MEDICAL EQUIPMENT / IN FORCE

Type approval of diagnostic X-ray machines: BIS certification mark and AERB safety testing

Each make and model of diagnostic X-ray unit needs the BIS certification mark under IS 7620 and AERB radiation safety testing before type approval.

THIS RECORD IS A letter of the Atomic Energy Regulatory Board, Radiological Protection Division, dated October 10, 1994, addressed to manufacturers of diagnostic X-ray machines in the country, on the subject of type approval of diagnostic X-ray machines.

STANDARDS 1

IS 7620 (Part 1)

KEY FACTS

ORDER

Type Approval of Diagnostic X-ray Machines

WHERE IT STANDS

In force

REFERENCES

AERB/443/39 MDX/3509/94 In force

Type approval of diagnostic X-ray machines: BIS certification mark and AERB safety testing

Type Approval of Diagnostic X-ray Machines · Atomic Energy Regulatory Board (Radiological Protection Division)

This record is a letter of the Atomic Energy Regulatory Board, Radiological Protection Division, dated October 10, 1994, addressed to manufacturers of diagnostic X-ray machines in the country, on the subject of type approval of diagnostic X-ray machines.

The letter states that each make and model of X-ray unit must bear the certification mark of the Bureau of Indian Standards, granted on demonstration of conformance with IS 7620, and that equipment bearing the mark will be further tested by the Board for compliance with radiation safety requirements. Equipment without the BIS certification will not be considered for type approval, and equipment without type approval is not to be supplied to users or used for radiological examination of humans.

Manufacturers must give the user a certificate of the quality assurance tests carried out after installation at the user's premises, repeat the tests whenever the equipment is serviced or repaired, and protect their workers against radiation exposure, entrusting that responsibility to a qualified and trained person approved by the competent authority under the Radiation Protection Rules, 1971. Formats for the type approval application, the quality assurance test report and the approval of a radiological safety officer are attached. Manufacturers were asked to comply at the earliest, and not later than a date in 1995.

Order	Type Approval of Diagnostic X-ray Machines
Issued by	Atomic Energy Regulatory Board (Radiological Protection Division)
Product group	Medical Equipment
Where it stands	In force
What it requires	Each make and model of diagnostic X-ray unit manufactured in the country must bear the certification mark of the Bureau of Indian Standards, granted on demonstration of conformance with IS 7620, and is then tested by the Atomic Energy Regulatory Board for compliance with radiation safety requirements. Equipment without the BIS certification will not be considered for type approval, and equipment without type approval must not be supplied to users or used for radiological examination of humans.
Enforcement	Type approval is granted by the Competent Authority; the Atomic Energy Regulatory Board tests equipment bearing the BIS

certification mark for compliance with radiation safety requirements.

The products and their standards

Product	Indian Standard
Diagnostic X-ray machines (each make and model of X-ray unit)	IS 7620 (Part 1)

Every notification on this order

Date	Notification	Status	What it did
January 31, 2001	AERB/443/39 MDX/3509/94 PDF, 1.1 MB	In force	A letter of the Atomic Energy Regulatory Board, Radiological Protection Division, dated October 10, 1994, on type approval of diagnostic X-ray machines, requiring the BIS certification mark and AERB radiation safety testing before type approval, quality assurance test certificates after installation and after each service or repair, and radiation protection of workers.

Each notification is linked, as a PDF, in the list above.

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