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**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)

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.

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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).