

BRITISH STANDARD

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Section 1.3 :
1995
IEC 601-1-3 :
1994**

Medical electrical equipment

Part 1. General requirements for safety

**Section 1.3 Collateral standard: General
requirements for radiation protection in
diagnostic X-ray equipment**

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee HCC/74, Radiation protection, upon which the following bodies were represented:

- Association of X-ray Equipment Manufacturers (BEAMA Ltd.)
- British Dental Association
- British Institute of Radiology
- British Medical Association
- College of Radiographers
- Department of Health
- Flat Glass Manufacturers' Association
- Health and Safety Executive
- Industrial Safety (Protective Equipment) Manufacturers' Association
- Institute of Physical Sciences in Medicine (Ipsm)
- Ministry of Defence
- National Radiological Protection Board
- Royal College of Radiologists
- Society of X-ray Technology

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National foreword

This British Standard has been prepared by Technical Committee HCC/74. It is the English language version of EN 60601-1-3 : 1994 *Medical electrical equipment — Part 1 : General requirements for safety — 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*, published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-1-3 : 1994 published by the International Electrotechnical Commission (IEC).

The requirements of this Collateral Standard are in addition to those of BS 5724 : Part 1 : 1989 hereinafter called the General Standard.

As in the General Standard, the requirements are followed by compliance tests. The numbers of the sections and clauses in this standard refer to the related sections and clauses in the General Standard. Clauses, subclauses or figures that are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc.

A rationale giving recommendations for the provision of information concerning stray radiation is given in annex AAA. This annex does not form a normative part of the standard.

Cross-references

Publication referred to	Corresponding British Standard
HD 356 S1 : 1977 (IEC 406 : 1975)	BS 7534 : 1991 <i>Specification for radiographic cassettes</i>
IEC 627 : 1978	BS 5913 : 1980 <i>Method for measuring and defining the characteristics of anti-scatter grids used in X-ray equipment</i>
IEC 658 : 1979	BS 6126 : 1981 <i>Specification for dimensions of radiographic intensifying screens for medical use</i>
HD 501 S1 : 1988 (IEC 788 : 1984)	BS 6641 : 1985 <i>Glossary of medical radiology terms</i>

The ICRP publications referred to in annex ZA are prepared by the Commission for Radiological Protection, Clifton Avenue, Sutton, Surrey SM2 5PU, and are available from Pergamon Press Ltd, Headington Hill Hall, Oxford OX3 0BW.

Additional information. The following print types are used in this standard.

Requirements, with which compliance can be tested, and definitions:
in roman type.

Explanations, advice, general statements, exceptions and references:
in small roman type.

Test procedures: in *italic* type.

Terms defined in clause 2 of BS 5724 : Part 1 or in BS 6641: in SMALL CAPITALS.

For the purposes of this British Standard, any references to IEC page numbers in the text should be ignored.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

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English version

Medical electrical equipment
Part 1: General requirements for safety
3. Collateral Standard: General requirements for radiation
protection in diagnostic X-ray equipment
(IEC 601-1-3 : 1994)

Appareils électromédicaux Première partie:
Règles générales de sécurité
3. Norme Collatérale: Règles générales pour
la radioprotection dans les équipements à
rayonnement X de diagnostic
(CEI 601-1-3 : 1994)

Medizinische elektrische Geräte
Teil 1: Allgemeine Anforderungen an die
Sicherheit
3. Ergänzung-Norm: Allgemeine
Anforderungen an den Strahlenschutz von
diagnostischen Röntengeräten
(IEC 601-1-3 : 1994)

This European Standard was approved by CENELEC on 1994-07-05. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 62B(CO)111, as prepared by Sub-Committee 62B: Diagnostic imaging equipment of IEC Technical Committee 62: Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote in December 1993.

The reference document was approved by CENELEC as EN 60601-1-3 on 5 July 1994.

The following dates were fixed:

- latest date of publication
of an identical national
standard (dop) 1995-07-01
- latest date of withdrawal
of conflicting national
standards (dow) 1995-07-01

For products which have complied with the relevant national standard before 1995-07-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2000-07-01.

This European Standard constitutes a Collateral Standard to EN 60601-1 *Medical electrical equipment Part 1: General requirements for safety*, hereinafter referred to as the General Standard.

In the EN 60601 series Collateral Standards specify general requirements for safety applicable to:

- a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment;
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the General Standard (e.g. electromagnetic compatibility).

The numbering of sections, clauses and subclauses of this Collateral Standard corresponds with that of the General Standard.

Subclauses and figures which are additional to those of the General Standard are numbered starting from 201: additional annexes are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

Annexes designated 'normative' are part of the body of the standard. Annexes designated 'informative' are given only for information. In this standard, annexes AAA, BBB, CCC and ZB are informative and annex ZA is normative.

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INTRODUCTION

The requirements in this Collateral Standard concern protective measures to be taken by the MANUFACTURER in the design and construction of medical diagnostic X-RAY EQUIPMENT and its subassemblies. They relate to the application of the X-RADIATION generated, both deliberately and incidentally, in fulfilling the medical purpose of the EQUIPMENT. Additional measures are necessary to regulate the generation processes themselves. These are described in the general requirements for safety, IEC 601-1, and, where appropriate, in particular requirements for the EQUIPMENT concerned.

The recommended principles governing the use of RADIATION for medical purposes, as stated in Publication 60 of the International Commission on Radiological Protection (ICRP), Chapter 4, have been taken into account. The implementation of these principles is essentially determined in the prevailing circumstances at the point of use. It requires judgements to be made by the USER and the establishment of measures and working practices that are not necessarily connected with the construction of EQUIPMENT. The requirements in this Collateral Standard are intended to be consistent with generally accepted good practice in the administration of X-RADIATION in medicine. In respect of economic factors, it is recognized that certain relatively inexpensive types of EQUIPMENT are sometimes justifiably preferred on grounds of cost. For these, this Collateral Standard avoids imposing requirements that would unduly restrict their medical effectiveness or would add disproportionately to the cost.

In some cases, the formulation of the requirements is deliberately designed to provide scope for accommodating local laws and regulations at the time of installation and commissioning. Several of the requirements include provisions for relevant technical information to be included in ACCOMPANYING DOCUMENTS.

USERS of medical diagnostic X-RAY EQUIPMENT should be aware that effective protection against IONIZING RADIATION requires the consideration of many aspects additional to the construction of the EQUIPMENT. Among these are the following:

- compatibility of components and correct installation of EQUIPMENT;
- the protective properties of rooms where X-RAY EQUIPMENT is installed;
- measures for monitoring and maintaining the safety and effectiveness of EQUIPMENT throughout its life, with particular attention to components that can deteriorate progressively with time and use;
- the need in appropriate circumstances for PROTECTIVE CLOTHING to be worn by staff and for suitable devices to be used to protect PATIENTS;
- the keeping of appropriate records concerning the usage of the EQUIPMENT and the results of tests, with systematic review and the application of corrective action when necessary;
- the training of staff in the principles of radiation protection and in the correct use of EQUIPMENT, including any protective devices provided.

Further advice on these aspects can be found in ICRP Publications 33, 34 and 60.

Readers of this Collateral Standard are reminded that, in accordance with IEC 601-1, clause 4, all the test procedures described are type tests, intended to be carried out in a dedicated testing environment in order to determine compliance. Tests to be carried out by manufacturers to ensure compliance during production or installation and tests for detecting non-compliance subsequently to delivery, are not included.

MEDICAL ELECTRICAL EQUIPMENT -

Part 1: General requirements for safety

3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment

SECTION 1: GENERAL

1 Scope, object and relationship to other standards

1.201 *Scope*

This Collateral Standard applies to medical diagnostic X-RAY EQUIPMENT and to sub-assemblies of such EQUIPMENT.

1.202 *Object*

The object of this Collateral Standard is to establish general requirements for protection against IONIZING RADIATION in medical diagnostic X-RAY EQUIPMENT, in order that the DOSE EQUIVALENT to the PATIENT, the OPERATOR and other staff can be kept as low as reasonably achievable.

Some of the requirements in this Collateral Standard include variations for different types of X-RAY EQUIPMENT. This is intended to widen the scope within which the Collateral Standard can be applied usefully without addition or modification, especially in respect of types of X-RAY EQUIPMENT that are commonly used in MEDICAL DIAGNOSTIC RADIOLOGY.

The requirements in this Collateral Standard apply mainly in respect of X-RADIATION after its generation. Requirements for the control of the electrical energy used to generate X-RADIATION, which is also an important aspect of RADIATION PROTECTION, are included in IEC 601-1 and in Particular Standards for the safety of the EQUIPMENT concerned.

1.203 *Relationship to other standards*

1.203.1 *IEC 601-1*

For diagnostic X-RAY EQUIPMENT, this Collateral Standard complements IEC 601-1: 1988, *Medical electrical equipment - Part 1: General requirements for safety*.

When referring to IEC 601-1 or to this Collateral Standard, either individually or in combination, the following conventions are used:

- "IEC 601-1" designates IEC 601-1 alone;
- "this Collateral Standard" designates this Collateral Standard alone;
- "this Standard" designates the combination of IEC 601-1 together with this Collateral Standard.

1.203.2 *Particular Standards*

A requirement in a Particular Standard takes priority over the corresponding requirement in this Collateral Standard.

1.203.3 *Superseded IEC Standards*

In the following IEC standards, requirements that relate to medical diagnostic X-RAY EQUIPMENT are superseded by the requirements in this Collateral Standard:

IEC 407: 1973, *Radiation protection in medical X-ray equipment 10 kV to 400 kV*

IEC 407A: 1975, *First supplement to IEC 407*

1.203.4 *Normative references*

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All normative documents are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

IEC 406: 1975, *Radiographic cassettes*

IEC 522: 1976, *Inherent filtration of an X-ray tube assembly*

IEC 627: 1978, *Characteristics of anti-scatter grids used in X-ray equipment*

IEC 658: 1979, *Radiographic intensifying screens for medical use - Dimensions*

IEC 788: 1984, *Medical radiology - Terminology*

ICRP Publication 33: *Protection against ionizing radiation from external sources used in medicine (Annals of the ICRP Vol. 9 No. 1, 1982). Published by Pergamon Press*

ICRP Publication 34: *Protection of the patient in diagnostic radiology (Annals of the ICRP Vol. 9 No. 2/3, 1982). Published by Pergamon Press*

ICRP Publication 60: *Recommendations of the International Commission on Radiological Protection (Annals of the ICRP Vol. 21 No. 1-3, 1990). Published by Pergamon Press*

1.203.5 *Other related IEC Standards*

At the time of publication, the following Particular Standards have been identified as containing concurrent requirements for RADIATION PROTECTION in diagnostic X-RAY EQUIPMENT:

IEC 601-2-7: 1987, *Medical electrical equipment - Part 2: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generator*

IEC 601-2-15: 1988, *Medical electrical equipment - Part 2: Particular requirements for the safety of capacitor discharge X-ray generators*

IEC 601-2-28: 1993, *Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

IEC 601-2-29: 1993, *Medical electrical equipment - Part 2: Particular requirements for the safety of radiotherapy simulators*

IEC 601-2-32: 1994, *Medical electrical equipment - Part 2: Particular requirements for the safety of associated equipment of X-ray equipment*

IEC 637: 1979, *Marking of and accompanying documents for X-ray tubes and X-ray tube assemblies for medical use*

NOTE - The requirements of IEC 637 are replaced by corresponding requirements in IEC 601-2-28.

IEC 878:1988, *Graphical symbols for electrical equipment in medical practice.*

2 Terminology and definitions

2.201 *Defined terms*

In this Collateral Standard, terms printed in SMALL CAPITALS are used in accordance with their definitions in IEC 601-1 or IEC 788. Associated conditions qualifying the usage of certain terms are given in 2.202. An index of defined terms used in this Collateral Standard is given in annex BBB.

2.202 *Qualifying conditions for defined terms*

2.202.1 *Boundary and dimensions of the X-RAY FIELD*

In this Collateral Standard, the boundary of an X-RAY FIELD (see rm-37-07+ in IEC 788), is described by the locus of points at which the AIR KERMA RATE is 25 % of the mean of the AIR KERMA RATES at the approximate centres of the quarters of the area enclosed.

The dimensions of an X-RAY FIELD are described in terms of the lengths of its intercepts on each of two orthogonal major axes in the plane of interest. Unless otherwise stated, it is to be assumed that the plane of interest is at right angles to the REFERENCE AXIS; also that the major axes intersect on the REFERENCE AXIS and are oriented so that one axis is collinear with the projection of the longitudinal axis of the X-RAY TUBE lying in the plane and passing through this point of intersection.

2.202.2 *Operating conditions for NOMINAL X-RAY TUBE VOLTAGE*

NOMINAL X-RAY TUBE VOLTAGE is defined in IEC 788 (rm-36-03) as the highest permitted X-RAY TUBE VOLTAGE for specific operating conditions. In this Collateral Standard, if specific operating conditions are not stated, it is to be assumed that the value referenced is unconditional and is thus the highest X-RAY TUBE VOLTAGE permitted for NORMAL USE of the item under consideration. Such a value cannot be higher, but is sometimes lower, than values permitted for certain separate subassemblies or parts of the item.

2.202.3 *Effective IMAGE RECEPTION AREA*

The term IMAGE RECEPTION AREA defined in IEC 788 (rm-37-16) is taken in this Collateral Standard to include only those parts of the surface that are configured at the relevant time to be able to receive an X-RAY PATTERN and have at the same time appropriate means of processing for DISPLAY or storage of the information contained.

NOTE - In accordance with this convention, the IMAGE RECEPTION AREA of a multi-field X-RAY IMAGE INTENSIFIER TUBE is considered to be restricted by the selection of magnification modes, to exclude any portion of the INPUT SCREEN from which the X-RAY PATTERN cannot be electronically processed.

2.202.4 *The IMAGE RECEPTOR PLANE in X-RAY IMAGE INTENSIFIER TUBES*

The IMAGE RECEPTOR PLANE of an X-RAY IMAGE INTENSIFIER TUBE is taken in this Collateral Standard to be the plane containing the largest selectable IMAGE RECEPTION AREA.

NOTE - In accordance with this convention, the position of the IMAGE RECEPTOR PLANE and thus also the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, are considered to be unaffected by the selection of different magnification modes.

2.202.5 *Modes of operation with CONTINUED DISPLAY*

An X-RAY IMAGING ARRANGEMENT operating with CONTINUED DISPLAY is regarded in this Collateral Standard as an X-RAY IMAGING ARRANGEMENT for RADIOLOGY if means are provided for automatic repetition of IRRADIATION.

2.203 *Composition of reference materials*

Values of ATTENUATION EQUIVALENT, HALF-VALUE LAYER and QUALITY EQUIVALENT FILTRATION expressed in this Collateral Standard as thicknesses of aluminium or lead, apply to reference materials of the following composition:

- aluminium of purity 99,99 % or higher and density 2,70 g cm⁻³;
- lead of purity 99,99 % or higher and density 11,35 g cm⁻³.

2.204 *Degrees of requirement and miscellaneous terms*

In this Collateral Standard, certain terms (which are not printed in small capitals) have particular meanings, as follows:

- | | |
|-------------------------|--|
| - "may" (need not) | indicates a permitted manner of complying with a requirement or of avoiding the need to comply; |
| - "shall" (shall not) | indicates a requirement that is mandatory for compliance; |
| - "should" (should not) | indicates a strong recommendation that is not mandatory for compliance; |
| - "specific" | is used to indicate definitive information stated in this Collateral Standard or referenced in other standards, usually concerning particular operating conditions, test arrangements or values connected with compliance; |

- "specified" is used to indicate definitive information stated by the MANUFACTURER in ACCOMPANYING DOCUMENTS or in other documentation relating to the EQUIPMENT under consideration, usually concerning its intended purposes, or the parameters or conditions associated with its use or with testing to determine compliance.

2.205 RADIATION QUANTITIES and units

This Collateral Standard uses the quantity AIR KERMA in preference to EXPOSURE. The unit of AIR KERMA is the gray (Gy). An AIR KERMA of 1 Gy corresponds to an EXPOSURE of $2,97 \times 10^2 \text{ C kg}^{-1}$.

4 General requirements for tests

4.201 Compliance

4.201.1 Statement of compliance

Any statement of compliance with the requirements of this Collateral Standard shall be given in the following form:

- xxxx with radiation protection in accordance with IEC 601-1-3:1994, where xxxx represents the object (e.g., "X-RAY EQUIPMENT") for which compliance is to be stated.

6 Identification, marking and documents

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

6.1.201 Marking requirements in subclauses

In this Collateral Standard particular requirements for marking and for the content of markings are given in various subclauses, as indicated in table 201.

Table 201 - Subclauses containing requirements for marking

Title	Subclause
General requirements	6.1.202
Indication of FILTRATION properties	29.201.6
Indication on the EQUIPMENT	29.202.5

6.1.202 General requirements

All sub-assemblies, components and ACCESSORIES of X-RAY EQUIPMENT that can be removed in NORMAL USE, and are relevant to compliance with this Collateral Standard, shall be marked to ensure

- that they can be identified readily and correlated with their ACCOMPANYING DOCUMENTS;

- that interchangeable devices are individually distinguishable to the OPERATOR both in NORMAL USE and for the purpose of obtaining replacements.

All markings shall be permanently affixed and clearly legible as defined in clause 6 of IEC 601-1.

6.8 ACCOMPANYING DOCUMENTS

6.8.201 References in subclauses

The subclauses of this Collateral Standard that contain requirements for statements in ACCOMPANYING DOCUMENTS (which include INSTRUCTIONS FOR USE and ASSEMBLING INSTRUCTIONS) are listed in table 202. The subjects of the normative references to ACCOMPANYING DOCUMENTS in these subclauses are listed in annex CCC.

Table 202 - Subclauses requiring statements in ACCOMPANYING DOCUMENTS

Title	Subclause
General requirements	6.8.202
FILTRATION in X-RAY TUBE ASSEMBLIES	29.201.3
FILTRATION in X-RAY SOURCE ASSEMBLIES	29.201.4
Indication of FILTRATION properties	29.201.6
Methods of beam limitation in X-RAY EQUIPMENT	29.202.4
Indication on the EQUIPMENT	29.202.5
Indication in the INSTRUCTIONS FOR USE	29.202.6
Accuracy of marked and written indications	29.202.8
Positioning of the REFERENCE AXIS	29.203.1
The FOCAL SPOT TO IMAGE RECEPTOR DISTANCE	29.203.2
Interception of the X-RAY BEAM in CONTINUOUS MODE	29.203.3
Correspondence between X-RAY FIELD and IMAGE RECEPTION AREA	29.203.4
Statement of reference LOADING CONDITIONS	29.204.2
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Control from a PROTECTED AREA	29.208.2
Designated SIGNIFICANT ZONES OF OCCUPANCY	29.208.3
Handgrips and control devices	29.208.5

6.8.202 General requirements

ACCOMPANYING DOCUMENTS shall clearly identify the items to which they refer and shall include:

- the replication of all information required in this Collateral Standard to be marked on the items;
- for subassemblies forming part of the items, the following information about the location and content of their required markings:
 - a) for markings accessible in the complete assembly, the location of the markings and instructions for enabling them to be inspected;
 - b) for markings inaccessible in the complete assembly, either
 - 1) replication of the information required in this Collateral Standard to be marked on the subassemblies or;
 - 2) a list of the subassemblies concerned, with references to their own accompanying documents;
- for items, such as components and subassemblies, specified to be supplied separately from the main assemblies of which they are intended to form a part, ASSEMBLING INSTRUCTIONS with the information necessary to maintain their compliance with this Collateral Standard in the main assemblies concerned.

SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

29 X-RADIATION

NOTE - 29.201 to 29.208 relate only to X-RADIATION from medical diagnostic X-RAY EQUIPMENT.

29.201 RADIATION QUALITY

NOTE - 29.201.1 to 29.201.9 relate to the need for the RADIATION QUALITY of X-RAY BEAMS to be appropriate for producing the intended diagnostic images without administering unnecessarily high ABSORBED DOSES to the PATIENT. The required measures address RADIATION QUALITY in terms of both FILTRATION and first HALF-VALUE LAYER in the interests of compatibility with established national regulations. In X-RAY EQUIPMENT for dental applications, restrictions are placed on the operating voltage range for NORMAL USE.

29.201.1 Limitation of operating voltage range in dental applications

In X-RAY EQUIPMENT specified for dental applications, the operating range of X-RAY TUBE VOLTAGE in NORMAL USE shall be restricted in accordance with table 203.

Compliance is checked by examination of the ACCOMPANYING DOCUMENTS.

Table 203 - Voltage restrictions in dental X-RAY EQUIPMENT

Specified dental application	Highest permitted NOMINAL X-RAY TUBE VOLTAGE (kV)	Lowest permitted X-RAY TUBE VOLTAGE for NORMAL USE (kV)
All applications	125	50
Applications using an intra-oral X-RAY IMAGE RECEPTOR	90	50
Cephalometric applications	125	60

29.201.2 HALF-VALUE LAYERS in X-RAY EQUIPMENT

In X-RAY EQUIPMENT, for all configurations available in NORMAL USE, the first HALF-VALUE LAYERS attained in the X-RAY BEAM incident to the PATIENT shall not be less than the minimum permissible values given in table 204.

Compliance is checked by the test described in 29.201.9.

Table 204 - HALF-VALUE LAYERS in X-RAY EQUIPMENT

Application	X-RAY TUBE VOLTAGE		Minimum permissible first HALF-VALUE LAYER mm Al
	Operating range for NORMAL USE kV	Selected value (see NOTE 1) kV	
Special low-voltage procedures	up to and including 50	< 30 30 40 50	see NOTE 2 0,3 0,4 0,5
Dental use with intra- oral X-RAY IMAGE RECEPTOR	from 50 up to and including 70	50 60 70	1,5 1,5 1,5
	from 50 up to and including 90	50 60 70 80 90	1,5 1,8 2,1 2,3 2,5
Other dental applications	from 50 up to and including 70	50 60 70	1,2 1,3 1,5
	from 50 up to and including 125	50 60 70 80 90 100 110 120 125	1,5 1,8 2,1 2,3 2,5 2,7 3,0 3,2 3,3
Other applications	from 30 upwards	< 50 50 60 70 80 90 100 110 120 130 140 150 >150	see NOTE 2 1,5 1,8 2,1 2,3 2,5 2,7 3,0 3,2 3,5 3,8 4,1 see NOTE 2
NOTES: 1 HALF-VALUE LAYERS for intermediate selected voltages are to be obtained by linear interpolation. 2 Linear extrapolation is to be used here.			

29.201.3 *FILTRATION in X-RAY TUBE ASSEMBLIES*

In respect of FILTRATION, X-RAY TUBE ASSEMBLIES shall comply with the following requirements:

- in X-RAY TUBE ASSEMBLIES, other than those specified exclusively for mammography with a NOMINAL X-RAY TUBE VOLTAGE not exceeding 50 kV, the QUALITY EQUIVALENT FILTRATION arising from materials intercepting the path of the X-RAY BEAM, shall be as follows:
 - a) not less than 0,5 mm Al from materials that are irremovable in NORMAL USE;
 - b) a value from fixed ADDED FILTERS such that the sum of this value and the amount arising from irremovable materials (see a) above) is not less than 1,5 mm Al;
- fixed ADDED FILTERS shall not be removable without the use of TOOLS;
- the ACCOMPANYING DOCUMENTS shall include, in the ASSEMBLING INSTRUCTIONS given for particular applications, instructions for attaining the TOTAL FILTRATION required to comply with 29.201.5 in respect of the items of X-RAY EQUIPMENT concerned.

Compliance is checked by inspection, by examination of the ACCOMPANYING DOCUMENTS and by the use, as appropriate, of the tests described in 29.201.7 and 29.201.8.

29.201.4 *FILTRATION in X-RAY SOURCE ASSEMBLIES*

In respect of FILTRATION, X-RAY SOURCE ASSEMBLIES shall comply with the following requirements:

- X-ray source assemblies may be provided with means to mount, to dismount, or to select, one or more ADDED FILTERS, without the use of TOOLS. When any such selectable ADDED FILTERS are provided they shall comply with the following requirements:
 - a) they shall be identifiable when in position for NORMAL USE;
 - b) if the presence of a selectable ADDED FILTER is necessary in order to attain the requirements for TOTAL FILTRATION in X-RAY EQUIPMENT, given in 29.201.5, means shall be provided to enable the presence of the appropriate selectable ADDED FILTER to be detected by the control system of an associated HIGH-VOLTAGE GENERATOR;

NOTE - This requirement for an INTERLOCK is of special importance in X-RAY EQUIPMENT for mammography, in respect of which there are no requirements for a minimum QUALITY EQUIVALENT FILTRATION from irremovable materials or for the provision of fixed ADDED FILTERS in the X-RAY TUBE ASSEMBLIES concerned.

- the ACCOMPANYING DOCUMENTS shall include, in the ASSEMBLING INSTRUCTIONS given for particular applications, instructions for attaining the TOTAL FILTRATION required to comply with 29.201.5 in respect of the X-RAY EQUIPMENT concerned.