film-screen combinations is defined in terms of speed (see ANSI PH2.43 — 1982). The speed of the film-screen combination is one of the most critical factors affecting the patient dose. Speed classes of 200 and above usually require the use of rare-earth or equivalent intensifying screens.
1 Diagnostic requirements

Image criteria
1.1 Performed at deep inspiration (as assessed by the position of the ribs above the diaphragm — either 6 anteriorly or 10 posteriorly) and with suspended respiration
1.2 Symmetrical reproduction of the thorax
1.3 Medial border of the scapulae to be outside the lung fields
1.4 Reproduction of the whole rib cage above the diaphragm
1.5 Reproduction of the vascular pattern in the whole lung, particularly the peripheral vessels
1.6 Visually sharp reproduction of
   (a) the trachea and proximal bronchi, the borders of the heart and aorta
   (b) the diaphragm and costo-phrenic angles
1.7 Visualisation of the retrocardiac lung and the mediastinum

2 Criteria for good imaging performance

2.1 Important image details
   Small round details in the whole lung, including the retrocardiac areas:
   high contrast : 0.7 mm diameter
   low contrast : 2 mm diameter
   Linear and reticular details out to the lung periphery:
   high contrast : 0.3 mm in width
   low contrast : 2 mm in width
2.2 Entrance surface dose for a standard-sized patient: 0.3 mGy

3 Example of good radiographic technique

3.1 Radiographic device : vertical stand with stationary or moving grid
3.2 Focal spot size : \( \leq 1.3 \text{ mm} \)
3.3 Total filtration : \( \geq 3.00 \text{ mm Al equivalence} \)
3.4 Anti-scatter grid : \( r = 12, 40/\text{cm} \)
3.5 Film-screen combination : speed class 200 - 400
3.6 FFD : 180 (140 - 200) cm
3.7 Radiographic voltage : 100 - 150 kV
3.8 Automatic exposure control : chamber selected — lateral
3.9 Exposure time : \(< 20 \text{ ms}\)
1  DIAGNOSTIC REQUIREMENTS

Image criteria
1.1 Performed at deep inspiration and with suspended respiration
1.2 Arms **should** be raised clear of the thorax
1.3 Visually sharp reproduction of the posterior border of the heart, aorta, mediastinum, trachea, diaphragm, sternum and thoracic spine

2  CRITERIA FOR GOOD IMAGING PERFORMANCE

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

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

3  EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

3.1 Radiographic device : vertical stand with stationary or moving grid
3.2 Focal spot size : \( \leq 1.3 \) mm
3.3 Total filtration : \( \geq 3.0 \) mm Al equivalence
3.4 Anti-scatter grid : \( r = 12; 40/cm \)
3.5 Film-screen combination : speed class 200 -400
3.6 FFD : 180 (140 - 200) cm
3.7 Radiographic voltage : 100 - 150 kV
3.8 Automatic exposure control : chamber selected --- central
3.9 Exposure time : \(< 40 \) ms
PA PROJECTION
or AP Projection if PA not possible

1  DIAGNOSTIC REQUIREMENTS

Image criteria
1.1 Symmetrical reproduction of the skull, particularly cranial vault, orbits and petrous bones
1.2 Projection of the apex of the petrous temporal bone into the centre of the orbits
1.3 Visually sharp reproduction of the frontal sinus, ethmoid cells and apex of the petrous temporal bones and the internal auditory canals
1.4 Visually sharp reproduction of the outer and inner tables of the cranial vault

2  CRITERIA FOR GOOD IMAGING PERFORMANCE

2.1 Important image details: 0.3 - 0.5 mm
2.2 Entrance surface dose for a standard-sized patient: 5.0 mGy

3  EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

3.1 Radiographic device: grid table, special skull unit or vertical stand with stationary or moving grid
3.2 Focal spot size: 0.6 mm
3.3 Total filtration: ≥ 2.5 mm Al equivalence
3.4 Anti-scatter grid: r = 8(12); 40/cm
3.5 Film-screen combination: speed class 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: < 200 ms
1 DIAGNOSTIC REQUIREMENTS

Image criteria
1.1 Visually sharp reproduction of the outer and inner tables of the cranial vault, the floor of the sella, and the apex of the petrous temporal bone
1.2 Superimposition respectively of the contours of the frontal cranial fossa, the lesser wing of the sphenoid bone, the clinoid processes and the external auditory canals
1.3 Visually sharp reproduction of the vascular channels, the vertex of the skull and the trabecular structure of the cranium

2 CRITERIA FOR GOOD IMAGING PERFORMANCE

2.1 Important image details: 0.3 - 0.5 mm
2.2 Entrance surface dose for a standard-sized patient: 3.0 mGy

3 EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

3.1 Radiographic device: grid table, special skull unit or vertical stand with stationary or moving grid
3.2 Focal spot size: 0.6 mm
3.3 Total filtration: $\geq 2.5$ mm Al equivalence
3.4 Anti-scatter grid: $r = 8(12); 40/cm$
3.5 Film-screen combination: speed class 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: $< 100$ ms
LUMBAR SPINE

AP/PA PROJECTIONS

1 DIAGNOSTIC REQUIREMENTS

Image criteria
1.1 Linear reproduction of the upper and lower-plate surfaces in the centred beam area and visualisation of the intervertebral spaces
1.2 Visually sharp reproduction of the pedicles
1.3 Visualisation of the intervertebral joints
1.4 Reproduction of the spinous and transverse processes
1.5 Visually sharp reproduction of the cortex and trabecular structures
1.6 Reproduction of the adjacent soft tissues, particularly the psoas shadows

2 CRITERIA FOR GOOD IMAGING PERFORMANCE

2.1 Important image details : 0.3 - 0.5 mm
2.2 Entrance surface dose for a standard-sized patient : 10 mGy

3 EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

3.1 Radiographic device : grid table or vertical stand with stationary or moving grid
3.2 Focal spot size : \( \leq 1.3 \) mm
3.3 Total filtration : \( \geq 3.0 \) mm Al equivalence
3.4 Anti-scatter grid : \( r = 12(8) ; 40/\)cm
3.5 Film-screen combination : speed class 400
3.6 FFD : 115 (100 - 150) cm
3.7 Radiographic voltage : 70 - 90 kV
3.8 Automatic exposure control : chamber selected — central
3.9 Exposure time : \( < 400 \) ms

REMARKS Radiation protection: where appropriate, gonad shields should be employed for male patients, and for female patients if possible.
LUMBAR SPINE

LATERAL PROJECTION

1 DIAGNOSTIC REQUIREMENTS

Image criteria
1.1 Linear reproduction of the upper and lower-plate surfaces in the centred beam area and visualisation of the intervertebral spaces
1.2 Full superimposition of the posterior vertebral edges
1.3 Reproduction of the pedicles and the intervertebral foramina
1.4 Visualisation of the intervertebral joints
1.5 Visually sharp reproduction of the cortex and trabecular structures
1.6 Reproduction of the adjacent soft tissues

2 CRITERIA FOR GOOD IMAGING PERFORMANCE

2.1 Important image details : 0.5 mm
2.2 Entrance surface dose for a standard-sized patient : 30 mGy

3 EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

3.1 Radiographic device : grid table or vertical stand with stationary or moving grid
3.2 Focal spot size : ≤ 1.3 mm
3.3 Total filtration : ≥ 3.0 mm Al equivalence
3.4 Anti-scatter grid : r = 12(8); 40/cm
3.5 Film-screen combination : speed class 400 - 800
3.6 FFD : 115 (100 - 150) cm
3.7 Radiographic voltage : 90 - 100 kV
3.8 Automatic exposure control : chamber selected — normally central
3.9 Exposure time : < 1000 ms

REMARKS Radiation protection: where appropriate, gonad shields should be employed for male patients, and for female patients if possible.
LUMBAR SPINE

LATERAL PROJECTION OF LUMBO-SACRAL JUNCTION
This Projection may be indicated if the lumbo-sacral junction is not adequadely visualised on the Lateral Projection of the lumbar spine

1 DIAGNOSTIC REQUIREMENTS

Image criteria
1.1 Reproduction by tangential projection of the inferior end plate of L 5 and the superior end plate of S 1
1.2 Visualisation of the anterior border of the upper sacrum
1.3 Reproduction of vertebral pieces of the upper sacrum

2 CRITERIA FOR GOOD IMAGING PERFORMANCE

2.1 Important image details : 0.5 mm
2.2 Entrance surface dose for a standard-sized patient : 40 mGy

3 EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

3.1 Radiographic device : grid table or vertical stand with stationary or moving grid
3.2 Focal spot size : ≤1.3 mm
3.3 Total filtration : ≥3.0 mm Al equivalence
3.4 Anti-scatter grid : r = 12(8); 40/cm
3.5 Film-screen combination : speed class 400 - 800
3.6 FFD : 115 (100 - 150) cm
3.7 Radiographic voltage : 90 - 110 kV
3.8 Automatic exposure control : chamber selected — central
3.9 Exposure time : < 1000 ms

REMARKS Radiation protection: where appropriate, gonad shields should be employed for male patients, and for female patients if possible.
1 DIAGNOSTIC REQUIREMENTS

Image criteria
1.1 Symmetrical reproduction of the pelvis
1.2 Visualisation of the sacrum and its intervertebral foramina
1.3 Visualisation of the pubic and ischial rami
1.4 Visualisation of the sacroiliac joints
1.5 Reproduction of the necks of the femora which should not be distorted by foreshortening or rotation
1.6 Reproduction of spongiosa and corticalis, and visualisation of the trochanters

2 CRITERIA FOR GOOD IMAGING PERFORMANCE

2.1 Important image details: 0.5 mm
2.2 Entrance surface dose for a standard-sized patient: 10 mGy

3 EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

3.1 Radiographic device: grid table
3.2 Focal spot size: ≤ 1.3 mm
3.3 Total filtration: ≥ 3.0 mm Al equivalence
3.4 Anti-scatter grid: r = 12(8); 40/cm
3.5 Film-screen combination: speed class 400
3.6 FFD: 115 (100 - 150) cm
3.7 Radiographic voltage: 70 - 90 kV
3.8 Automatic exposure control: chamber selected — central or both lateral
3.9 Exposure time: < 400 ms

REMARKS Radiation protection: where appropriate, gonad shields should be employed for male patients, and for female patients if possible.
URINARY TRACT

AP PROJECTION
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
1.2 Reproduction of the kidney outlines
1.3 Visualisation of the psoas outlines
1.4 Visually sharp reproduction of the bones

2 CRITERIA FOR GOOD IMAGING PERFORMANCE

2.1 Important image details : 1 mm
2.2 Entrance surface dose for a standard-sized patient : 10 mGy

3 EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

3.1 Radiographic device : grid table
3.2 Focal spot size : \( \leq 1.3 \) mm
3.3 Total filtration : \( \geq 3.0 \) mm Al equivalence
3.4 Anti-scatter grid : \( r = 12(8); 40/cm \)
3.5 Film-screen combination : speed class 400 - 800
3.6 FFD : 115 (100 - 150) cm
3.7 Radiographic voltage : 70 - 90 kV
3.8 Automatic exposure control : chamber selected — central or both lateral
3.9 Exposure time : \(< 100 \) ms

REMARKS Radiation protection: where appropriate, gonad shields should be employed for male patients.
URINARY TRACT

After administration of contrast medium

1 DIAGNOSTIC REQUIREMENTS

Image criteria
Image criteria are to be referred to a series of radiographs
1.1 Increase in parenchymal density (nephrographic effect)
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

2 CRITERIA FOR GOOD IMAGING PERFORMANCE

2.1 Important image details : 1 mm
2.2 Entrance surface dose for a standard-sized patient : 10 mGy per
   radiograph

3 EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

3.1 Radiographic device : grid table or vertical stand with
   moving grid
3.2 Focal spot size : ≤ 1.3 mm
3.3 Total filtration : ≥ 3.0 mm Al equivalence
3.4 Anti-scatter grid : r = 12(8); 40/cm
3.5 Film-screen combination : speed class 400 - 800
3.6 FFD : 115 (100 - 150) cm
3.7 Radiographic voltage : 70 - 90 kV
3.8 Automatic exposure control : chamber selected — central or
   both lateral
3.9 Exposure time : < 100 ms

REMARKS Satisfactory reduction of overlying bowel gases and faeces is essential
for adequate urinary tract reproduction. If reproduction is inadequate
tomography or zonography might be useful.
1 DIAGNOSTIC REQUIREMENTS

Image criteria
1.1 Visually sharp reproduction of the whole glandular breast
1.2 Visually sharp reproduction of the cutis and subcutis
1.3 Nipple should be parallel to the film

2 CRITERIA FOR GOOD IMAGING PERFORMANCE

2.1 Important image details: round details: 3 mm diameter
  micro-calcifications: 0.2 mm
2.2 Entrance surface dose for a standard-sized patient,
  4.5 cm compressed breast, with anti-scatter grid: 7 mGy

3 EXAMPLE OF GOOD RADIOGRAPHIC TECHNIQUE

3.1 Radiographic device: specially dedicated equipment
  Anode material: Mo
3.2 Focal spot size: ≤ 0.6 mm
3.3 Total filtration: 0.03 mm Mo
3.4 Anti-scatter grid: specially designed moving grid (see
  REMARKS) might be necessary
3.5 Film-screen combination: dedicated high resolution film-screen
  combination with dedicated processing
3.6 FFD: ≥ 60 cm
3.7 Radiographic voltage: 25 - 35 kV
3.8 Automatic exposure control: chamber selected — specially
  positioned
3.9 Exposure time: < 2 s
3.10 Breast compression: shall be applied to a level which the
  patient can tolerate

REMARKS

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

- For more dense and/or thicker breasts (in excess of 6 cm compressed) a rhodium or a tungsten anode, aluminium or other special filtration, higher tube voltages and use of an anti-scatter grid might be preferable.
- For thinner breasts (less than 4 cm) the use of an anti-scatter grid will not be necessary.
ANNEX 3 DOSE INDICES FOR ASSESSING RADIATION EXPOSURE OF PATIENTS

Patient doses in diagnostic radiology are measured because x-rays are potentially harmful. The "amount" of radiation used to perform an x-ray examination should be expressed in terms of a dose quantity that relates closely to the radiation risks associated with x-ray examinations. The partial body exposures invariably used in diagnostic radiology make the task of choosing an appropriate dose index suitable for use across all types of x-ray examinations difficult.

The 1990 recommendations of the ICRP define radiation detriment in terms of cancer (fatal and non-fatal), serious hereditary effects over all generations, and years of life lost. The ICRP also sets up a dose quantity called effective dose, which converts the actual dose distribution in the body (and its ensuing detriment) into an equivalent uniform whole body dose that would have the same detriment. Although effective dose is intended for use in occupational and public protection, its link to a sound definition of detriment and its ability to cope with partial body irradiations make it very attractive as a dose index for assessing the amount of radiation being used in diagnostic x-ray procedures. Although the age and sex distributions of the worker and public populations used to formulate effective dose are not the same as the distributions typically found for x-ray patients, this is not a serious drawback for using effective dose as a means of monitoring the amount of radiation being used for "average patients".

For these reasons effective dose has been used in this Code as the primary dose quantity for the reference doses. However, effective dose cannot be measured directly, and in the absence of the more complex dosimetric information required to estimate effective dose, it will often be sufficient to use entrance surface dose or dose-area product as a means of assessing patient doses for particular radiographic projections or complete x-ray examinations respectively. These two quantities are secondary quantities in specifying the reference doses. Dose-area product can be used to estimate effective dose if the beam orientation is known.

Entrance surface dose in this Code is defined as the absorbed dose to air at the point of intersection of the x-ray beam axis with the incident surface of the
patient. It includes backscatter. *Entrance surface dose* per radiograph is commonly measured in two ways:

(a) TLD placed on the patient's skin,

(b) an ionization chamber, usually used free-in-air, with corrections for backscatter and distance.

*Dose-area product* in this Code is defined as the absorbed dose to air averaged over the area of the x-ray beam in a plane perpendicular to the beam axis, multiplied by the area of the x-ray beam in the same plane. This quantity does not include backscatter from the patient. *Dose-area product* can be measured directly using a large area, parallel plate ionization chamber, typically mounted on the LBD. This chamber fully intercepts the entire cross-section of the x-ray beam. Alternatively *dose-area product* can be calculated from a measurement of dose to air in the primary beam, and the known dimensions of the x-ray beam in the plane perpendicular to the beam axis at the dose measurement position.
## ANNEX 4 PERMISSIBLE VALUES OF FOCAL SPOT DIMENSIONS FOR NOMINAL FOCAL SPOT VALUES*

<table>
<thead>
<tr>
<th>Nominal focal spot value</th>
<th>Focal spot dimension Permissible values in mm</th>
</tr>
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<tr>
<td></td>
<td>width</td>
</tr>
<tr>
<td>f</td>
<td></td>
</tr>
<tr>
<td>0.1</td>
<td>0.10 ... 0.15</td>
</tr>
<tr>
<td>0.15</td>
<td>0.15 ... 0.23</td>
</tr>
<tr>
<td>0.2</td>
<td>0.20 ... 0.30</td>
</tr>
<tr>
<td>0.25</td>
<td>0.25 ... 0.38</td>
</tr>
<tr>
<td>0.3</td>
<td>0.30 ... 0.45</td>
</tr>
<tr>
<td>0.4</td>
<td>0.40 ... 0.60</td>
</tr>
<tr>
<td>0.5</td>
<td>0.50 ... 0.75</td>
</tr>
<tr>
<td>0.6</td>
<td>0.6 ... 0.9</td>
</tr>
<tr>
<td>0.7</td>
<td>0.7 ... 1.1</td>
</tr>
<tr>
<td>0.8</td>
<td>0.8 ... 1.2</td>
</tr>
<tr>
<td>0.9</td>
<td>0.9 ... 1.3</td>
</tr>
<tr>
<td>1.0</td>
<td>1.0 ... 1.4</td>
</tr>
<tr>
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<td>1.1 ... 1.5</td>
</tr>
<tr>
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<td>1.2 ... 1.7</td>
</tr>
<tr>
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<td>1.3 ... 1.8</td>
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<tr>
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<tr>
<td>2.6</td>
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</tr>
<tr>
<td>2.8</td>
<td>2.8 ... 3.6</td>
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<tr>
<td>3.0</td>
<td>3.0 ... 3.9</td>
</tr>
</tbody>
</table>

Note: For nominal focal spot values from 0.3 to 3.0 inclusive, the permissible values in the table include the factor 0.7.

* From Table 5 IEC 336, 1993.
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