

March 8, 2017

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

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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
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