

Regulatory Requirements for Manufacturers of X-Ray Equipment and X-Ray Tubes

It is statutory requirement for the indigenous manufacturer of medical diagnostic x-ray equipment and x-ray tubes to obtain a-priori Licence for commercial production from the competent authority as per Atomic Energy (Radiation Protection) Rules 2004.

The manufacturer shall obtain import permission for x-ray tubes and x-ray tube inserts. He shall maintain data of testing of x-ray tubes and equipment.

Indigenous manufacturer of x-ray equipment shall also obtain Type Approval certificate from the competent authority for the prototype of every model of x-ray equipment before manufacturing on commercial scale.

Pre-requisites to obtain Licence for commercial production of x-ray equipment and x-ray tubes

Radiation-testing facility

A dedicated radiation testing facility shall be available, located away from other working areas not related to radiation testing. The shielding and space requirements for the testing facility shall be such that the dose limits for radiation workers and members of public, as prescribed by the Competent Authority are met with and the exposures are maintained ALARA. The facility shall be equipped with required protective devices. A warning placard shall be displayed outside the testing facility.

Radiation protection devices

Manufacturer shall have appropriate radiation protection devices to be used during radiation testing of x-ray equipment. These devices shall be verified periodically for its shielding adequacy. The requirements for radiation protection devices are specified in Appendix-II.

Quality Assurance (QA) equipment

Manufacturer shall have appropriate QA and radiation monitoring equipment for radiation testing of the x-ray equipment and x-ray tubes. Any dosimetry equipment used to perform such checks needs to have a valid calibration traceable to an acceptable national or international standard.

Staff requirements

Manufacturers shall employ qualified, trained and certified personnel for radiation testing and performing QA checks of x-ray equipment. The minimum qualification and training shall be as prescribed by the Competent Authority. The employees involved in these activities are considered as radiation workers and shall comply with the duties and responsibilities as stipulated in this Code.

Radiological Safety Officer (RSO)

Manufacturer shall designate one of his employees as RSO to be approved by the Competent Authority. The minimum qualification and training shall be as prescribed by the Competent Authority.

Conditions of Licence

The employer and licensee shall

- (i) manufacture on commercial scale only those x-ray equipment which are AERB Type Approved.
- (ii) supply only Type Approved x-ray equipment to AERB authorized suppliers.
- (iii) cease commercial production of all type approved equipment, on expiry of the validity of Licence.
- (iv) ensure that if part or complete activity of manufacturing is outsourced to any agency, it is the responsibility of the Original Equipment Manufacturer (OEM) to ensure that all the quality protocols with respect to radiation safety are duly complied with, by the outsourced agency. The outsourced agency shall also be subject to inspection by the regulatory body as applicable to OEM.
- (v) obtain procurement permission from the Competent Authority for procurement/import of x-ray tube(s)/x-ray tube inserts.
- (vi) maintain data of testing of x-ray tubes and x-ray equipment.
- (vii) make premises available for inspection to inspector/s authorised by the Competent Authority.
- (viii) adhere to any other requirements stipulated by the Competent Authority from time to time.

Type Approval

Prior to commercial production of every model of x-ray equipment the indigenous manufacturer shall obtain a Type Approval Certificate from the Competent Authority, on demonstration of satisfactory performance of the prototype model of x-ray equipment. Type Approval may be issued only if the x-ray equipment satisfies the safety requirements of this Code and the standards in force.

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

Type Approval shall be renewed before its expiry.

Periodic safety reports

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

Renewal of Licence

The Licence accorded by the Competent Authority shall be renewed before its expiry.

Decommissioning of the manufacturing facility

The licensee shall obtain the requisite approval from the Competent Authority for decommissioning of the manufacturing facility.

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

The supplier shall obtain the requisite Authorization to supply x-ray equipment and x-ray tubes. In case the supplier intends to market x-ray equipment of foreign make, shall obtain No Objection Certificate (NOC) for import, for that particular model, from the Competent Authority and demonstrate its performance for Type Approval, prior to marketing in the country.

Pre- requisites for obtaining Authorization for supply of x-ray equipment

OEM Authorisation

Supplier shall have an OEM authorisation, for all models of x-ray equipment proposed to be supplied.

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 radiation testing facility shall be such that the dose limits for radiation workers and public, as prescribed by the Competent Authority are met with. The facility shall be equipped with required protective devices. A radiation warning placard shall be displayed outside the radiation testing facility.

Radiation protection devices

In case radiation testing facility is available, supplier shall have appropriate radiation protection devices to be used during radiation testing of x-ray equipment. These devices shall be verified periodically for its shielding adequacy. The requirements for radiation protection devices are as specified in Appendix-II.

Quality Assurance (QA) equipment

Supplier shall have appropriate QA and radiation monitoring equipment for radiation testing of the x-ray equipment. Any dosimetry equipment used to perform such checks needs to have a valid calibration traceable to an acceptable national or international standard.

Staff requirements

Supplier shall employ qualified, trained and certified personnel for radiation testing, QA, and servicing of diagnostic x-ray equipment. The minimum qualification and training shall be as prescribed by the Competent Authority. The employees involved in these activities are considered as radiation workers and shall comply with the duties and responsibilities as stipulated in this Code.

Radiological Safety Officer (RSO)

Supplier having radiation testing facility shall have RSO approved by the Competent Authority. The minimum qualification and training shall be as prescribed by the Competent Authority.

Pre- requisites for obtaining Authorization for supply of x-ray tubes

OEM Authorisation

Supplier shall obtain an OEM authorisation, for all models of x-ray tubes proposed to be supplied.

Conditions of Authorization for suppliers of x-ray equipment and x-ray tubes, as applicable.

- (i) The Authorization issued by the Competent Authority will be valid for the duration and models for which OEM authorization exists.
- (ii) supplier shall obtain procurement permission from the Competent Authority for procurement/import of x-ray tube(s).
- (iii) supplier of x-ray equipment shall obtain procurement permission from the Competent Authority for procurement/import of x-ray equipment
- (iv) supplier of x-ray equipment, shall supply to the end user only Type approved models and shall,
 - (a) carry out acceptance testing/quality assurance as part of commissioning of x-ray equipment after installation of the x-ray equipment;
 - (b) provide servicing and maintenance during the useful life-time of diagnostic x-ray equipment;
 - (c) ensure that the end user 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.
 - (d) provide training on radiation safety and operating procedures of the x-ray equipment to all the associated staff.
 - (e) submit after every installation, an installation report to the regulatory body in the specified format.
 - (f) verify the layout and check shielding adequacy of x-ray installation at the end user site.
 - (g) carry out dismantling/ decommissioning of x-ray equipment at end user site and inform regulatory body.
- (v) supplier of x-ray equipment shall ensure that the pre-owned x-ray equipment are supplied, sold and marketed as per the prevailing guidelines of AERB and in compliance with directions issued by other Governmental agencies.
- (vi) Supplier shall adhere to any other requirements stipulated by the Competent Authority from time to time.

Type Approval/ No Objection Certificate (NOC)

In case of imported x-ray equipment, Type Approval shall be obtained by the authorized supplier (s)

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 x-ray equipment.

Import of x-ray equipment, meant for Type Approval, shall be carried out by the authorized supplier only after obtaining NOC for import for Type Approval, from the Competent Authority.

Type Approval/NOC will be issued only if the equipment satisfies the safety requirements of this Code and the standards in force.

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.

Only NOC validated/Type Approved x-ray equipment shall be marketed in the country.

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

Type Approval shall be renewed before its expiry.

Periodic safety reports

The Licensee shall submit periodic status reports in the format and frequency specified by the Competent Authority.

Renewal of Authorization

The Authorization accorded by the Competent Authority shall be renewed before its expiry.

Termination of services

The licensee shall obtain the approval from the Competent Authority in case supplier decides to cease functioning as supplier.

Minimum Qualifications and Experience required for personnel

a) Service Engineer:

1. Degree/ Diploma in Electrical /Electronic /Biomedical /Mechanical engineering or in an associated discipline/Basic degree in Science with Physics as one of the subject from a recognized University/Institution, and
2. Certification of successful completion of training course on “Radiation Safety and Quality Assurance in Diagnostic Radiology” conducted by authorized agencies.

b) Radiological Safety Officer(RSO)

1. Degree/ Diploma in Electrical /Electronic /Biomedical /Mechanical Engineering or in an associated discipline/Basic degree in Science with Physics as one of the subject from a recognized University/Institution, and
2. Certification of successful completion of training course on “Radiation Safety and Quality Assurance in Diagnostic Radiology” conducted by authorized agencies, and
3. A certification from the competent authority

Guidelines for design of Radiation Testing Facility

Introduction:

The shielding and space requirements to the radiation 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.

The adequacy of shielding depends on the material and thickness used for this purpose. Different materials can be used for shielding. However, brick or concrete are considered the most common materials, as they are easily available, economical, and have good structural strength.

While lead is a suitable shielding option for energies encountered in diagnostic x-rays, it is a weak structural material with tendency to lose uniformity and needs periodic radiation survey to ensure its continued adequacy. Also, Lead poses a serious environmental hazard and the use of it is being discouraged the world over. Recently, many new materials are being used/ developed as potential shielding materials, as an alternate to Lead. AERB would like to promote use of these materials, on demonstration of shielding adequacy.

Regulatory recommendations to set up testing facility at manufacturing premises:

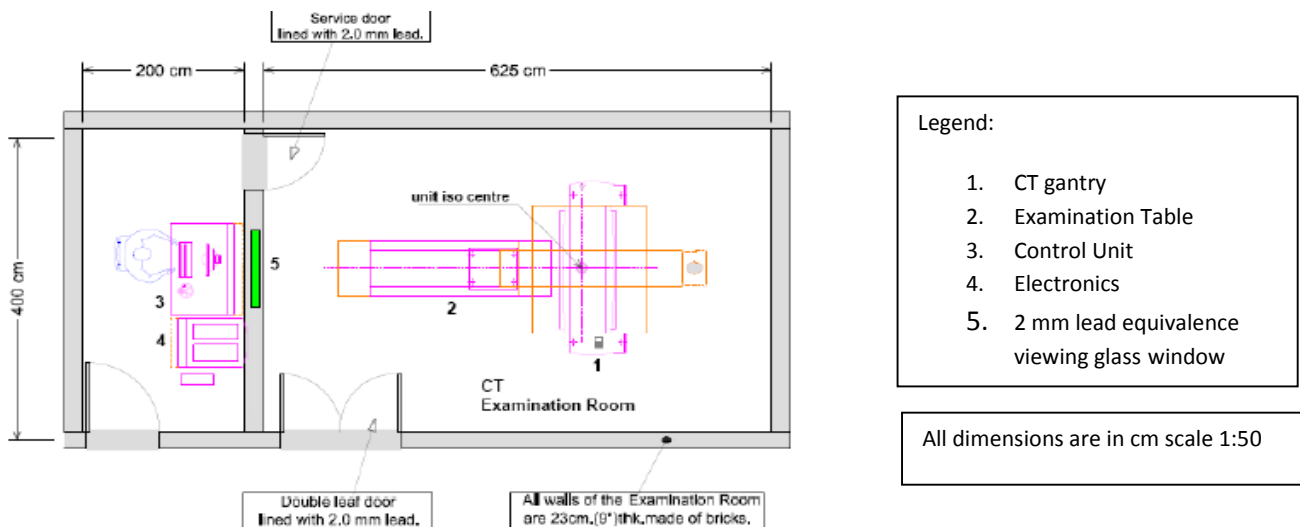
- Decide a suitable room/bay for testing of X-ray equipment located as far away as feasible from other working areas not related to radiation testing and area of high occupancy and general traffic.
- Ensure that the thickness of the wall(s) of the testing room(s) should not be less than 23 cm thick brick or equivalent.
- Testing room should have preferably only one entrance door having shielding equivalent of 2 mm of Lead and window if present should be at above height of 2 m from the outside finished floor level of testing facility.
- Area of the X-ray equipment testing room should be at least 18 m² for testing of general purpose radiography / Fluoroscopy / C-Arm/ Mammography /BMD/ OPG/Dental & CBCT equipment.
- Area of the CT scan & Interventional Radiology (IR) equipment testing room should be at least 25 m².
- In case of CT & IR equipment, separate control room should be available adjacent to testing room with proper lead glass viewing window of adequate size.
- X-ray equipment, control console, protective barrier etc. should be appropriately placed in the testing room so as to avoid primary beam facing control console or entrance door.
- Appropriate warning sign, and placards shall be displayed outside the testing facility

General information:

- Testing room layout or bay shall be constructed as per AERB recommendations only.
- Testing of x-ray equipment shall be carried out by trained & authorised personnel.
- Personnel monitoring badges (TLD) shall be provided to all the radiation workers.
- All types of radiation protection devices shall be provided to radiation workers.

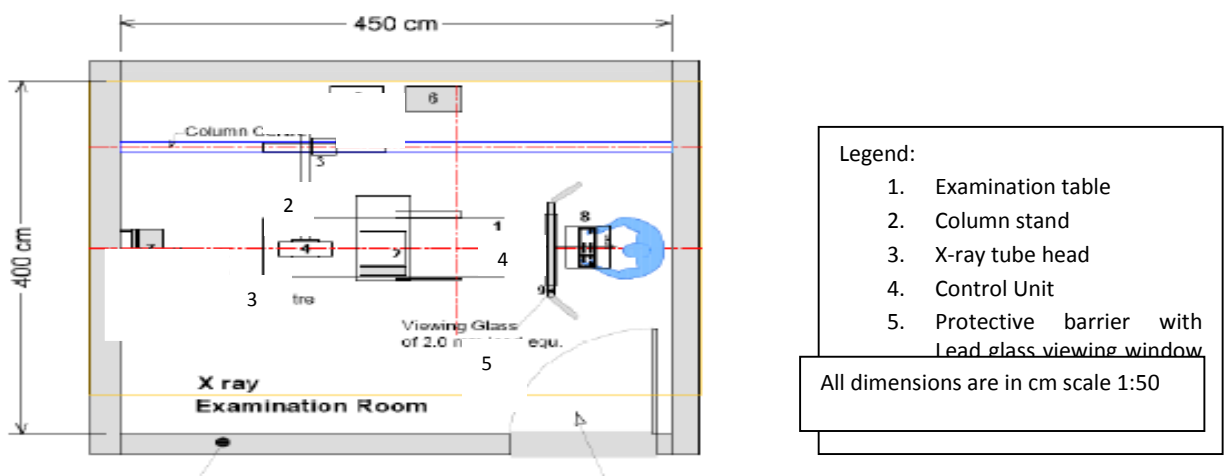
- After constructing the testing facility, radiation protection survey should carry out to ensure the shielding adequacy of the testing room / bay.
- If the radiation assessment survey shows deficiencies, additional shielding or modification in the testing facility are required.
- **Prepare a sketch of layout of test facility to the scale 1:50 mentioning all the details such as Area, wall thickness, shielding material (wall material), position of doors, windows, equipment, control console, protective barriers etc.**
- **Prepare a sketch of floor layout of test facility to the scale 1:100 mentioning the areas around the test facility and details of occupancy.**
- **Duly signed and stamped copies of both the layouts shall be submitted to AERB along with application for Licence for commercial production.**

Testing room model layout for CT or Cath Lab equipment*:



***Note:** Same type of room layout plan can be used for testing of Cath Lab equipment.

Testing room model layout for general X-ray radiography equipment*:



***Note:** Same room layout plan can be used for testing of Radiography/Radiography & Fluoroscopy, C-Arm, Mammography, BMD, Dental, OPG/CBCT etc equipment.