GUIDELINES FOR MANUFACTURERS AND SUPPLIERS OF MEDICAL DIAGNOSTIC X-RAY EQUIPMENT

MANUFACTURERS

1) Licence for commercial production of X-Ray Equipment

The pre-requisites for obtaining Licence are:

a) Layout and shielding shall be as per AERB requirements

b) Availability of qualified and trained service engineers, and approved Radiological Safety Officer with Personnel Monitoring Services

c) Availability of necessary quality assurance (QA) equipment, survey meter and other associated equipment for performance evaluation of diagnostic x-ray equipment

d) Personnel protective accessories (such as protective aprons)

e) For RSO approval Completely filled, duly signed and stamped application form (AERB/RSD/RSO/APP)

a. Completely filled duly signed and stamped application form (AERB/RSD/MDX/Manuf/CP-EQUIP and AERB/RSD/MDX/Manuf/CP-TUBE) shall be submitted to AERB along with enclosures as per the application form as applicable.

2) Type Approval

Manufactures have to obtain Type Approval as per the table given below

3) Monitoring of Licensed manufacturer by AERB:

i) Periodic reporting to AERB: Manufactures shall submit quarterly report of activities carried out to AERB in the prescribed format

ii) Maintenance of records for Regulatory inspection

a) Quarterly reports submitted to AERB
b) A copy of valid Licence issued by AERB
c) List of authorized suppliers
d) Calibration records of QA and radiation survey equipments.

iii) Renewal of License: Initial Licence will be valid for a period of 5 years, which needs to be renewed before expiry. The application form for renewal of authorization shall be submitted by the licencee two months prior to the expiry . Renewal of Licence will be issued based on satisfactory performance during the period of Licence.

iv) Cancellation/Suspension of Licence: In case of violations of Terms and Conditions of the Authorization, AERB may initiate appropriate regulatory action against the Agency, which may include fine and/or suspension /cancellation of authorization.

SUPPLIERS

Authorisation for Supply of Diagnostic X-Ray Equipment

The pre-requisites for obtaining Authorisation are:

a) Availability of qualified and trained service engineers, and approved Radiological Safety Officer with Personnel Monitoring Services

b) Availability of necessary quality assurance (QA) equipment, survey meter and other associated equipment for performance evaluation of diagnostic x-ray equipment

c) Personnel protective accessories (such as protective aprons)

d) For RSO approval completely filled, duly signed and stamped application form (AERB/RSD/RSO/APP)

Completely filled duly signed and stamped application form shall be AERB/RSD/MDX/Supplier submitted to AERB along with enclosures as per the application form.

2) Type Approval

Suppliers have to obtain Type Approval as per the table given below
Renewal needs to be obtained within a month of expiry of the Type Approval certificate.

3) **Monitoring of Authorised Suppliers by AERB:**

i) Periodic reporting to AERB: Manufactures shall submit quarterly report of activities carried out to AERB in the prescribed format

ii) Maintenance of records for Regulatory inspection

a) Quarterly reports submitted to AERB
b) A copy of valid Authorisation issued by AERB
c) OEM authorisation
d) Calibration records of QA and radiation survey equipments.
e) Authenticated copies of Installation report, Acceptance tests and radiation survey report records of equipment supplied to end-users. (Can be maintained for period of two years)

iii) Renewal of Authorisation: Initial Authorisation will be valid for a period of 5 years, which needs to be renewed before expiry. The application form for renewal of authorization shall be submitted by the licencee two months prior to the expiry . Renewal of Licence will be issued based on satisfactory performance during the period of Licence.

iv) Cancellation/Suspension of Licence: In case of violations of Terms and Conditions of the Authorization, AERB may initiate appropriate regulatory action against the Agency, which may include fine and/or suspension /cancellation of authorization.

REQUIREMENTS FOR TYPE APPROVAL OF EQUIPMENT		
Type of X-ray equipment	**NOC/Type Approval**	**Conditions**
Computed Tomography	• **Application form : AERB/RSD/ MDX-CT-CATH/TA** • Copy of BIS certificate for local manufacturers • Copy of IEC certificate • Product technical catalogue • X-Ray tube catalogue • Detector/Image intensifier tube catalogue • QA report (as per AERB/RSD/MDX-CT/QAR/2010) • Manual for installation, operation, servicing, maintenance, dismantling and decommissioning • QA Manual covering design and manufacturing aspects	1. Manufacturers should submit Periodic Safety Report annually to AERB. 2. Type approved equipment should be installed in the approved premises of a facility. 3. Acceptance Tests (QA) should be performed at each premises after installation. 4. Manufacturer shall ensure that the user obtains the requisite regulatory consents from AERB for routine operation of RGE. 5. List of the users to whom the Type Approved equipment is supplied shall be submitted to AERB every Quarter.
	In case of NOC for import equipment (In addition to the above requirements) Declaration from the original manufacturer/ designer authorizing the local supplier/vendor for marketing the unit with	
Interventional Radiology (Cath- Lab)	• **Application form : AERB/RSD/ MDX-CT-CATH/TA** • QA report (as per AERB/RSD/MDX-IR/QAR/2010) • **All requirements as above**	
X-Ray units	• **Application form: AERB/RSD/MDX/TA** • QA report (as per AERB/RSD/MDX-IR/QAR/2010 • **All requirements as above**	
Mammography	• **Application form: AERB/RSD/MDX/TA** • QA report (as per AERB/RSD/MDX-MAMMO/QAR/2010) • **All requirements as above**	