

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS Z 4701 : 1997

**General rule for medical X-ray
equipment**

ICS 11.040.50

Descriptors : radiology apparatus (medical), X-ray apparatus, medical radiography

Reference number : JIS Z 4701 : 1997 (E)

Z 4701 : 1997

Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of International Trade and Industry through deliberations at Japanese Industrial Standards Committee in accordance with the Industrial Standardization Law.

Date of Establishment: 1972-01-01

Date of Revision: 1997-07-20

Date of Public Notice in Official Gazette: 1997-07-22

Investigated by: Japanese Industrial Standards Committee

Divisional Council on Medical and Safety

JIS Z 4701 :1997, First English edition published in 1998-11

Translated and published by: Japanese Standards Association
4-1-24, Akasaka, Minato-ku, Tokyo, 107-8440 JAPAN

In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

© JSA 1998

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

Printed in Japan

General rule for medical X-ray equipment

Introduction This Japanese Industrial Standard is prepared based on IEC 601-1, *Medical electrical equipment — Part 1: General equipments for safety* published in 1988 as the second edition, **Amendment 1**, *Medical electrical equipment — Part 1: General equipments for safety* published in 1991 and IEC 601-1-3, *Medical electrical equipment — Part 1: General equipments for safety — 3. Collateral standard: General equipments for radiation protection in diagnostic X-ray equipment* published in 1994 as the first edition, for X-ray equipment corresponding to those stated in the International Standards, without modification of technical contents. However the Amendments to the above Standards are compiled and integrated in this Standard.

In IEC 601-1, all medical equipments including X-ray equipment, radiation equipment and ultrasonic equipment are specified, but in this Standard, X-ray equipment only is specified.

1 Scope This Japanese Industrial Standard specifies X-ray generator, X-ray machine assembly, X-ray image system and X-ray image processing equipment which constitute a medical X-ray equipment at a tube voltage of 10 kV to 400 kV, other associated equipment which utilizes X-ray radiated from the X-ray tube equipment and access ones thereof. However, this Standard is not applicable to therapeutic X-ray equipment in medical X-ray equipment. The items specified herein but not appropriate to a certain equipment do not apply to the equipment. Individual matters relating each equipment which constitutes medical X-ray equipment shall comply with Japanese Industrial Standard relating with each equipment (hereafter referred to as “detail specification”). The provision of the detail specification proceeds this general rules.

Remarks 1 The normative references to and the International Standards corresponding to this Standard are given in Attached Table 1.

2 In this Standard, the units and numerical values in { } are based on traditional units and given for informative reference.

2 Definitions For the purpose of this Standard, in addition to the definitions stated in JIS T 1001 and JIS Z 4005, the following principal definitions apply. Correspondence of Japanese terms and English terms is shown in Attached Table 2.

- (1) **medical X-ray equipment** This means the individual sub-assembly or a combination of X-ray generator, X-ray machine assembly, X-ray imaging system, X-ray image processing equipment, other associated equipment and their accessories for use in diagnosis (including dental purpose) or therapeutics.
- (2) **diagnostic X-ray equipment** This means the individual sub-assembly or a combination of X-ray generator, X-ray machine assembly, X-ray imaging system, X-ray image processing equipment, other associated equipment and their accessories for use in diagnosis (including dental purpose) (hereafter referred to as “X-ray equipment”).
- (3) **X-ray generator** This means a combination of X-ray source assembly, high voltage generator and their accessories (including mono-tank X-ray unit at least equipped with X-ray field limiter).

- (4) **mono-tank X-ray unit** This means a combination of a structure in which X-ray tube and high voltage generator are integrated and its X-ray control assembly; or of a structure in which X-ray tube, high voltage generator and X-ray control assembly are integrated and its accessories.
- (5) **X-ray source assembly** This means a X-ray tube assembly or a mono-tank X-ray unit at least equipped with X-ray field limiter.
- (6) **high voltage generator** This means a combination of a high voltage generating device and X-ray control assembly.
- (7) **X-ray control assembly** This means an assembly of electrical apparatus which supervise all the auxiliary functions necessary for controlling X-ray. However, components in X-ray tube circuit are included in high voltage generator.
- (8) **X-ray machine assembly** This is the generic name of radiographic/fluoroscopic table, radiographic table, supports, comprised tomography table, etc. which are in the category of associated equipment and used for diagnosis utilizing X-ray.
- (9) **radiographic/fluoroscopic table** This is an equipment, to which X-ray imaging system is equipped or attached, which positions the human body for carrying out X-ray fluoroscopy (hereafter called "fluoroscopy") and X-ray radiography (hereafter called "radiography"), accessories are included.
- (10) **radiographic table** This is an equipment which positions the human body for carrying out radiography.
- (11) **X-ray imaging system** This is the generic name of devices or apparatus for detection or observation of radiogram of a part of human body in the category of associated equipment. X-ray film cassette, the part of radiographic/fluoroscopic table corresponding thereto, etc. are included, but X-ray film, intensifying screen, anti-scatter grid, etc., are excluded.
- (12) **X-ray image processing equipment** This is an equipment, in the category of associated equipment, which carries out the processing of video signals. This is called digital radiographic equipment, digital fluoroscopic equipment and in some cases includes the detecting part of radiogram.
- (13) **associated equipment** This means the equipment which has functions other than generation and control of X-ray and is indispensable to utilization of X-ray equipment and accessories thereof.
- (14) **sub-assembly** This means an independent equipment which forms a part of X-ray equipment and has the connector with the power supply.
- (15) **equipment** In this Standard, this is the generic name of X-ray equipment, sub-assembly which constitutes X-ray equipment and associated equipment.
- (16) **protective earthing** This earthing carried out for protection against electric shock.

- (17) **functional earthing** The earthing carried out for functional purpose (normally equipotentialization of a point in control circuit).
 - (18) **long-term rating** The rating for fluoroscopic purpose.
 - (19) **short-term rating** The rating for radiographic purpose.
 - (20) **useful beam** Such a primary X-ray that its divergence is limited for diagnostic purpose. In some cases residual radiation is included in an useful beam.
 - (21) **residual radiation** This means the part of useful beam which does not enter into the effective image reception area or the useful beam which transmitted through the image reception area.
 - (22) **leakage technique factor** The X-ray loading conditions used as the reference when calculating amount of leakage X-ray per 1 h at maximum nominal voltage of X-ray tube assembly and X-ray source assembly.
 - (23) **boundary of the X-ray field** This means the locus of the points where the air kerma rate is 25 % of the average value which is obtained in such a manner that the X-ray field is divided into four, the air kerma rate⁽¹⁾ is measured at almost center of each division and the values so obtained are averaged.
- Note ⁽¹⁾ This is the air kerma rate measured in air.
- (24) **dimensions of the X-ray field** The size determined by the lengths on X axis and Y axis of the boundary of the X-ray field when the X-ray field is cut, on a plane perpendicular to the reference axis, by a straight line parallel to X-ray tube axis (X axis) and a straight line crossing at right angle (Y-axis).
 - (25) **image reception area** The part which is structured to receive the X-ray pattern at adequate time and which also has adequate processing means to display or store the information included in the X-ray pattern. In the case of X-ray image intensifier tube whose field is selectable according to this definition, the area which is electronically processing the X-ray pattern is named as the image reception area.
 - (26) **image receptor plane in X-ray image intensifier tube** The plane which includes the maximum selectable image reception area.

Therefore, the focal spot to image receptor distance does not change due to selection of visual field.

3 Classification and organization of X-ray equipment

3.1 Classification of medical X-ray equipment Unless otherwise specified medical X-ray equipment shall be classified as stated below based on the provision of 4 in JIS T 1001.

- (1) **Type of protection against electric shock** According to classification by type of protection against electric shock, this equipment is class I equipment.

- (2) **Degree of protection against electric shock** ⁽²⁾ According to classification by degree of protection against electric shock, this equipment is the equipment with B type applied part.

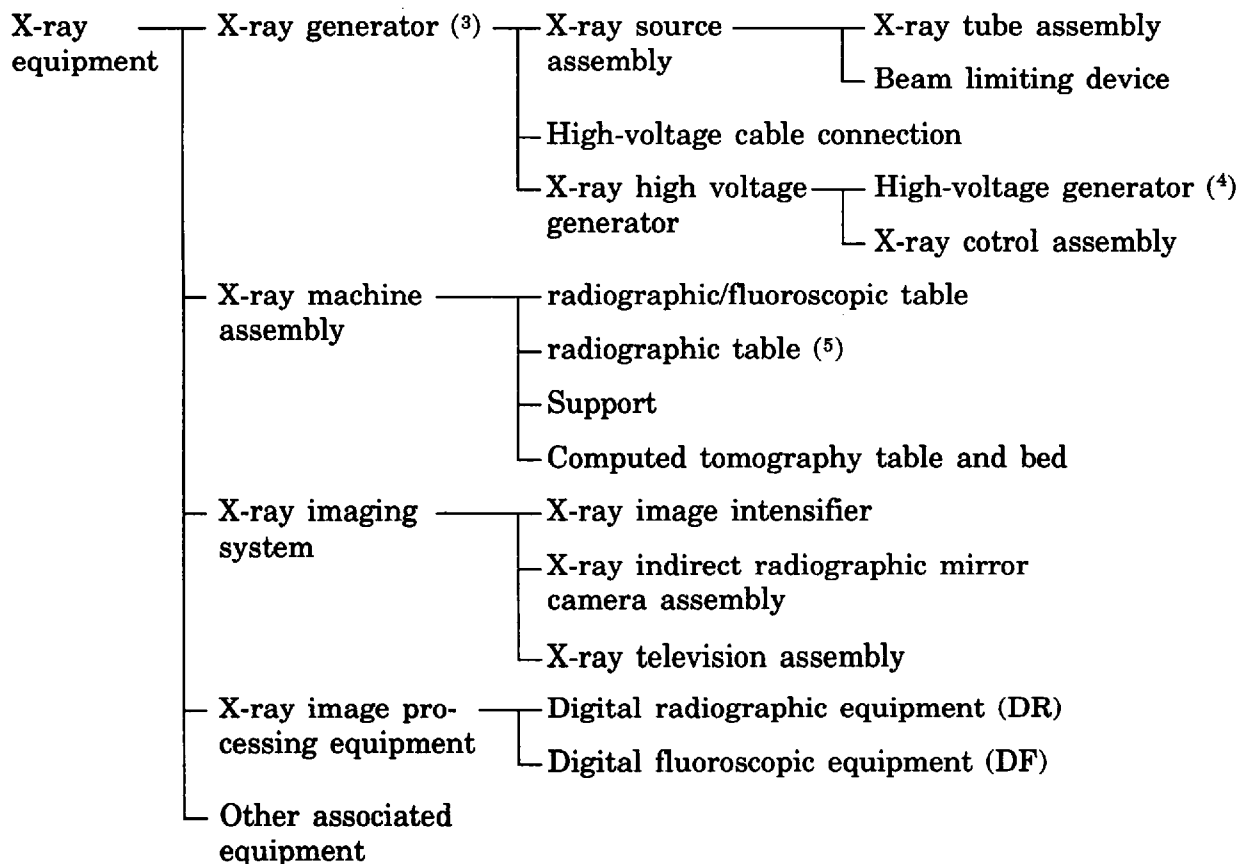
Note ⁽²⁾ The applied part may be B type, BF type or CF type.

- (3) **Degree of protection against harmful ingress of liquid** According to classification by degree of protection against harmful ingress of liquid, this equipment is ordinary equipment.

- (4) **Degree of safety of service in flammable anesthetic mixture with air or with oxygen or nitrous oxide (laughing gas), or in flammable anesthetic gas** According to classification by degree of safety of service in flammable anesthetic mixture with air or with oxygen or nitrous oxide (laughing gas), or in flammable anesthetic gas, this equipment is an equipment not suitable for service in the said gases.

- (5) **mode of operation (running)** According to classification by mode of operation (running), this equipment is continuous operating (running) with intermittent loading equipment.

3.2 Configuration of X-ray equipment X-ray equipment is configured as follows :



Notes ⁽³⁾ Mono-tank X-ray unit equipment with beam limiting device is included.

⁽⁴⁾ X-ray control assemblies for DR and RF equipment are included.

⁽⁵⁾ Radiographic table of therapeutic X-ray equipment, circulator system catheter table, etc, are included.

4 Environmental conditions and power supply

4.1 Environmental conditions Unless otherwise stated in the instruction manual the equipment shall endure transportation, storage and service under the climatic environmental conditions prescribed below.

- (1) **Transportation and storage** Transportation and storage conditions shall be as stated in 3.1 of JIS T 1001.
- (2) **Service (operation)** Service conditions shall be as stated in 3.1 of JIS T 1001.

4.2 Power supply The power supply shall comply with the following requirements :

- (1) **Rated voltage** The rated voltage shall be as stated in 3.2 of JIS T 1001.
- (2) **Rated frequency** The rated frequency shall be as stated in 3.2 of JIS T 1001.
- (3) **Impedance** The internal impedance of power supply shall be sufficiently low. The reference values relating with ratings (voltage, number of phases, frequency) and internal impedance of power supply, details of allowable fluctuations, and the reference values relating with the distribution transformer, low voltage circuit and overcurrent protector (fuse, molded-case circuit-breaker, etc) shall be as specified in the detail specification.

The instruction manual shall explain the above details.

4.3 Earthing facilities The earthing of the site where the equipment is installed shall comply with the following requirements :

- (1) The earthing terminal of the installation shall be securely connected with the wire earthed by class 3 earthing work (special class 3 earthing work, for 400 V system) determined in the ministerial order determining the technical standard for electrical installation (ministerial order of MITI number 61). This earthing terminal is the protective earthing terminal of the installation.
- (2) When it is so designed that the protective earthing wire of each equipment is connected directly with the protective earthing terminal of the installation, a potential equalization busbar which has adequate length⁽⁶⁾, enough mechanical strength, a negligible electric resistance as compared with electric resistance of earthing facilities, and a size of such degree that allows installation of earthing terminal complying with the provision of 5.6, shall be provided. The potential equalization busbar shall be securely connected with the earthing terminal of installation specified in (1).

Note (6) At installation of X-ray equipment, this potential equalization busbar shall be so arranged that earthing terminals of every associated equipment can be connected with this busbar. This point shall be stated in the instruction manual.

4.4 Cooling water When the temperature of cooling water used for an equipment is not exceeding 25 °C at its inlet port, the equipment shall not cause an abnormality.

The cooling conditions of X-ray tube assembly shall be stated in the instruction manual.

5 Protection against electric shock

5.1 Classification according to type of protection The equipment shall provide any means for protection against electric shock stated below.

- (1) **Portion of class I equipment** The accessible metal parts shall be connected with the protective earthing terminal of equipment and a means to connect the said terminal with the protective earthing terminal of installation or potential equalization busbar shall be provided, so that the accessible metal parts do not become live when the basic insulation fails. A portion of class II equipment may exist in some portions of class I equipment.
- (2) **Portion of class II equipment** The power supply circuit shall be insulated from the accessible metal parts by means of double insulation or reinforced insulation. No protective earthing means is provided, but functional earthing means may be provided in class II equipment. The portion of class II equipment shall be marked by using the graphical symbol of number 02-01 in **JIS Z 4004**.
- (3) **Internally powered equipment** A power supply having a power sufficient to operate the equipment shall be built-in the equipment. If the equipment of this type is connectable with commercial frequency power supply for charging, the equipment shall have the performances of class I equipment or class II equipment, during the charging. However, the equipment of such type that the battery is removed and then charged is excluded.

5.2 Classification according to degree of protection The equipment and its applied part are classified according to the degree of protection against electric shock shown in Table 1 in 5.4, into the equipment with B type applied part, the equipment with BF type applied part and the equipment with CF type applied part, and the classification shall be marked by using the graphical symbols in **JIS Z 4004** of the numbers 02-02, 02-03 and 02-05.

Applied parts of different degree of protection against electric shock may be provided in an equipment. In such a case the classification shall be marked on each applied part, and shall not be marked on the body of the equipment. X-ray equipment having no applied part is classified as the equipment with B type applied part.

5.3 Single fault condition The equipment shall not cause safety hazard when one of the following single fault condition occur. When a single fault condition inevitably results in another single fault condition, the two failures are considered as one single fault condition.

- (1) Single fault condition in which safety shall be verified by testing.
 - (a) Breaking of protective earthing conductor.
 - (b) Breaking of one power supply conductor (including fusion of fuse).
 - (c) Such a failure that external voltage appears on F type applied part (see III of Table 1).
 - (d) Such a failure that external voltage appears on signal input part or signal output part (see II of Table 1).

- (e) Leakage of flammable anesthetic mixture gas (only for the equipment which complies with the provision of 7.1).
 - (f) Failure of electrical component which might cause safety hazard.
 - (g) Failure of mechanical component which might cause safety hazard.
 - (h) Failure of temperature limiter.
- (2) The fault conditions stated below shall not be considered as single fault condition, because the probability of generation is very low.
- (a) Dielectric breakdown which occurs simultaneously on both of double insulation.
 - (b) Dielectric breakdown of reinforced insulation.
 - (c) Break of protective earthing wire fixed and permanently earthed.

5.4 Allowable value of continuous leakage current The equipment shall not cause continuous leakage current exceeding the appropriate value given in Table 1 under normal condition or single fault condition shown in 5.3.

In the case of portable X-ray equipment connected with and disconnected from the power supply, the earth leakage current under normal condition or single fault condition shall not exceed 2 mA, and the enclosure leakage current under such condition that protective earthing is not performed shall not exceed 2 mA.

Further additional protective earthing wire shall be provided to prevent occurrence of such single-fault condition.

Table 1 Allowable values of continuous leakage currents

Unit : mA

Current		Equipment with B type applied part		Equipment with BF type applied part		Equipment with CF type applied part	
		Normal condition	Single fault condition	Normal condition	Single fault condition	Normal condition	Single fault condition
Earth leakage current	Ordinary equipment	0.5	1 (7)	0.5	1 (7)	0.5	1 (7)
	Class II equipment (8) or mobile equipment (9)	2.5	5 (7)	2.5	5 (7)	2.5	5 (7)
	Permanently installed equipment (10)	5	10 (7)	5	10 (7)	5	10 (7)
Enclosure leakage current		0.1	0.5	0.1	0.5	0.1	0.5
Patient leakage current	I (current flows from applied part to the earth)	0.1	0.5	0.1	0.5	0.01	0.05
	II (due to voltage super- posed on signal input or output part)	—	5	—	—	—	—
	III (due to voltage super- posed on applied part)	—	—	—	5	—	0.05

Notes (7) The single fault condition concerned with earth leakage current is the break of one power supply conductor only.

- (8) The equipment which has no protective earthed accessible part, has no means for protective earthing of other equipment, and which complies with the requirement for enclosure and patient (if appropriate) leakage current.

The class II equipment means also a portion of class II equipment.

- (9) A mobile X-ray equipment or a mobile equipment employing in organic insulating materials.
- (10) The equipment specified to be permanently installed with a protective earth conductor which is electrically so connected that the connection can only be loosened with the aid of a tool and which is so fastened or otherwise so secured mechanically at a specific location that it can only be moved after the use of a tool.

Remarks 1 The allowable value shown in Table 1 is the value of d.c. or r.m.s. value of a.c. at a frequency not exceeding 1 kHz. In the case of a.c. at a frequency exceeding 1 kHz, the product of the numerical value expressing the frequency in kHz unit and the allowable value shown in Table 1 shall be taken as the allowable value. However, the limit of allowable value is 10 mA.

- 2 The allowable value shown in Table 1 applies to each equipment directly connected.
- 3 Protective earth terminal of another equipment may be connected to a protective earth terminal of stationary X-ray equipment or sub-assembly which constitutes X-ray equipment. In this case the allowable value in Table 1 is not applicable to the earth leakage current which flows between the said principal earth terminal and the protective earth terminal of the installation. However, the enclosure leakage current of the equipment shall not exceed the allowable value under single fault condition given in Table 1.

5.5 Protective means

5.5.1 Enclosure and protective covers Enclosures and protective covers shall be as stated in 7.3 of JIS T 1001.

5.5.2 Protection of high voltage part High voltage part shall be covered with a protective cover and the graphical symbol 03-01 specified in JIS Z 4004 shall be marked on the said part.

The applied part with X-ray high voltage cable connection shall be so constructed that the applied part is not removable without use of tools or shall be so interlocked that the high voltage cable is not removable unless the following requirements are satisfied :

- (1) High voltage generator is cut off from its power supply.
- (2) The capacitor in the high voltage circuit is discharged to a voltage touchable by a man and the condition is maintained.

5.5.3 Protection of power supply and other low voltage circuits Appearance of high voltage in the power supply or other low voltage circuit shall be prevented. The preventive means are exemplified below.

- (1) A shield protectively earthed is inserted between the primary winding and the secondary winding of a transformer which produces a high voltage.
- (2) A voltage limiter (e.g. arrestor) is provided on a part where a high voltage appears when the equipment connected externally is removed.
- (3) A protective cover which is not removable without the aid of a tool is provided, in addition to the enclosure, on the part where electric charge remains even the power supply is opened and notice expressing residual electric charge is indicated on the protective cover.

5.5.4 Electrical separation of applied part The electrical separation of applied part shall be as specified in 7.4 of JIS T 1001.

5.5.5 Residual charge The residual charge shall be as stated in 7.2 of JIS T 1001. However, the discharge of residual charge of radiographic capacitor of capacitor type high voltage equipment shall be as specified in the detail specification.

5.6 Protective earthing The protection earthing shall, in addition to compliance with 7.5 of JIS T 1001, be as stated below.

- (1) For a class I equipment, its accessible metal parts are connected with its protective earth terminal so that the impedance is not exceeding 0.1Ω , and a protective earth conductor which can connect the said protective earth terminal with the protective earth terminal of installation or potential equalization busbar at an impedance not exceeding 0.1Ω shall be provided.
- (2) For a class I equipment which uses power supply wires with a nominal sectional area not exceeding 10 mm^2 , a 3-core or 4-core cable including the protective earth conductor shall be used. When power supply conductors with a nominal sectional area exceeding 10 mm^2 are used, a protective earth conductor with such a sectional area that the conductor will not melt down until the instant when the overcurrent release (e.g. molded-case circuit breaker, fuse, etc.) operates if the power supply circuit short circuits with the parts protectively earthed, may be provided separately.
- (3) For a transportable equipment 3- core power supply cord shall be used and its one core shall be connected with the power supply plug as the earth conductor. In this case the impedance between the earth pin of power supply plug and accessible metal parts shall not exceed 0.2Ω .
- (4) For a transportable equipment, in addition to the protective earth conductor in the power supply cord, a separate protective earth conductor shall be provided.
- (5) The nominal sectional area of protective earth conductor and that of additional protective earth conductor shall be not less than the nominal sectional area of the power supply conductor, excluding the case stated in proviso in item (2), by taking the mechanical strength into consideration.

The color of the insulating covering shall, through its whole length, be green/yellow (stripe or spiral coloring with almost equal width for green and yellow). The above provision referring to the sectional area does not apply to the internal wiring for connection of accessible metal parts with protective earth terminal.

- (6) Any functional current other than earth leakage current shall not be passed through the protective earth conductor, additional protective earth conductor and internal wiring for protective earthing. However, special purpose X-ray source assembly to be used in intra-corporeal is excluded.

5.7 Insulation and dielectric strength

5.7.1 Insulation The insulation shall be as specified in 7.7.1 of JIS T 1001.

5.7.2 Dielectric strength The dielectric strength shall, in addition to compliance with 7.7.2 of JIS T 1001, be as stated below.

- (1) The test voltage and loading time shall be as specified in the detail specification.
- (2) For a motor equipped with a capacitor, then resonance voltage at the joint of the winding and the capacitor shall be employed as the reference voltage (U).
- (3) The reference voltage (U) of the starter circuit in rotary anode X-ray tube assembly shall be the voltage at normal rotation. If there is a resonance voltage on the way of reducing the voltage from the voltage at start to the voltage at normal rotation, the resonance voltage shall be taken.

6 Protection against mechanical hazards

6.1 Enclosure and protective covers Enclosures including any access covers forming part of them, with all components thereon, shall have strength and rigidity.

6.2 Support and immobilization of patients Equipment parts serving for support and/or immobilization of patients shall be designed and manufactured so as to minimize the risk of physical injuries and of accidental loosening of fixings.

6.3 Hand-held parts Equipment or part thereof which are hand held during normal use shall be as specified in 8.1.4 of JIS T 1001.

6.4 Portable and mobile equipment Portable and mobile equipment shall withstand the stress caused by rough handling. The details shall be as specified in the detail specification.

6.5 Moving parts Moving parts shall, in addition to compliance with 8.2 of JIS T 1001, be as follows :

- (1) Moving parts which do not need to be exposed for the operation of equipment and which, if exposed, constitute a safety hazard shall be constructed as follows :
 - (a) In the case of transportable equipment, adequate guards integrated with the equipment shall be provided.

- (b) In the case of stationary equipment, similar adequate integrated guards are provided or technical description requiring adequate guard separately shall be described in the accompanying documents.
- (2) Wire ropes, chains and bands shall either be confined so that they cannot run or jump out of their guiding devices, or a safety hazard shall be prevented by other means. Mechanical means applied for this purpose shall be removable only with the aid of a tool.
- (3) Movable parts which may cause physical injury to the patient shall be under dead man's type control⁽¹¹⁾.
- Note ⁽¹¹⁾ The dead man's type control means such a control that the circuit is closed only when the operator applies force to the switch and opened immediately when he removes the force.
- (4) Part subject to mechanical wear likely to result in a safety hazard shall easily accessible for inspection.
- (5) If an electrically produced mechanical movement could cause a safety hazard, readily identifiable and accessible means shall be provided for emergency switching of the relevant part of equipment.

Such means shall only be recognized as a safety device if the emergency situation becomes obvious to the operator and his reaction time is taken into account.

- (a) The operation of such means shall not introduce a further safety hazard nor interfere with the operation necessary to remove the original safety hazard.
- (b) Such means shall be able to break the full load current of the relevant circuit, taking into account of possible stalled motor current or the like.
- (c) Such means shall stop the equipment as a result of one single action.

6.6 Surfaces, corners and edges Surfaces, corners and edges shall be as specified in 8.3 of JIS T 1001.

6.7 Stability The stability shall, in addition to compliance with 8.4 of JIS T 1001, be as specified in the detail specification.

6.8 Grips and handles Grips and handles shall be as specified in 8.5 of JIS T 1001.

6.9 Expelled parts Expelled parts shall be as specified in 8.6 of JIS T 1001.

6.10 Suspended masses Suspended masses shall, in addition to compliance with 8.7 of JIS T 1001, be as specified in the detail specification.

7 Protection against other hazards

7.1 Protection against hazards of flammable anesthetic mixtures Protection against hazards of ignition of flammable anesthetic mixtures shall be as specified in 10 of JIS T 1001.

7.2 Protection against excessive temperatures Protection against excessive temperatures shall be as specified in 11.1 of JIS T 1001.

7.3 Fire prevention Fire prevention shall be as specified in 11.2 of JIS T 1001.

7.4 Protection against overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection Protection against overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection shall be as specified in 11.3 of JIS T 1001.

7.5 Protection of pressure vessels and parts subjected to pressure Protection of pressure vessels and parts subjected to pressure shall be as specified in 11.4 of JIS T 1001.

7.6 Protection against interruption of power supply Protection against interruption of power supply shall be as specified in 11.5 of JIS T 1001.

7.7 Protection against hazardous output Protection against hazardous output shall be as specified in 12 of JIS T 1001.

During radiation of X-ray, including such a case that the patient is not irradiated, yellow (including orange) display light calling attention shall be indicated.

8 Protection against hazards from unwanted or excessive radiation

8.1 Radiation quality

8.1.1 Limitation of X-ray tube voltage range in dental X-ray equipment The setting range of X-ray tube voltage in normal service of a dental X-ray equipment shall be limited within the values specified in Table 2, and the values shall be written in the accompanying documents.

**Table 2 Setting voltage restrictions
in dental X-ray equipment**

Unit : kV

Division of dental use	Highest permitted nominal X-ray tube voltage	Lowest permitted X-ray tube voltage for normal use
All applications	125	50 ⁽¹³⁾
Application using an intra-oral X ray image receptor ⁽¹²⁾	90	50 ⁽¹³⁾
Cephalometric applications	125	60

Notes ⁽¹²⁾ In dental application, this means films, imaging plate, etc.

⁽¹³⁾ A voltage not less than 60 kV is desirable from the view point of X-ray protection.

8.1.2 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 be not less than the values given in Table 3.

Table 3 Half-value layers in X-ray equipment

Application	Tube voltage (V)		Minimum permissible first half-value layer mmAl
	Operating range for normal use kV	Selected value ⁽¹⁴⁾ kV	
Special low tube voltage radiography	≤ 50 ⁽¹³⁾	<30	— ⁽¹⁵⁾
		30	0.3
		40	0.4
		50	0.5
Application using an intra-oral X ray image receptor ⁽¹²⁾	50 ⁽¹³⁾ $\leq V \leq 70$	50	1.5
		60	1.5
		70	1.5
	50 ⁽¹³⁾ $\leq V \leq 90$	50	1.5
		60	1.8
		70	2.1
		80	2.3
		90	2.5
Cephalometric applications	50 ⁽¹³⁾ $\leq V \leq 70$	50	1.2
		60	1.3
		70	1.5
Cephalometric applications	50 ⁽¹³⁾ $\leq V \leq 125$	50	1.5
		60	1.8
		70	2.1
		80	2.3
		90	2.5
		100	2.7
		110	3.0
		120	3.2
Other applications	$30 \leq V$	125	3.3
		<50	— ⁽¹⁵⁾
		50	1.5
		60	1.8
		70	2.1
		80	2.3
		90	2.5
		100	2.7
		110	3.0
		120	3.2
		130	3.5
		140	3.8
		150	4.1
		>150	— ⁽¹⁵⁾

Notes ⁽¹⁴⁾ Half-value layer not stated in the above table shall be obtained by linear interpolation.

⁽¹⁵⁾ To be obtained by linear extrapolation.

8.1.3 Filtration in X-ray tube assemblies In respect of filtration, X-ray tube assemblies shall comply with the following requirements :

- (1) In X-ray tube assembly, the quantity equivalent filtration arising from materials that are irremovable in normal use shall be not less than 0.5 mmAl.

X-ray tube assembly specified for mammography with a nominal X-ray tube voltage not exceeding 50 kV is excluded.

- (2) Fixed added filters shall not be removable without the use of tools.
- (3) The accompanying documents shall include instructions for attaining the total filtration required to comply with 8.1.5, in respect to the X-ray equipment concerned. For particular applications, instruction shall be entered in assembling instructions.

8.1.4 Filtration in X-ray source assemblies In respect of filtration, X-ray source assemblies shall comply with the following requirements :

- (1) 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 be indentifiable when in position for normal use.
- (2) If the presence of a selectable added filter is necessary in order to attain the requirements for total filtration in X-ray equipment specified in 8.1.5, means shall be provided to enable the presence of appropriate added filter to be detected by the control assembly.
- (3) The accompanying documents shall include instructions for attaining the total filtration required to comply with 8.1.5, in respect of the X-ray equipment concerned. For particular applications, instructions shall be entered in assembling instructions.

8.1.5 Total filtration in X-ray equipment In X-ray equipment, the total filtration arising from materials in the X-ray beam shall comply with the following requirements :

- (1) In X-ray equipment specified exclusively for mammography with a nominal X-ray tube voltage not exceeding 50 kV, while configured to operate with a molybdenum target, the filtration shall be not less than the filtration afforded by a molybdenum edge filter ⁽¹⁶⁾ of 0.03 mmMo thickness.

Note ⁽¹⁶⁾ This is a filter which shows discontinuity of absorption characteristic within the range of service tube voltages, and molybdenum, rhodium, etc. are in this category.

- (2) In X-ray equipment specified exclusively for mammography with a nominal X-ray tube voltage not exceeding 50 kV, while configured to operate with a target of a material other than molybdenum, the filtration shall comply with 8.1.2, in combination with the material of the target.

- (3) In X-ray equipment specified exclusively for mammography with a nominal X-ray tube voltage not exceeding 70 kV, the quality equivalent filtration shall be not less than 1.5 mmAl.
- (4) The X-ray equipment not included above, the quality equivalent filtration shall be not less than 2.5 mmAl.
- (5) The additional filtration originally present in an X-ray source assembly forming an integral part of the X-ray equipment may be reduced to the value required above, provided that the requirements of 8.1.2 are complied with.

8.1.6 Indication of filter properties Filter properties shall be indicated on X-ray equipment as stated in the following items :

- (1) X-ray tube assemblies shall be marked with the quality equivalent filtration from irremovable materials or with the thickness of the materials concerned, together with their chemical symbols.
- (2) Added filters [including edge filters⁽¹⁶⁾] shall be marked so that the thickness and chemical symbol of each material employed can be identified. If the chemical symbol can not be simply indicated, the indication may be made in the converted aluminum equivalent. If the marking is impossible, the data may be entered in the accompanying documents.
- (3) For all added filters [including edge filters⁽¹⁶⁾], the accompanying documents shall state the quality equivalent filtration in thickness of aluminium or another suitable reference material, together with the radiation quality used for its determination. Any value of quality equipment filtration given for an edge filter shall relate to the low-energy side of discontinuity.
- (4) Materials in the X-ray beam incident to the patient, other than added filters and irremovable materials in X-ray tube assemblies, shall be marked to show the quality equivalent filtration in thickness of alminum together with the radiation quality used for its determination. These data may be entered in the accompanying documents. Such materials need not be marked if the quality equivalent filtration from materials other than added filters [including edge filters⁽¹⁶⁾] and irremovable materials in X-ray tube assembly is not exceeding 0.2 mmAl and they are not intended to be taken into account as part of the total filtration required for compliance with 8.1.5.

8.2 Limitation and indication of extent of X-ray beam

8.2.1 Enclosure of X-ray tubes No X-ray tubes shall be utilized unless mounted in an X-ray tube housing to which a beam limiting device can be fitted.

8.2.2 Limiting of useful beam An X-ray tube assembly shall not have a radiation aperture larger than is needed to provided the largest X-ray beam required for its application. If necessary, the radiation aperture shall be restricted to the appropriate size by means of a fixed-size diaphragm, fitted as close as practicable to the focal spot.

8.2.3 Confinement of extra-focal X-ray X-ray source assembly employing rotating anode X-ray tubes shall be so constructed that the extra-focal X-ray that passes through the aperture shall not extend more than 15 cm outside the boundary of the largest selectable X-ray field on a plain (normal to the reference axis) at 1 m from the focal spot. However, X-ray equipments for mammography and for stereography are excluded.

Remarks: Zone of extra-focal X-ray is obtained by means of geometric construction (see Attached Fig. 1).

8.2.4 X-ray beam limitation in X-ray equipment In X-ray equipment, the extent of the X-ray beam shall be limited by one or more of the following means :

- (1) In X-ray equipment specified solely for radiography with a single image reception area at a fixed focal spot to image receptor distance, the beam shall be limited by means of a fixed beam limiting device having a radiation aperture of a single fixed size.
- (2) In X-ray equipment specified for dental panoramic tomography with an extra-oral X-ray source assembly, the beam shall be limited by means of a beam limiting device that prevents the X-ray beam from falling outside the boundary of the X-ray image receptor.
- (3) In X-ray equipment specified for indirect radioscopy during surgery at a fixed focal spot to image receptor distance and having an image reception area not exceeding 300 cm², the beam shall be limited by means enabling the X-ray field at the image receptor plane to be reduced to 125 cm² or less.
- (4) In X-ray equipment in which various fixed size beam limiting device is selectable, the beam shall be limited by providing interchangeable or selectable beam limiting device.
- (5) The beam shall be limited by means of a beam limiting device enabling the extent of the X-ray beam to be adjusted within the range of normal use. The adjusting means may be done manually or automatically and shall have the following characteristics :
 - (a) The minimum selectable size of the X-ray field shall not exceed 5 cm in length and width in a plane normal to the reference axis at a distance of 1 m from the focal spot.
 - (b) If the adjustment is stopwise, selectable steps shall not exceed 1 cm in the length and width of the X-ray field, in a plane normal to the reference axis at a distance of 1 m from the focal spot.
 - (c) If the adjustment is automatic means, the operation of which shall be described in the instruction for use, enabling the operator to reduce the size of the X-ray field to the minimum required in (a) above, while not permitting the operator to increase the size beyond that currently selected by the automatic mechanism, shall be provided. Where automatic adjustment is provided, the instructions for use shall contain details of a method by which its operation can be checked and shall describe the method by which the size of the X-ray field can be reduced, as required.