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Australian Standard 2398—1980

FIXED DIAGNOSTIC X-RAY EQUIPMENT — DESIGN, CONSTRUCTION AND INSTALLATION — SAFETY REQUIREMENTS

STANDARDS ASSOCIATION OF AUSTRALIA
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THE FOLLOWING SCIENTIFIC, INDUSTRIAL AND GOVERNMENTAL ORGANIZATIONS and departments were officially represented on the committee entrusted with the preparation of this standard:

Australasian Institute of Radiography
Australian Federation for Medical and Biological Engineering
Australian Medical Association
Australian Radiation Laboratory, Victoria
Australian Society of Anaesthetists
Confederation of Australian Industry
Department of Defence
Department of Health
Department of Health, Qld
Department of Productivity
Department of Public Works, N.S.W.
Department of Veterans' Affairs
Health Commission of New South Wales
Health Services Department, Tasmania
Hospitals and Charities Commission of Victoria
Hospital Electronic Engineers
Institute of Hospital Engineers
Institution of Biomedical Engineering (Austr[illegible])
Medical Department, W.A.
Royal Australasian College of Physician[illegible]
Royal Australasian College of Surg[illegible]ns
State X-ray Laboratory, W.A.
State X-ray Laboratory, S.A

Also represented on the c[illegible]mittee were hospital biomedical engineers and Committee EL/2, Elec[illegible]ric[illegible] A[illegible]provals Standards.

This standard pre[illegible]ed by Committee EL/18, Electromedical Equipment, was approved o[illegible] b[illegible]alf of the Council of the Standards Association of Australia on 29 Se[illegible]ten[illegible]er 1980, and was published on 1 December 1980.

To [illegible]ep abreast of progress in industry, Australian standards are subject to continuous review and are kept up-to-date by the issue of amendments or new editions as necessary. It is important therefore that standards users ensure that their standards are up-to-date. Full details of all SAA publications will be found in the Annual List of Australian Standards; these details are supplemented by monthly listings in the SAA journal 'The Australian Standard'. Information on the Annual List and 'The Australian Standard' may be obtained from any sales office of the Association, where details are also available of the current status of individual standards. Suggestions for improvements to published standards, addressed to the head office of the Association, are welcomed.

This standard was issued in draft form for public review as DR 79006.

AUSTRALIAN STANDARD

FIXED DIAGNOSTIC X-RAY EQUIPMENT — DESIGN, CONSTRUCTION AND INSTALLATION — SAFETY REQUIREMENTS

AS 2398—1980

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PREFACE

This standard was prepared by Committee EL/18/10 under the supervision of the Association's Committee on Electromedical Equipment, in an endeavour to establish mechanical, electrical and radiation safety levels acceptable to the community for X-ray equipment used for diagnostic and medical purposes.

The standard is one of a series of electromedical standards issued by the Association, covering safety matters and conditions necessary in environments where electromedical appliances are used for the purpose of diagnosis and for the treatment of patients.

This standard is intended for use with fixed radiological installations with a rated output of 10 kV (peak) to 400 kV (peak) but does not apply to dental and mobile medical X-ray machines for which reference should be made to AS 3201.5. X-ray machines used for therapeutic purposes are not covered in this standard.

NOTE: It should be noted that for electromedical equipment (which is not yet prescribed), statutory and supply authorities may require compliance with local regulations. For this reason, voluntary examination schemes are functioning under the supervision of these authorities.

The standard describes the design and construction requirements of X-ray equipment and associated equipment and sets out the measures to be taken to ensure the safety of the mechanical and electrical installations.

It details the necessary measures to be taken to protect patients and staff against execessive and/or harmful-radiations.

This standard also includes the safety requirements to be implemented by designers, manufacturers, suppliers and users of fixed diagnostic X-ray equipment by—

(a) setting out specific requirements for the design, construction, installation and modus operandi of fixed diagnostic X-ray equipment; and

(b) indicating the limits of leakage radiation.

NOTE: Committee EL/18/10 is in the process of developing guidelines for safe practices in the use of radiological and auxiliary equipment and expects a public review draft to be available at the time of publication of this standard. These guidelines should be consulted and studied in conjunction with the safety measures provided for in this standard.
In cases where operational procedures are involved, explanatory notes on recommended practices and/or procedures are also given.

Following the publication of AS 1000—1979, The International System of Units (SI) and Its Application, the values of exposure in this standard are in SI units. In response to a number of requests received during the public review period of the standard, the former non-SI units have been included in a glossary of SI terms and values in Appendix B. The contents of this Appendix may be of assistance in the conversion process and is in deference to entrenched practices.

In the preparation of this standard, reference was made to the following documents:

AS 3201.5 Dental and Mobile Medical X-ray Machines

International Electrotechnical Commission (IEC) Publication 407 (1973) Radiation Protection in Medical X-ray Equipment — 10 kV to 400 kV

International Commission on Radiological Protection (ICRP)
Publication No 9 and 15 Recommendations of the ICRP
Publication No 15 and 21 Protection Against Ionizing Radiation from External Sources
Publication No 16 Protection of the Patient in X-ray Diagnosis

National Health and Medical Research Council (NH&MRC) Recommended Radiation Protection Standards for Individuals Exposed to Ionizing Radiation (1980)

Acknowledgement is made of the assistance received from these sources.

This standard makes reference to the following Australian standards:

AS 1656	Steel Wire Ropes (Other Than for Mining Purposes)
AS 1939	Classification of Degrees of Protection Provided by Enclosures for Electrical Equipment
AS 3000, Part 1	SAA Wiring Rules
AS 3003	SAA Code for Electrical Installations in Electromedical Treatment Areas
AS 3200	Approval and Test Specification for Electromedical Equipment — General Requirements
AS C100	Approval and Test Specification for Definitions and General Requirements for Electrical Materials and Equipment
AS MB 1	SAA Steel Wire Rope Manual*
AS	Safe Radiological Practices†

* In course of revision and issued as DR 79061, Application of Steel Wire Rope, and DR 79062, Glossary of Terms for Lifting Tackle.

† In course of preparation.

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FOREWORD

Although the protective measures specified in this standard as forming an integral part of the equipment will if properly used minimize radiation exposure of the patient, they will not by themselves be sufficient for protection of the radiological staff and the occupants of surrounding areas.

Additional protective measures, such as structural shielding and the wearing of protective clothing which will minimize radiation from exposure of the patient, will normally be required. These additional requirements are usually unique to each installation since they are affected by work load and occupancy factor, and thus only measurements or estimates of radiation exposure to personnel, patients and other persons necessarily present will give information about any additional protection required.

In the need to limit the undesirable effects of X-radiation and to achieve the desired results in diagnostic examinations, a radiologist has the responsibility of continually considering the benefits to the patients against the risks of exposure to radiation. By applying appropriate X-ray technology he can achieve the required safety levels. The need for a considerable effort at all stages of the design, construction and installation of diagnostic X-ray equipment and the operation of such equipment is required for there is no such thing as absolute safety in the use of X-radiation.

It should be considered that the implementation of safety measures, which are normally established by statistical methods and are of acceptable levels, will provide the limitations above which the occurring detrimental effects on human beings are not acceptable.

For existing X-ray installations where additional work is being carried out in order to comply with safety measures set out in this standard, the following are required:

(a) The additional work should be considered in detail, so that design changes will not render the equipment unsafe.

(b) The addition of electrical circuits should not nullify the original earthing requirements prescribed in this standard.

(c) The maintenance of good workmanship is necessary.

SECTION 1. SCOPE, APPLICATION AND DEFINITIONS

1.1 SCOPE. This standard prescribes safety requirements, with particular reference to design, construction and installation, for fixed diagnostic X-ray equipment that operates at rated output voltages from 10 kV (peak) to 400 kV (peak).

1.2 APPLICATION. The standard is intended for use by persons having knowledge of radiation hazards and methods of radiation protection, and shall be read in conjunction with AS 3200, AS C100, and AS ....*.

Electrical equipment and mechanical components and parts which are incorporated in X-ray equipment and its accessories, shall comply with the relevant requirements of the appropriate standards.

1.3 DEFINITIONS. For the purpose of the standard, the relevant definitions in AS 3200 and AS C100, except as varied herein and where out of context, and the following definitions apply.

1.3.1 Collimators.

1.3.1.1 *Collimator* — a fixed or adjustable device to limit the useful beam to specific dimensions.

1.3.1.2 *Light beam collimator* — a fixed or adjustable device to limit the useful beam to specific dimensions indicated by a light beam emitted from the collimator.

1.3.2 Documents.

1.3.2.1 *Accompanying documents* — documents accompanying a radiological installation or accessories, containing all important information for the user, in particular that relevant to safety.

1.3.2.2 *Instruction documents* — those parts of accompanying documents giving the necessary detailed information on the equipment to enable the user to operate the equipment properly and safely.

1.3.3 Dose.

1.3.3.1 *Dose equivalent* (*H*) — the product of *D*, *Q*, and *N*, at the point of interest in tissue, where *D* is the absorbed dose, *Q* is the quality factor and *N* is the product of any other modifying factors.

The unit of dose equivalent is the sievert (Sv).

1.3.4 Exposure.

1.3.4.1 *Exposure* — the actuation of X-ray equipment producing radiation.

1.3.4.2 *Exposure* (*X*) — quantity for the measurement of electric charge produced by ionizing radiation in air, determined as the quotient of d*Q* by d*m*, where d*Q* is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (positrons and negatrons) liberated by photons in a volume element of air having a mass d*m* are completely stopped in air.

The unit of exposure is the coulomb per kilogram (C/kg).

1.3.4.3 *Exposure rate* ($\dot{X}$) — quantity for the measurement of exposure in time, determined as the quotient of d*X* by d*t*, where d*X* is the increment of exposure during a time interval d*t*.

The unit of exposure rate is the coulomb per kilogram second (C/kg.s).

1.3.5 Filtration.

1.3.5.1 *Filtration* — modification of the spectral distribution of an X-ray beam as it passes through matter, due to the differential absorption of the less energetic photons.

1.3.5.2 *Added filtration* — quantity indicating the filtration effected by added (metallic) filters in the useful beam, but excluding inherent filtration.

1.3.5.3 *Inherent filtration* — the filtration effected by the irremovable materials of an X-ray tube assembly, *i.e. glass, oil and port seal,* through which the radiation beam passes before emerging from the X-ray tube assembly. It is expressed in thickness of reference material which, at a specified potential difference and waveform, gives the same radiation quality in terms of half-value layer.

1.3.5.4 *Total filtration* — the total of inherent filtration and added filtration between the radiation source and the patient or a defined plane.

1.3.5.5 *Lead equivalent* — the thickness of lead effecting the same attenuation of a beam of a specified radiation quality as the material under consideration.

1.3.6 Radiation.

1.3.6.1 *Radiation* — energy propagated through space or through a material medium in the form of electromagnetic waves or in the form of kinetic energy of particles.

1.3.6.2 *Half-value layer* — the thickness of specified material which reduces the exposure rate of a given X-ray beam to half its original value.

1.3.6.3 *Ionizing radiation* — photons or particles which, either directly or indirectly, produce ionization in matter.

1.3.6.4 *Leakage radiation* — ionizing radiation transmitted through the protective shielding of a radiation source.

1.3.6.5 *Radiation quality* — a characteristic of radiation determined by its spectral distribution which controls its penetration. For an X-ray beam, it depends on the magnitude and waveform of the tube potential difference and the amount of filtration and is described, in part, by its half-value layer.

* AS . . ., Safe Radiological Practices (in course of preparation).