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Regulatory Requirements for Diagnostic Radiology facilities

General Requirements

The 'Employer' and 'Licensee' of the organization as defined in Atomic Energy (Radiation Protection) Rules, 2004, shall fulfill the responsibilities prescribed in the AERB safety code on radiation safety in manufacture, supply and use Of Medical diagnostic x-ray equipment [AERB/RF-MED/SC-3 (Rev. 2)].

Procurement of X-ray Equipment

The employer shall procure NOC validated/ Type Approved X-ray equipment from authorized suppliers and after obtaining procurement permission from the Competent Authority.

Operation of X-ray Equipment

No diagnostic X-ray equipment shall be operated for patient diagnosis unless Licence for operation is obtained from the Competent Authority.

Pre-requisites for obtaining Licence for Operation of X-ray Equipment

X-ray Room Layout and Shielding Requirement

The room housing X-ray equipment shall have an appropriate area to facilitate easy movement of staff and proper patient positioning. Appropriate structural shielding shall be provided for walls, doors, ceiling and floor of the room housing the X-ray equipment so that radiation exposures received by workers and the members of the public are kept to the minimum and shall not exceed the respective limits for annual effective doses as per directives issued by the Competent Authority. Appropriate overlap of shielding materials shall be provided at the joints or discontinuities.

The control console of computed tomography equipment shall be installed in a separate room located outside but adjoining to computed tomography room and provided with appropriate shielding, direct viewing and oral communication facilities between the operator and the patient. The gantry and couch shall be placed such that it enables the operator to have the complete view of the patient from the control room viewing window.

Interventional Radiology equipment room shall have an adjoining control room with appropriate facilities for shielding, direct viewing and oral communication. In case of room housing radiography equipment, chest stand shall be located in X-ray room such that no significant stray radiation reaches at control console/entrance door/ areas of full time occupancy such that the dose limits to radiation worker and members of public are not exceeded.

Mobile X-ray equipment, when used as fixed X-ray equipment, shall comply with all the requirements of those of fixed X-ray installation. Movement of mobile X-ray equipment shall be restricted within the institution for which it is registered.

A permanent radiation warning symbol and instructions for pregnant/likely to be pregnant women shall be pasted on the entrance door of the X-ray installation, illustrating that the equipment emits x-radiation.

Vehicle Mounted X-ray Equipment:

X-ray equipment installed in a mobile van or vehicle, shall be provided with an appropriate shielding enclosure to ensure adequate built-in protection for persons likely to be present in and around the vehicle. Shielding shall be provided around the equipment from all the sides up to height of 2m from external ground surface. Radiation warning symbol shall be displayed on all sides of the vehicle.

Staffing Requirements

X-ray installations shall have a radiologist/related medical practitioner/ X-ray technologist with adequate knowledge of radiation protection, to operate the X-ray equipment. The employees involved in these activities are considered as radiation workers and shall comply with the duties and responsibilities as prescribed in AERB safety code on radiation safety in manufacture, supply and use Of Medical diagnostic x-ray equipment [AERB/RF-MED/SC-3 (Rev. 2)]. The minimum qualification and training shall be as prescribed by the Competent Authority. All installations having X-ray equipment with fluoroscopy facility, computed tomography and all establishments performing special procedures, shall have the services of a qualified radiologist or related medical practitioner, with adequate knowledge of radiation protection for interpretation and reporting.

Radiological Safety Officer (RSO)

X-ray department shall have a RSO approved by the Competent Authority. The RSO may either be the employer himself/herself or an employee to whom the employer shall delegate the responsibility of ensuring compliance with appropriate radiation safety/regulatory requirements applicable to his X-ray installation. The minimum qualification and training shall be as prescribed by the Competent Authority.

Radiation Protection Devices

Appropriate radiation protection devices such as barrier, apron, goggles, and thyroid shields shall be used during operation of X-ray equipment. These devices shall be verified periodically for their shielding adequacy. The requirements for radiation protection devices are as specified in Appendix-II.

Personnel Monitoring Service

Personnel monitoring services shall be provided to all the radiation workers.

Quality Assurance (QA) Requirements

The end user shall ensure that periodic QA of the equipment is carried out by AERB authorized agencies. Periodic Quality Assurance shall be carried out at least once in two years and also after any repairs having radiation safety implications.

Servicing

The end user shall ensure that servicing of the X-ray equipment is carried out by agencies authorized by the regulatory body.

Periodic Safety Reports

The utility shall submit periodic safety reports in the format and frequency specified by the regulatory body.

