Information for Suppliers and Service Engineers involved with Medical Diagnostic X-ray Equipment

As you are aware, safety code for "**Radiation Safety in Manufacture, Supply and Use of Medical Diagnostic X-Ray Equipment**" **AERB/RF-MED/SC-3 (Rev. 2)** has been revised by AERB in March 2016 and is available on AERB website.

The important regulatory requirements for suppliers/manufacturers as stipulated in the revised Code are once again re-iterated here.

You are requested to ensure compliance of the same, which are verified during the regulatory inspections conducted by AERB at the manufacturer/suppliers/users premises.

Also, we take opportunity to inform you about responsibilities of Supplier and its Service Engineers for supply of new X-ray equipment to end user.

Salient features of the revised Safety Code:

As per the salient features of the revised Safety Code, Supplier of X-ray equipment has to comply with the following regulatory requirements:

Import of X-ray equipment for Type Approval Purposes:

- Obtain AERB Authorisation by submitting the application for Authorization for Supply of medical diagnostic X-ray equipment (through AERB's eLORA system).
- AERB Authorised supplier of X-ray equipment may submit the application for NOC for import of X-ray equipment for Type Approval Purposes.
- Supply the equipment only to AERB authorised end user (i.e. users who has obtained procurement permission from AERB).
- Submit the application for Type Approval of imported X-ray equipment.

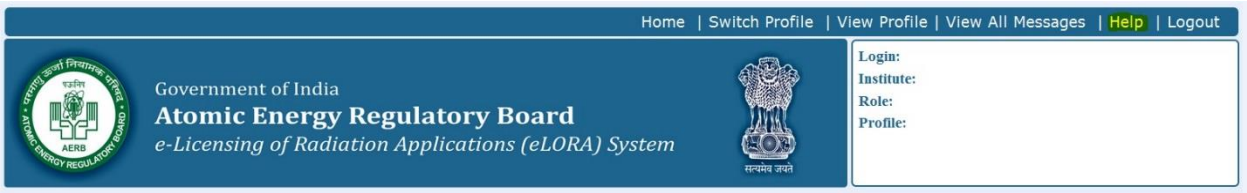
Supply and installation of X-ray equipment:

- Supplier should supply equipment only to AERB authorised end-user (i.e. user who has obtained procurement permission from AERB). [Once the X-ray end-user obtains the procurement permission for new X-ray equipment through their eLORA account, supplier will receive intimation for the same in its eLORA account]
- Ensure the supplied equipment has a valid Type Approval certificate

- Ensure that the supplied equipment meets the design specifications as stipulated in the Safety Code (Kindly refer chapter-2 of Safety Code for design specification of various types of X-ray equipment).
- Before installing the X-ray equipment, ensure that room layout details are verified by the Service/Installation Engineer.
- Supply the associated radiation protection accessories to the end-user.
- After installation of X-ray equipment, carry out the Quality Assurance (QA) tests as per AERB standards (Formats for QA are available on AERB website)
- Hand over a signed copy of the QA report to the end user. The QA report should be endorsed by end-user and the supplier service engineer, when it is submitted to AERB.
- Provide training to the end-user on operation of equipment and radiation safety/dose saving features of equipment.
- Hand over user manual of X-ray equipment to user.
- Supplier should submit installation report (enclosing QA report endorsed by end-user) against the user's procurement permission through its eLORA account.
- It may be noted that, only after supplier submits installation report, equipment appears in end user's eLORA account.
- Inform the end user for obtaining License for operation of X-ray equipment through their eLORA account.

Few guidelines for ease of obtaining Type Approval and renewal of Type Approval of X-ray equipment:

- While submitting application form for NOC/Type Approval, necessary technical inputs for evaluation of application shall be provided. The format for providing "Technical Inputs" is available "HELP" menu your eLORA account.
- Maintain the list of all end-users to whom you have supplied X-ray equipment. The formats for end-user list is available in "HELP" menu your eLORA account.



- Get the operational feedback from end users after installation / servicing / maintenance. The formats for operational feedback is available in "HELP" menu your eLORA account.
- Ensure to provide list of all end-users and operational feedback obtained from end users during renewal of Type Approval.
- Application for renewal of Type Approval is liable for rejection if above information not provided along with application form.

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