

AS/NZS 3200.1.3:1996
IEC 601-1-3:1994

Australian/New Zealand Standard[®]

**Approval and test specification—
Medical electrical equipment**

**Part 1.3: General requirements
for safety—Collateral Standard:
Requirements for radiation
protection in diagnostic X-ray
equipment**

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 Australian and New Zealand Society of Nuclear Medicine
 Australian Chamber of Commerce and Industry
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 Australian Dental Industry Association
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PREFACE

This Standard was prepared by the Joint Standards Australian/Standards New Zealand Committee HT/23 on Medical Diagnostic Imaging Equipment, as a Joint Standard.

This Standard is technically equivalent to and has been reproduced from IEC 601-1-3:1994, *Medical electrical equipment, Part 1: General requirements for safety—3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*.

This Standard is one of a series of approval and test specifications issued by Standards Australia and Standards New Zealand for various categories of medical equipment. It is supplementary to AS 3200.1.0 (NZS 6150):1990, *Approval and test specification—Medical electrical equipment, Part 1.0: General requirements for safety—Parent Standard*.

The international Standard IEC 601-1-3:1994 is a collateral standard to IEC 601-1:1988, *Medical electrical equipment, Part 1: General requirements for safety* which has been adopted as AS 3200.1.0 (NZS 6150) hereinafter referred to as the General Standard. Collateral Standards specify safety requirements for groups of equipment (for example, radiology equipment) or for a characteristic common to all medical electrical equipment not covered by the General Standard.

In the text of this Standard, the following print types are used:

- (a) Requirements, compliance with which can be tested and definitions in large roman type
- (b) Explanations, advice, introductions, general statements, exceptions and references in smaller roman type
- (c) Headings of sub-clauses and text specifications in italic
- (d) Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index IN SMALL CAPITALS
- (e) Marginal bars are added to the text wherever the requirements of the Standard have been varied to meet Australian and New Zealand requirements; these variations are detailed in Appendix ZZ.

Under arrangements made between Standards Australia, Standards New Zealand and the IEC, as well as certain other Standards organizations, users of this Standard are advised that the number of this Standard is not reproduced on each page; its identity is shown only on the cover and title page.

For the purposes of this Standard the IEC text should be modified as follows:

- (i) *Terminology* The words ‘this Australian/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.
- (ii) *Decimal marker* Substitute a full point for a comma where it appears as a decimal marker.
- (iii) *References* The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

Reference to International Standard or other publication		Australian/New Zealand Standard
IEC		AS/NZS
406	Radiographic cassettes	—
522	Inherent filtration of an X-ray tube assembly	—
601	Medical electrical equipment	3200(NZS 6150) Approval and test specification—Medical electrical equipment

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IEC		AS/NZS	
601-2-7	Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	3200.2.7	Part 2.7: Particular requirements for safety—High-voltage generators of diagnostic X-ray generators
601-2-15	Part 2-15: Particular requirements for the safety of capacitor discharge X-ray generators	3200.2.15	Part 2.15: Particular requirements for safety—Capacitor discharge X-ray generators
601-2-28	Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	3200.2.28	Part 2.28: Particular requirements for safety—X-ray source assemblies and X-ray tube assemblies for medical diagnosis
601-2-29	Part 2-29: Particular requirements for the safety of radiotherapy simulators	—	
601-2-32	Part 2-32: Particular requirements for the safety of associated equipment of X-ray equipment	3200.2.32	Particular requirements for safety—Associated equipment of X-ray equipment
627	Characteristics of anti-scatter grids used in X-ray equipment	—	
637	Marking of and accompanying documents for X-ray tubes and X-ray tube assemblies for medical use	—	
658	Radiographic intensifying screens for medical use—Dimensions	—	
788	Medical radiology—Terminology	—	
878	Graphical symbols for electrical equipment in medical practice	4334	Graphical symbols for use on medical electrical equipment
ICRP			
Publication 33	Protection against ionizing radiation from external sources used in medicine	—	
Publication 34	Protection of the patient in diagnostic radiology	—	
Publication 60	Recommendations of the International Commission on Radiological Protection	—	

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First published as AS/NZS 3200.1.3:1996.

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.

AUSTRALIAN/NEW ZEALAND STANDARD

Approval and test specification—Medical electrical equipment**Part 1.3:****General requirements for safety—Collateral Standard: 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
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Information in the ACCOMPANYING DOCUMENTS	29.206.2
Requirements	29.207.1
Protection by distance	29.208.1
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	50	1,5
	up to and including 70	60	1,5
		70	1,5
	from 50	50	1,5
	up to and including 90	60	1,8
		70	2,1
		80	2,3
		90	2,5
Other dental applications	from 50	50	1,2
	up to and including 70	60	1,3
		70	1,5
	from 50	50	1,5
	up to and including 125	60	1,8
		70	2,1
		80	2,3
		90	2,5
		100	2,7
		110	3,0
		120	3,2
		125	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.