REGULATORY REQUIREMENTS FOR SUPPLIERS OF X-RAY EQUIPMENT AND X-RAY TUBES

The supplier shall obtain the requisite recognition to supply x-ray equipment and x-ray tubes. In case the supplier intends to market equipment of foreign make, he shall obtain NOC for import, for the prototype, from the competent authority and demonstrate it for Type Approval, prior to marketing in the country.

As per AE (RP) R, 2004, Head of the institute is identified as Employer and Licencee under AE (RP)R by default. Employer may designate any of his employees as Licensee under AE (RP) R. The employer and Licencee shall fulfill the responsibilities as specified in this Code.

I) Pre- requisites for obtaining Authorization for supply of X-Ray Equipment

- a) **OEM Authorisation:** Supplier shall obtain an OEM authorisation, for all models(equipment and tubes) proposed to be supplied.
- b) **Radiation testing facility for demonstration of Type Approval**: A testing facility, if available, shall be located away from other working areas not related to radiation testing. The shielding and space requirements to the testing facility shall be such that the dose limits for radiation workers and public, as prescribed by competent authority are met with. The facility shall be equipped with required protective accessories. A warning placard shall be displayed outside the testing facility.
- c) **Staff requirements**: Suppliers shall employ qualified and trained personnel for radiation testing, QA, and servicing of diagnostic x-ray equipment. The minimum qualification and training shall be as prescribed by regulatory body.
- d) **Radiological Safety Officer (RSO):** In case supplier has radiation testing facility, shall have Radiological Safety Officer (RSO) approved by the competent authority. The minimum qualification and training shall be as prescribed by regulatory body.

II) Conditions of Supplier Authorization

- a) The AERB recognition will be valid for the duration and models for which OEM authorisation exists.
- b) The supplier shall adhere to requirements prescribed in this code
- c) For procurement/import of x-ray tube(s), the supplier shall obtain procurement permission from the competent authority.
- d) The supplier shall adhere to any other conditions stipulated by competent authority from time to time.
- f) The supplier shall supply to the customer (utility) only AERB Type approved models and

- on installation of the x-ray equipment, shall carry out acceptance testing/quality assurance as part of commissioning of x-ray equipment;
- shall provide servicing and maintenance during the useful life-time of diagnostic x-ray equipment;
- shall ensure that the customer has the requisite radiation protection devices such as protective barrier, protective apron, couch hanging lead equivalent rubber flaps, as applicable. In case of computed tomography equipment, the supplier shall provide the required phantoms for performance checks.
- shall submit after every installation, an installation report to the regulatory body in the specified format.
- shall check for layout and shielding adequacy at the customer site.
- shall carry out dismantling/ decommissioning of equipment at customer end and inform AERB on further action.
- g) Any other conditions stipulated by competent authority from time to time.

III) Type Approval/ No Objection Certificate (NOC)

The Type Approval of the x-ray equipment shall be obtained by the Authorised suppliers:

- a) Prior to marketing the x-ray equipment the supplier of imported equipment, shall obtain a Type Approval Certificate from the competent authority, on demonstration of performance of the prototype of x-ray equipment.
- b) Import of prototype of x-ray equipment, meant for Type Approval, shall be carried out by the recognized supplier only after obtaining NOC for import for Type Approval, from the competent authority.
- c) Type Approval/NOC will be issued only if the equipment satisfies the safety specifications of this Code and the standards in force.
- d) Once x-ray equipment is Type approved, routine Import of the type approved models shall be carried out only after obtaining procurement permission, for each consignment, from the competent authority.

Type Approval becomes invalid if any change is made in the design of the Type approved model.

- **IV) Periodic Safety Reports:** The Licensee shall submit periodic safety status reports in the format and frequency specified by the regulatory body.
- V) **Renewal of Authorization:** The Authorization accorded by the competent authority shall be renewed before expiry.
- **VI)** Termination of Services: AERB shall be intimated in case the supplier decides to cease functioning as a supplier.