7/2

परमाणु ऊर्जा नियामक परिषद
ENERGY REGULATORY BOARD

AERB/443/39/MDx/3503/94, Oct 94

The format of application for approval of radiological safety officer (RSO) is given as attachment-III.

The manufacturers of x-ray machines in the country are required to comply with the above stipulations at the earliest but not later than December 31, 1995.

(I.S. Sundara Rao)

Attachments:

1. The format Application for Type Approval of Diagnostic X-ray units.
2. The format of Quality Assurance (QA) tests on Diagnostic X-ray units.
3. The format of Application for approval of radiological safety officer Level-I

Manufacturers/vendors of diagnostic x-ray equipment,

: ATOMERG
: (022) 551 21
50 22
551 32 12
551 30 79
551 9 09

VIKRAM SARABHAI BHAVAN,
4TH FLOOR, NORTH WING,
ANUSHAKTINAGAR
BOMBAY-400 094

GOVERNMENT OF INDIA
ATOMIC ENERGY REGULATORY BOARD

Radiological Protection Division

S. Sundara Rao,
Director and Head, RPD.

43/39/MDX/3509/94

October 10, 1994

Sub: Type Approval of Diagnostic X-ray Machines

The manufacturers of diagnostic X-ray machines in the country are hereby informed that each make / model of x-ray unit manufactured by them shall bear a certification mark of the Bureau of Indian Standards (BIS) issued by BIS upon demonstration of conformance with IS: 7620 Parts 1 & 2 for electrical, mechanical and non-radiological safety of the x-ray unit.

The manufactured equipment bearing the BIS certification mark will be further tested by AERB for certification of compliance with Radiation Safety requirements in accordance with IS: 7620 Medical Electrical Equipment - Diagnostic X-ray Equipments (Part 3), 1991 and AERB Safety Code for Medical Diagnostic X-ray Equipments and Installations, AERB/SC/MED-1, 1986.

The format of application for obtaining Type Approval from AERB is given as attachment-I.

The manufactured equipment without the BIS certification will not be considered for type approval by the Competent Authority.

Equipment without type approval shall not be supplied to users and shall not be used for radiological examination of humans.

The manufacturers of diagnostic x-ray machines are required to provide to the user a certificate stating the results of QA tests carried out on the diagnostic x-ray unit after installation at the user's premises. Such tests shall be repeated whenever the equipment is serviced or repaired and the results shall be entered by the service engineer in the certificate issued to the user. The manufacturers and service engineers shall use an appropriate Quality assurance (QA) kit for carrying out the relevant tests.

The format of reporting the QA test results is given as attachment-II.

The manufacturers of diagnostic X-ray units are required to ensure adequate protection of its workers against radiation exposure during manufacture, testing, installation, commissioning, servicing and maintenance of x-ray units. The manufacturers shall entrust the responsibility of ensuring radiation protection to a suitably qualified and trained person in their employment, with the approval of the competent authority in accordance with Rule 12 of the Radiation Protection Rules, (1971).

-104-