

AERB SAFETY CODE NO. AERB/RF-MED/SC-3 (Rev. 2)

**RADIATION SAFETY IN MANUFACTURE, SUPPLY AND USE
OF
MEDICAL DIAGNOSTIC X-RAY EQUIPMENT**

Approved by the Board in November 2015

**Atomic Energy Regulatory Board
Mumbai 400094
India**

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Price:

Order for this safety code should be addressed to:

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FOREWORD

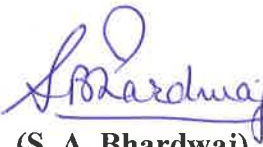
Activities concerning establishment and utilization of nuclear facilities and use of radioactive sources are to be carried out in India in accordance with the provisions of the Atomic Energy Act, 1962. In pursuance of the objective of ensuring safety of occupational workers, members of the public and protection of the environment, the Atomic Energy Regulatory Board (AERB) has been entrusted with the responsibility of laying down safety standards and enforcing rules and regulations for such activities. The Board has, therefore, undertaken a programme of developing safety standards, safety codes, and related guides and manuals for the purpose. While some of these documents cover aspects such as siting, design, construction, operation, quality assurance and decommissioning of nuclear and radiation facilities, other documents cover regulatory aspects of these facilities.

Safety codes and safety standards are formulated on the basis of internationally accepted safety criteria for design, construction and operation of specific equipment, structures, systems and components of nuclear and radiation facilities. Safety codes establish the objectives and set requirements that should be fulfilled to provide adequate assurance for safety in nuclear and radiation facilities. Safety guides elaborate various requirements and furnish approaches for their implementation. Safety manuals deal with specific topics and contain detailed scientific and technical information on the subject. These documents are prepared by experts in the relevant fields and are extensively reviewed by advisory committees of the Board before they are published. These documents are revised, when necessary, in the light of experience and feedback from users as well as new developments in the field.

The Medical X-ray diagnostic radiology practice is the most widespread utilization of ionizing radiation in the public domain. The first version of AERB Safety Code titled 'Medical Diagnostic X-ray Equipment and Installations' (AERB/SC/MED-2) was issued by AERB in December 1986, and subsequently revised in 2001 as Revision-1. The current version (Revision-2) takes into account the provisions of the Atomic Energy (Radiation Protection) Rules, 2004 and the interim amendment to the safety code issued by AERB in November 2012. Since the issue of Revision-1, additional requirements for Interventional Radiology and new requirements for Dental Cone Beam Computed Tomography are introduced. There have been obsolescence of certain radiation dose intensive technologies for which additional requirements are either specified or amended. The revised safety code supersedes the earlier versions and reflects the regulatory provisions for medical diagnostic X-ray equipment of the Manufacturer (to ensure safety by design), the Supplier (to ensure safe commissioning of equipment) and the Utility (to ensure proper utilisation of safety features of the X-ray equipment on a routine basis).

The first draft of the present safety code was prepared by in-house members of AERB. It has been reviewed experts in the field. AERB Task Group for Revision of Safety Code for Medical Diagnostic X-ray Equipment and Installations, Standing Committee for Review and Revision of AERB Radiation Safety Documents (SC-RRRSD) and Advisory Committee on Radiological Safety (ACRS) have further reviewed and vetted it for issue. The draft safety code was placed on AERB website for public comments.

AERB wishes to thank all individuals and organisations who have prepared and reviewed the draft and helped in its finalisation. The list of experts, who have participated in this task, along with their affiliations, is included for information.


(S. A. Bhardwaj)
Chairman, AERB

DEFINITIONS

Adequate Protection

Protection against radiation so provided that the prescribed operational limits on levels of radiation or contamination are not exceeded.

ALARA

An acronym for 'As Low As Reasonably Achievable'. A concept meaning that the design and use of sources, and the practices associated therewith, should be such as to ensure that exposures are kept as low as reasonably practicable, with economic and social factors taken into account.

Applicant

Any person who applies to the Competent Authority for consent to undertake any of the actions for which the consent is required.

Classified Worker

The employees designated by employer, who are likely to receive an effective dose in excess of three-tenths of the average annual dose limits notified by the Competent Authority.

Commissioning

The process during which equipment, structures, systems and components of a nuclear and radiation facility, on being constructed, are made functional and verified to be in accordance with design specifications and to have met the performance criteria.

Competent Authority

Any official or authority appointed, approved or recognized by the Government of India for the purpose of the Rules promulgated under the Atomic Energy Act, 1962.

Decommissioning

The process by which a nuclear or radiation facility is finally taken out of operation, in a manner that provides adequate protection to the health and safety of the workers, the public and the environment.

Deterministic Effects

A radiation effect for which generally a threshold level of dose exists, above which the severity of the effect is greater for a higher dose. (Ref: ICRP 103: For skin erythema deterministic threshold is 2 Gy)

Dose Limit

The value of the effective dose or the equivalent dose to individuals from controlled practices that shall not be exceeded.

Dose

A measure of the radiation absorbed by a target. The quantities termed absorbed dose, organ dose, equivalent dose, effective dose, committed equivalent dose, or committed effective dose are used, depending on the context.

Dosimeter

A device, instrument or system, which can be used to measure or evaluate any quantity that can be related to the determination of either absorbed dose or equivalent dose.

Dosimetry

Measurements and/or calculations performed in connection with the determination of radiation dose and/or dose distributions in the irradiated volume.

Effective Dose

The quantity 'E' is defined as a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor:

$$E = \sum W_T \cdot H_T$$

where 'H_T' is the equivalent dose in tissue 'T' and 'W_T' is the tissue weighting factor for tissue 'T'.

Emergency

A situation which endangers or is likely to endanger safety of the site personnel, the nuclear / radiation facility or the public and the environment.

Equivalent Dose (H_{T,R})

The quantity H_{T,R} is defined as: $H_{T,R} = D_{T,R} \cdot W_R$

where D_{T, R} is the absorbed dose delivered by radiation type 'R' averaged over a tissue or organ 'T' and 'W_R' is the radiation weighting factor for radiation type 'R'. When the radiation field is composed of different radiation types with values of 'W_R', the equivalent dose is $H_T = \sum_R W_R D_{T,R}$

Exposure

The act or condition of being subject to radiation. Exposure can be either external (irradiation by sources outside the body) or internal (irradiation by sources inside the body). Exposure can be classified as either normal exposure or potential exposure; either occupational, medical or public exposure; and in intervention situations, either emergency exposure or chronic exposure. The term 'exposure' is also used in radiation dosimetry to express the amount of ions produced in air by ionizing radiation.

Filter

A radiation attenuating material incorporated in the path of the radiation beam to absorb preferentially the less penetrating components of the primary beam. It may consist of a permanent filter which is an integral part of the X-ray tube housing and which cannot be removed by the end user, and/or an added filter which is intended to increase the total filter thickness.

Fluoroscopic Screen

A plastic base upon which a layer of fluorescent material is evenly spread and which emits visible radiation on being subjected to X-rays.

Grid (Diagnostic X-rays)

A device composed of alternate strips of lead and radiolucent material encased and suitably placed between the patient and X-ray film to absorb scattered radiation. 'Potter Bucky grid' or 'Bucky' means a device containing a grid and a mechanism to impart motion to the grid during radiography exposure.

Handle

Manufacture, possess, store, use, transfer by sale or otherwise export, import, transport or dispose off.

Inspector (Regulatory)

A person authorized by the regulatory body to carry out regulatory inspection.

Justification

The process of determining for a planned exposure situation whether a practice is overall beneficial; i.e., whether the expected benefits to individuals and to society from introducing or continuing the practice outweigh the harm (including radiation detriment) resulting from the practice.

Licence

A type of regulatory consent, granted by the regulatory body for all sources, practices and uses for nuclear facilities involving the nuclear fuel cycle and also certain categories of radiation facilities. It also means authority given by the regulatory body to a person or to an organisation having overall responsibility to perform specified functions related to a facility or an activity.

Lead Equivalence

The thickness of lead, which, under specified conditions of irradiation, affords the same attenuation as the material under consideration.

Leakage Radiation

Any radiation coming out of the source/X-ray tube housing, except the useful beam or primary beam.

Maintenance

Organized activities covering all preventive and remedial measures, both administrative and technical, to ensure that all structures, systems and components are capable of performing as intended for safe operation of the plant.

Medical Exposure

Exposure incurred by patients as part of their own medical or dental diagnosis or treatment; by persons, other than those occupationally exposed, knowingly while voluntarily helping in the support and comfort of patients and; by volunteers in a programme of biomedical research involving their exposure.

Member of the Public

Any individual in the population except for one who is subject to occupational or medical exposure. For the purpose of verifying compliance with the annual dose limit for public exposure, the member of the public is the representative individual in the relevant critical group.

Monitoring

The continuous or periodic measurement of parameters for reasons related to the determination, assessment in respect of structure, system or component in a facility or control of radiation.

Occupational Exposure

All exposures of personnel incurred in the course of their occupational work.

Operation

All activities following and prior to commissioning performed to achieve, in a safe manner, the purpose for which a nuclear/radiation facility is constructed, including maintenance.

Optimization of Protection (Radiological)

The process of determining what level of protection and safety makes exposures and the probability and magnitude of potential exposures, 'as low as reasonably achievable, (ALARA), economic and social factors being taken into account' as required by the ICRP system of radiological protection.

Person

Any individual, or a company, or association, or body of individuals, whether incorporated or not; or central government or a state government.

Practice

Any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people, or the number of people exposed.

Prescribed Limits

Limits established or accepted by the regulatory body.

Primary Beam

That part of the emergent radiation from an X-ray tube housing which is capable of being used for the purpose for which the X-ray equipment is intended.

Protective Barrier or Shielding (Radiation)

A barrier of appropriate thickness used to reduce radiation levels to specified values.

Quality Assurance

Planned and systematic actions necessary to provide adequate confidence that an item or facility will perform satisfactorily in service as per the design specifications.

Quality Control (QC)

Quality assurance actions, which provide means to control and measure the characteristics of an item, process or facility in accordance with the established Requirements.

Radiation

Gamma rays, X-rays or rays consisting of alpha particles, beta particles, neutrons, protons and other nuclear subatomic particles, but not sound or radio-waves, or visible, infrared, ultraviolet light.

Radiation Facility

Any installation/equipment or a practice involving use of radiation-generating equipment or use of radioisotopes in the field of research, industry, medicine and agriculture.

Radiation Generating Equipment

Device capable of generating radiation, such as X-rays, neutrons, electrons or other charged particles.

Radiation Surveillance

Measures that may be specified by the Competent Authority to provide adequate protection either generally or in an individual case.

Radiation Worker

Any person who is occupationally exposed to radiation and who in the opinion of the regulatory body should be subjected to radiation surveillance.

Radiography Technician/ Radiography Technologist/Radiographer

A worker, who performs radiography operations employing radiography sources and possesses valid qualification, duly recognized by the Competent Authority for the specific purpose.

Radiation Protection Survey/Radiological Survey

An evaluation of radiation safety using appropriate radiation measuring instruments.

Radiological Safety Officer (RSO)

Any person who is so designated by the employer and who, in the opinion of the Competent Authority, is qualified to discharge the functions outlined in the Atomic Energy (Radiation Protection) Rules, 2004.

Records

Documents, which furnish objective evidence of the quality of items and activities affecting quality. They include logging of events and other measurements.

Regulatory Inspection

An examination through review of documents, observation, measurement or test undertaken by or on behalf of the regulatory body during any stage of the regulatory consenting process, to ensure conformance of materials, components, systems and structures as well as operational and maintenance activities, processes, procedures, practices and personnel competence with predetermined requirements.

Review

Documented, comprehensive and systematic evaluation of the fulfillment of requirements, identification of issues, if any.

Scattered Radiation

Radiation that, during passage through matter, gets deviated in direction. (It may have been modified by a decrease in energy).

Source

Anything that may cause radiation exposure, either by emitting ionizing radiation or releasing radioactive substances or materials.

Stray Radiation

The sum of leakage and scattered radiations.

Stochastic Effects (Radiation)

Radiation effects generally occurring without a threshold level of dose whose probability is proportional to the dose and whose severity is independent of the dose.

Type Approval

Approval issued by the Competent Authority based on evaluation of the device to ensure that it conforms to safety standards.

Unusual Occurrence

Any occurrence which has the potential to impair or impairs the plant safety, radiological safety, industrial safety and/or environmental safety.

Workload (W)

For the purpose of shielding computation, the radiation output or equivalent quantity integrated usually over a working week.

X-ray Tube Housing

A shielding enclosure provided around an X-ray tube, in order to:

- (i) define the useful beam; and
- (ii) limit the radiation levels outside primary beam so as not to exceed the radiation leakage levels as prescribed by the Competent Authority.

SPECIAL DEFINITIONS

(Specific for the present Safety Code)

Employer

Any person who employs workers or imparts training using sources or who is self-employed as a worker in a radiation installation.

Focus

That area of the anode in an X-ray tube on which X-ray-producing electrons are incident.

Imaging Device

A device element of a detector unit or array of detectors which receives X-rays and responds by producing an electrical or light signal. The entire assembly of X-ray receiver may contain a single element of a detector or an array of detectors.

Licensee:

A person to whom Licence has been issued under AE (RP) R, 2004.

Mobile X-ray Equipment

X-ray equipment intended to be moved from one location to another between periods of use while supported by its own wheels or equivalent means of support, without dismantling for its use within the institution.

Manufacturer/ Original Equipment Manufacturer (OEM)

Any person involved in the manufacturing of X-ray equipment and X-ray tubes.

Medical Practitioner

An individual who: (a) has been accredited through appropriate national procedures as a health professional; (b) fulfils the national requirements on training and experience for prescribing procedures involving medical exposure; and (c) is a licensee or a worker who has been designated by employer for the purpose of prescribing procedures involving medical exposure.

Operator (X-ray)

All radiation workers involved in operation of the X-ray equipment such as radiographer/X-ray technologist, radiologist and related medical practitioner.

Portable X-ray Equipment

X-ray equipment intended to be moved from one location to another while used or between periods of use while being carried by one or two persons. The weight of the equipment shall not exceed 12 kg.

Radiation Installation

Any location or facility, including mobile facility, in which a radiation generating equipment or radioactive material is present and which, in the opinion of the Competent Authority, requires radiation surveillance for ensuring adequate protection against radiation.

Radiation Testing Facility

A facility meant for testing of radiation related parameters of radiation generating equipment

Supplier

Any person involved in the supply of medical diagnostic X-ray equipment /X-ray tubes and who is authorized by the Manufacturer.

X-ray Equipment

An assembly of functional elements including an assembly of electrical devices necessary to energize for a pre-determined period an X-ray tube(s), devices for the support and positioning of the patient, and/or X-ray tube.

X-ray Tube

The integrated assembly consisting of X-ray tube insert along with its housing meant for radiation shielding, cooling and supporting structures.

X-ray Tube Insert

A glass or metal assembly for generating X-rays by accelerating electrons to high energies and causing them to strike a metal target from which the X-rays are emitted, without tube housing.

Note: Words and expressions not defined in this Code, but defined in the Act and Rules shall have meanings respectively assigned to them in the Act and Rules.

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BIBLIOGRAPHY

LIST OF PARTICIPANTS

TASK GROUP FOR REVISION OF AERB SAFETY CODE FOR MEDICAL DIAGNOSTIC X-RAY EQUIPMENT AND INSTALLATIONS

STANDING COMMITTEE FOR REVIEW AND REVISION OF AERB RADIATION SAFETY DOCUMENTS (SCRRRSD)

ADVISORY COMMITTEE ON RADIOLOGICAL SAFETY (ACRS)

LIST OF REGULATORY SAFETY DOCUMENTS ON MEDICAL FACILITIES INVOLVING RADIATION

1. INTRODUCTION

1.1 General

Medical use of X-rays for diagnosis and treatment has proven to be immensely beneficial to the society at large. However, unsafe use of X-ray radiation has health risks associated with it and hence it is required that proper care is exercised throughout the life cycle of the equipment i.e. from manufacture, supply, installation, operation, maintenance, servicing and decommissioning.

The Atomic Energy (Radiation Protection) Rules, 2004, promulgated under the Atomic Energy Act, 1962, provides the legal framework for the safe handling of radiation generating equipment.

1.2 Objective

The safety code is intended to govern radiation safety in design, manufacture, installation, operation and decommissioning of X-ray generating equipment for medical diagnostic purposes in order to:

- i) ensure that radiation workers and members of public are not exposed to radiation in excess of dose limits prescribed by the Competent Authority;
- ii) reduce radiation exposures, of radiation workers and members of public, are below these limits to levels as low as reasonably achievable (ALARA); and
- iii) ensure that radiation exposures received by patients undergoing diagnosis are optimised.

1.3 Scope

The safety code stipulates radiological safety requirements for indigenous manufacturers of X-ray equipment/X-ray tubes, suppliers of imported/indigenous medical diagnostic X-ray equipment/X-ray tubes and facilities using these equipments.

The following X-ray equipment used with various imaging systems, such as radiographic film, computed radiography, digital radiography, image intensifier, are covered in this safety code.

- (i) Radiography (Fixed, Mobile, Portable)
- (ii) Interventional Radiology, Fluoroscopy, C-Arm
- (iii) Computed Tomography¹
- (iv) Dental radiography [*Intra Oral Peri-apical* radiograph (IOPA), Ortho Pantomography (OPG), Cone Beam Computed Tomography (CBCT)]
- (v) Mammography
- (vi) Bone Mineral Densitometer
- (vii) Any of the above X-ray equipment mounted on vehicles
- (viii) Any other type of X-ray equipment used for medical diagnosis purposes

The safety code also covers roles and responsibilities of individuals involved in the manufacture, supply, servicing, operation and decommissioning of X-ray equipment.

This safety code does not address the industrial, electrical, mechanical and fire safety requirements of the medical diagnostic X-ray equipment. The various consents issued under this safety code are from radiological safety considerations. This safety code does not address requirements for all other applicable permissions/approvals/licences from the state/central/local authorities that should be obtained by stakeholders while manufacturing, supplying or operating medical diagnostic X-ray facilities.

¹ Requirements for PET-CT /SPECT-CT and CT simulator shall be met in conjunction with those spelt out in the safety code on Nuclear medicine and Radiotherapy practices respectively.

2. DESIGN REQUIREMENTS FOR X-RAY EQUIPMENT

2.1 General

The design requirements prescribed in this section shall be met by the manufacturer of the medical diagnostic X-ray equipment. In case the equipment is imported, the supplier shall ensure that the equipment meets these requirements and is certified by relevant international bodies or the regulatory body of the country of origin.

2.2 Generic Requirements

The generic design requirements are those that shall be met for all X-ray equipment. The modality specific safety requirements are addressed separately.

2.2.1 X-ray Tube Housing

X-ray tube housing for medical diagnostic X-ray equipment shall be so constructed that leakage through the protective tube housing in any direction shall not exceed the limits as specified in Appendix-I.

2.2.2 Beam Limiting Device/Collimator

X-ray tube shall be provided with beam limiting device to restrict the X-ray field. There shall be light field and an indicator showing the center and borders of the light field. These beam limiting device shall comply with the leakage radiation limit specified for X-ray tube housing.

The beam limiting device shall be adjusted such that radiation field and light field alignment shall be within the tolerances specified by the regulatory body.

2.2.3 X-ray Beam Filtration

X-ray tube shall be provided with appropriate filters. The minimum total filtration in primary beam for maximum rated operating tube potential shall meet the requirements as specified in Appendix-I.

2.2.4 Identification, Marking & X-ray Caution Symbol

The identification marking label containing make, model, maximum operating parameters, serial number, name and address of the manufacturer shall be provided on the X-ray equipment such that it is visible when the equipment is installed.

X-ray tube housing shall be conspicuously marked with make, model and serial number. X-ray tube housing shall also be marked with (i) X-ray tube inherent filtration, (ii) X-ray tube added filtration and (iii) focal spot position.

2.2.5 X-ray Tube Positioning

X-ray equipment shall have facilities for tube positioning, target-to-film distance selection, beam centering and angulations and appropriate features to display the same. Tube housing and tube support shall have appropriate locking devices to immobilize the tube in the desired location and orientation.

2.2.6 Control Console

Control console shall clearly indicate the appropriate exposure parameters. In case more than two X-ray tubes are available in the X-ray equipment, there shall be visible and clear indication on control console, of which X-ray tube is energized and under use.

2.2.7 Exposure Switch

Control console shall have provision to terminate X-ray exposure automatically after a pre-set time or manually at any moment before this time.

2.2.8 Automatic Exposure Control (AEC)

Accuracy of AEC system shall be as specified in Appendix-I for all phantom thicknesses.

Manual selection of X-ray tube current-exposure time product (mAs) or at least one of its component parts X-ray tube current (mA) and/or exposure time (s) shall be available.

2.2.9 Couch

The couch used with the X-ray equipment shall meet the requirements as specified in Appendix-I.

2.2.10 Anti-scatter Grid

If the X-ray equipment is provided with anti-scatter grid, it shall be detachable.

2.3 Modality-Specific Requirements

2.3.1 Radiography Equipment (Fixed, Mobile & Portable)

In addition to the generic requirements stated in section 2.2, the radiography equipment shall comply with following

2.3.1.1 Cable Length

X-ray equipment shall be provided with electrical cables of sufficient length so that the control console/operation switch can be located and operated in safe manner. For Radiography (Mobile)/Radiography (Portable) X-ray equipment, the exposure cable length shall not be less than 2 m.

2.3.2 Interventional Radiology Equipment

In addition to the generic requirements stated in section 2.2, the equipment used for interventional radiology procedures including cardiology, neurology etc. shall comply with following:

2.3.2.1 Dose-Area-Product (DAP) Meter

Duly calibrated DAP meter shall be provided with the interventional radiology equipment.

2.3.2.2 Patient Dose Monitoring and Recording

The monitor shall display and record the dose related quantities i.e. total fluoroscopy time, number of cine runs, Dose Area Product ($\text{mGy}\cdot\text{cm}^2$), Dose rate, cumulative Air Kerma and exposure parameters.

2.3.2.3 *Built-in Protective Device*

Couch hanging protective flaps and ceiling suspended lead glass shall be provided as specified in Appendix-II.

2.3.2.4 *Fluoroscopy Timer*

The equipment shall be provided with a cumulative timer with indicator. The timer and indicator alarm shall be set such that the unidirectional dose at the same area of the skin shall be much less than the deterministic threshold.

2.3.2.5 *Foot-switch and Visual Indicator*

A foot-operated pressure switch shall be provided for conducting fluoroscopy examinations. There shall be a visual indication on the control console when the beam is 'ON'.

2.3.3 C-arm Equipment

In addition to the generic requirements stated in section 2.2, the C-arm equipment shall comply with following:

2.3.3.1 *Dose-Area-Product (DAP) Meter*

In case C-arm is used for interventional procedures, duly calibrated DAP meter shall be provided with the equipment.

2.3.3.2 *Patient Dose Monitoring and Recording*

The monitor shall display and record the dose related quantities i.e. total fluoroscopy time, number of cine runs, Dose Area Product (as applicable), Dose rate, cumulative Air Kerma and exposure parameters.

2.3.4 Conventional Fluoroscopy Equipment

In addition to the generic requirements stated in section 2.2, the conventional fluoroscopy equipment shall be provided with built-in design safety features such as protective lead glass on the fluorescent screen and personnel protective barriers. The specifications of these shall be as per Appendix-I.

The focus-to-table top distance, table-top exposure rate, fluoroscopy timer and foot-switch, visual indicator and tube- image receptor alignment shall meet the requirements specified in Appendix-I.

2.3.5 Computed Tomography (Fixed and Mobile) Equipment

In addition to the generic requirements stated in section 2.2, the Computed Tomography equipment shall comply with following:

2.3.5.1 *Control Console*

All conditions of operation for CT such as the exposure parameters, section thickness, pitch factor, and filtration to be used during a scan series shall be indicated prior to the initiation of a scan or scan series.

2.3.5.2 *Scan Plane Visualizer*

A scan plane visualization device shall be provided to indicate directly or indirectly the position of slice plane(s) (tomographic plane and/or a reference plane offset from the tomographic plane) on the patient.

2.3.5.3 *Exposure Control*

Initiation or continuation of irradiation shall be possible only from the control console.

2.3.5.4 *Emergency Termination of Motorized Movements and Loading*

An emergency stop switch shall be in place on or near the patient support and/or gantry to immediately terminate the motion of the equipment and the emission of X-rays.

2.3.5.5 *Patient Dose Monitoring and Recording*

The monitor shall display and record the dose related quantities i.e. Computed Tomography Dose Index (CTDI), Dose length product (DLP) and exposure parameters.

2.3.6 Dental X-ray Equipment

All types of dental X-ray equipment shall satisfy the generic requirements stated in section 2.2 wherever it is appropriate and applicable. In addition they shall meet the specifications as per Appendix-I.

Dental X-ray equipment includes (i) X-ray equipment used for intra-oral radiography (IOPA) (stand/wall mounted and hand- held), (ii) X-ray equipment for panoramic radiography (OPG) and cephalometry (iii) Dental Cone Beam Computed Tomography (Dental CBCT).

All dental equipment shall be provided with suitable collimation and shielding features such that the radio-sensitive organs i.e. the eye and thyroid are not exposed to the primary beam. The collimation/cone shall provide the same degree of radiation shielding as specified for X-ray tube housing. The collimation shall be such that the primary radiation beam is fully intercepted by the image receptor at the maximum focal spot to image receptor distance.

2.3.7 Mammography X-ray Equipment

In addition to the generic requirements stated in section 2.2, the mammography equipment shall comply with following:

2.3.7.1 *Cassette Carrier*

The cassette carrier should be interlocked such that exposure is not possible, unless film cassette is in the cassette carrier.

2.3.7.2 *Focal Spot Selection*

- (a) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.
- (b) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target and filter material.

2.3.7.3 *Compression Device*

All mammography systems shall incorporate a compression device that meets the following requirements:

- (a) An initial power-driven compression activated by hands-free controls; and shall be such that the compression will be released immediately after the end of exposure.
- (b) The compression device shall be flat and parallel to the breast support.
- (c) The chest wall edge shall be smooth and bent upward to allow for patient comfort and shall not appear on the image. A spot compression device shall also be provided with the mammography equipment.

2.3.7.4 *Viewing Box Requirements*

Appropriate viewing boxes with higher luminance shall be used for mammography.

2.3.8 Bone Mineral Densitometer (BMD)

BMD equipment shall comply with generic requirements stated in section 2.2, as applicable.

2.4 **Imaging Systems**

All the imaging systems including radiographic film, computed radiography and digital processing of radiological images, should aim at optimization of image quality and patient dose.

2.4.1 Film-based Systems

Film storage, use and darkroom techniques shall be as per manufacturers' recommendations.

2.4.2 Computed Radiography (CR) Imaging Plates and CR Cassettes

CR plates shall be periodically evaluated for any artifacts. The cleaning frequency shall be as per manufacturer recommended procedures.

2.4.3 Digital Imaging Systems

Digital detectors shall be calibrated periodically as per manufacturer's recommendations.

2.4.4 Picture Archiving and Communication System

Wherever picture archiving and communications system (PACS) is used, it shall be ensured that quality of patient images is maintained in the PACS system and patient information is not lost or unintentionally altered.

Imaging devices and other medical radiological equipment which are interconnected by computer networks and exchange information shall be in accordance with national /international standards. These digital information systems and procedures shall be designed such that there is no loss of data.

3. REGULATORY REQUIREMENTS FOR MANUFACTURERS OF X-RAY EQUIPMENT AND X-RAY TUBES

3.1 General Requirements

The indigenous manufacturer of medical diagnostic X-ray equipment and X-ray tubes shall obtain Licence prior to commercial production from the Competent Authority.

Indigenous manufacturer of X-ray equipment shall also obtain Type Approval certificate from the Competent Authority for every model of X-ray equipment before manufacturing on a commercial scale.

The 'Employer' and 'Licensee' of the organization as defined in Atomic Energy (Radiation Protection) Rules, 2004, shall fulfil the responsibilities prescribed in this safety code.

3.2 Pre-requisites to Obtain Licence for Commercial Production of X-ray Equipment and X-ray Tubes

3.2.1 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 exposures to radiation workers and members of public does not exceed the limits prescribed by the Competent Authority and are maintained ALARA. The facility shall be equipped with required protective devices. A warning placard shall be displayed outside the testing facility.

3.2.2 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 their shielding adequacy. The requirements for radiation protection devices are specified in Appendix-II.

3.2.3 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.

3.2.4 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 Regulatory Body. The employees involved in these activities are considered as radiation workers and shall comply with the duties and responsibilities as stipulated in this Code.

3.2.5 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.

3.3 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.

3.4 Type Approval

- 3.4.1 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 safety code and the standards in force.
- 3.4.2 Type Approval becomes invalid if any change is made in the design specifications of the Type approved model.
- 3.4.3 Type Approval shall be renewed before its expiry.

3.5 Periodic Safety Reports

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

3.6 Renewal of Licence

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

3.7 Decommissioning of the Manufacturing Facility

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

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

4.1 General Requirements

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.

The 'Employer' and 'Licensee' of the organization as defined in Atomic Energy (Radiation Protection) Rules, 2004, shall fulfil the responsibilities prescribed in this safety code.

4.2 Pre- requisites for Obtaining Authorization for Supply of X-ray Equipment

4.2.1 OEM Authorisation

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

4.2.2 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 the 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.

4.2.3 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.

4.2.4 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.

4.2.5 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 safety code.

4.2.6 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.

4.3 Pre- requisites for obtaining Authorization for Supply of X-ray Tubes

4.3.1 OEM Authorisation

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

4.4 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.

4.5 Type Approval/ No Objection Certificate (NOC)

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

- 4.5.1 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.

- 4.5.2 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.
- 4.5.3 Type Approval/NOC will be issued only if the equipment satisfies the safety requirements of this safety code and the standards in force.
- 4.5.4 Once X-ray equipment is Type approved, routine import of the type approved models shall be carried out only after obtaining permission for procurement, for each consignment, from the Competent Authority.
- 4.5.5 Only NOC validated/Type Approved X-ray equipment shall be marketed in the country.
- 4.5.6 Type Approval becomes invalid if any change is made in the design specifications of the Type approved model.
- 4.5.7 Type Approval shall be renewed before its expiry.

4.6 Periodic Safety Reports

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

4.7 Renewal of Authorization

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

4.8 Termination of Services

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

5. REGULATORY REQUIREMENTS IN THE USE OF X-RAY EQUIPMENT

5.1 General Requirements

The 'Employer' and 'Licensee' of the organization as defined in Atomic Energy (Radiation Protection) Rules, 2004, shall fulfill the responsibilities prescribed in this safety code.

5.2 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.

5.3 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.

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

5.4.1 X-ray Room Layout and Shielding Requirement

5.4.1.1 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.

5.4.1.2 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.

5.4.1.3 Interventional Radiology equipment room shall have an adjoining control room with appropriate facilities for shielding, direct viewing and oral communication.

5.4.1.4 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.

5.4.1.5 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.

5.4.1.6 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.

5.4.1.7 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.

5.4.2 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 this safety code. 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.

5.4.3 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.

5.4.4 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.

5.4.5 Personnel Monitoring Service

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

5.4.6 Quality Assurance (QA) Requirements

The end user shall ensure that periodic QA of the equipment is carried out by agencies authorized by the regulatory body.

5.5 Servicing

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

5.6 Periodic Safety Reports

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

5.7 Renewal of Licence

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

5.8 Decommissioning of X-ray Equipment

Decommissioning of the X-ray equipment shall be carried out by authorized agencies with prior intimation to the Competent Authority.

6. RESPONSIBILITIES OF EMPLOYER, LICENSEE, RADIOLOGICAL SAFETY OFFICER (RSO) AND RADIATION WORKERS

6.1 General

Responsibilities of individuals, who are directly or indirectly associated with the radiation safety of radiation workers, patient and general public are stipulated in Atomic Energy (Radiation Protection) Rules, 2004. The relevant responsibilities with respect to medical diagnostic radiology practice are prescribed in this safety code. All individuals shall comply with their responsibilities.

6.2 Responsibilities of Employer

- 6.2.1 The ultimate responsibility of ensuring radiation safety in handling the X-ray equipment shall rest with the employer and is the custodian of X-ray equipment in his possession.
- 6.2.2 No person under the age of 18 years shall be employed as a worker. No worker under the age of 16 years shall be taken as trainee or employed as an apprentice for radiation work.
- 6.2.3 Prior to employment of a worker, obtain the dose records from his former employer, where applicable.
- 6.2.4 Every employer shall designate, with the written approval of the Competent Authority, a person having appropriate qualifications as Radiological Safety Officer.
- 6.2.5 Employer shall designate those of his employees as classified workers, who are likely to receive an effective dose in excess of three-tenths of the average annual dose limits notified by the Competent Authority and shall forthwith inform those employees that they have been so designated.
- 6.2.6 Employer shall provide facilities and equipment to the Licensee, Radiological Safety Officer and other worker(s) to carry out their functions effectively in conformity with the provisions of this safety code, directives and guidelines issued by the Competent Authority from time to time.
- 6.2.7 Ensure that provisions of the Atomic Energy (Radiation Protection) Rules 2004 are implemented by the licensee, RSO and radiation workers.
- 6.2.8 Health surveillance of classified workers and radiation surveillance of all radiation workers shall be carried out as specified in Atomic Energy (Radiation Protection) Rules, 2004.
- 6.2.9 Upon termination of service of worker provide to his new employer on request his dose records.
- 6.2.10 Inform the Competent Authority if the licensee and/or the Radiological Safety Officer leaves the employment.
- 6.2.11 Comply with the terms and conditions of Licence.

6.3 Responsibilities of Licensee

- 6.3.1 Establish written procedures and plans for controlling, monitoring and assessment of exposure for ensuring adequate protection of workers, members of the public, environment and patients, wherever applicable.
- 6.3.2 Ensure periodic training in radiation safety for radiation workers towards performing their intended task.
- 6.3.3 Subject the radiation workers to personnel monitoring and maintain dose records.

- 6.3.4 In consultation with the Radiological Safety Officer, investigate any case of exposure in excess of prescribed regulatory limits received by individual workers, implement the follow-up actions, take steps to prevent recurrence of such incidents and promptly inform the Competent Authority of the same. The licensee shall also maintain records of such investigations.
- 6.3.5 Arrange for or conduct quality assurance tests of equipment and arrange for preventive maintenance of radiation protection equipment, and monitoring instruments.
- 6.3.6 Advise the employer about the modifications in working condition of a pregnant radiation worker.
- 6.3.7 Ensure that the workers are familiar with contents of the relevant safety documents issued by the Competent Authority.
- 6.3.8 Inform the Competent Authority when he/she leaves the employment.
- 6.3.9 Comply with the terms and conditions of Licence.

6.4 Responsibilities of Radiological Safety Officer

The Radiological Safety Officer shall be responsible for advising and assisting the employer and licensee on safety aspects aimed at ensuring that the provisions of Atomic Energy (Radiation Protection Rules) 2004 are complied with.

To this effect, the responsibilities of Radiological Safety Officer are as follows:

- 6.4.1 Carry out routine measurements and analysis on radiation safety of the radiation installation and maintain records of the results thereof.
- 6.4.2 Investigate any situation that could lead to potential exposures.
- 6.4.3 Prepare and make available periodic reports on safety status of the radiation installation to the employer and the licensee for reporting to the Competent Authority.
- 6.4.4 Prepare and make available the reports on all hazardous situations along with details of any immediate remedial actions taken to the employer and the licensee for reporting to the Competent Authority.
- 6.4.5 Verify the performance of radiation monitoring systems, safety interlocks, protective devices such as lead (equivalent) aprons, and other safety systems such as structural shielding in the radiation installation if any.
- 6.4.6 Advise the employer and the licensee regarding:
 - (a) necessary steps that ensure the dose of radiation workers are well within the dose limits prescribed by the Competent Authority.
 - (b) the good work practices that ensure radiation doses are maintained As Low As Reasonably Achievable (ALARA).
 - (c) initiation of suitable remedial measures in respect of any situation that could lead to potential exposures.
 - (d) **carrying out** periodic QA tests as prescribed by regulatory body.
 - (e) promptly carrying out servicing and maintenance of the equipment, which can impact radiation safety.
 - (f) Ensuring periodic calibration of monitoring instruments.

(g) modifications in working condition of a pregnant worker.

6.4.7 Assist the employer and licensee in instructing the workers on hazards of radiation, suitable safety measures and work practices aimed at optimizing exposures.

6.4.8 Inform the Competent Authority when he leaves the employment.

6.5 Responsibilities of Operators and Other Radiation Workers

The operators and other radiation workers shall ensure radiation safety while operating the X-ray equipment, as applicable, by adhering to the following:

6.5.1 Provide to the employer information about his previous occupations including radiation work, if any.

6.5.2 Undergo training provided by the supplier, towards appropriate exposure parameters and dose reduction protocols.

6.5.3 Use appropriate exposure parameters for adults and children X-ray examinations.

6.5.4 Use protective devices during operation of X-ray equipment.

6.5.5 Use personnel monitoring devices appropriately within the facility and monitor dose received.

6.5.6 Inform the Radiological Safety Officer and the Licensee of any accident or potentially hazardous situation that may come to his notice.

6.5.7 Female workers shall, on becoming aware of her pregnancy, notify the employer, licensee and Radiological Safety Officer in order that her working conditions may be modified if necessary.

6.6 Responsibility of Students/Trainees

6.6.1 Medical students/trainees shall not operate X-ray equipment except under direct supervision of authorized operating personnel.

6.6.2 They shall not receive an effective dose in excess of as stipulated by regulatory body.

6.7 Responsibilities of Medical Practitioner

The medical practitioner shall undertake an X-ray examination on the basis of medical requirement. The medical practitioner shall:

6.7.1 be satisfied that the necessary clinical information is not available from radiological examinations already done or from any other medical tests or investigations.

6.7.2 be conscious of the patient dose and for any given examination shall attempt to be in line with international reference levels or those recommended by the regulatory body.

6.7.3 evaluate medical procedures continuously for possible reduction of doses, especially for paediatric procedures.

6.7.4 customize the exposure protocols as per his expectation for optimum image quality for new installations.

6.8 Offences and Penalties

Any person who contravenes the provisions of the Atomic Energy (Radiation Protection) Rules, 2004, elaborated in this safety code, or any other terms or conditions of the Licence/Registration/Certification granted to him/her by the Competent Authority, is punishable under sections 24, 25 and 26 of the Atomic Energy Act, 1962. The punishment may include suspension of licence, fine, imprisonment, or both, depending on the severity of the offence.

7. REQUIREMENTS FOR OCCUPATIONAL RADIATION PROTECTION

7.1 General

The personnel working with the X-ray equipment such as X-ray technologists, medical practitioners, service engineers and personnel carrying out QA shall comply with the following operational radiation safety requirements, as applicable.

7.2 Operational Safety in the Use of X-ray Equipment

The operator shall:

- (i) avoid routine holding of patients without protective aprons.
- (ii) always work from behind a protective barrier, such as a wall, control room or mobile protective barrier (MPB).
- (iii) always wear protective apron while operating the mobile and portable X-ray equipment.
- (iv) ensure that while operating the mobile X-ray equipment a minimum of 2m distance between the equipment and himself is maintained.
- (v) use personnel monitoring devices appropriately as per the guidelines issued by RSO and the regulatory body.
- (vi) ensure that patients/relatives/ staff do not crowd inside the X-ray room
- (vii) keep the X-ray room door closed during exposure.
- (viii) provide relatives or escort with protective aprons when there is a need to hold the children or infirm patients during X-ray examination.

7.3 Additional Requirements in Fluoroscopy

Interventional procedures constitute higher radiation exposures to the physicians and allied medical professionals, as the procedures are lengthy, complex and carried out at close proximity to radiation field. Therefore all personnel associated with the use of the interventional radiology / C-Arm/fluoroscopy equipment shall:

- (i) use design provided protective ceiling suspended screens and table curtains/flaps
- (ii) position the imaging system as close to the patient surface, as possible.
- (iii) in oblique orientation, position themselves opposite to the X-ray tube.

APPENDIX -I
DESIGN SPECIFICATIONS FOR X-RAY EQUIPMENT

I.1 : X-ray Tube Housing

I.1.1 All Modalities of X-ray Equipment (except Mammography and Dental-IOPA)

X-ray tube housing for medical diagnostic X-ray equipment shall be so constructed that leakage radiation through the protective tube housing in any direction, averaged over an area not larger than 100 cm² with no linear dimension greater than 20 cm, shall not exceed an air kerma of 1 mGy in one hour at a distance of 1.0 m from the target when the tube is operating at the maximum rated kVp and for the maximum rated current at that kVp.

I.1.2 Mammography

X-ray tube housing shall be so constructed that leakage radiation averaged over an area of 10 cm², with no linear dimension greater than 5 cm and located at 5 cm from any point on the external surface of X-ray tube housing, shall not exceed 0.02 mGy in one hour.

I.1.3 Dental (IOPA) X-ray Equipment

X-ray tube housing for dental (IOPA) X-ray equipment shall be so constructed that leakage radiation through the protective tube housing in any direction, averaged over an area not larger than 100 cm² with no linear dimension greater than 20 cm, shall not exceed an air kerma of 0.25 mGy in one hour at a distance of 1.0 m from the X-ray target when the tube is operating at the maximum rated kVp and for the maximum rated current at that kVp.

I.2 : X-ray Beam Filtration

I.2.1 All Modalities of X-ray Equipment (except Mammography)

X-ray tube shall be provided with appropriate filters. The total filtration arising from the materials in the X-ray beam shall not be less than 2.5 mm Al equivalent filtration for X-ray equipment operating at constant potential* X-ray tube voltage. The minimum permissible values of first Half-Value-Layer (HVL) corresponding to the total filtration of 2.5 mm Al equivalent is given in Table-1A. The HVL for other X-ray tube voltages shall be obtained by interpolation or extrapolation. Total filtration shall be indicated on the tube housing. In case of dental X-ray equipment, for maximum X-ray tube voltage not exceeding 70 kVp, alternative to the requirements of HVL in Table 1A, a total filtration of at least 1.5 mm Al is permitted [Ref: IEC 60601-2-65]

TABLE-1A: FIRST HVL Vs TUBE VOLTAGE [Ref: IEC 60601-1-3]

X-ray Tube Voltage (kV)	First Half-Value Layer of Aluminum (mm) or Equivalent
50	1.8
60	2.2
70	2.5
80	2.9
90	3.2
100	3.6
X-ray Tube Voltage (kV)	First Half-Value Layer of

	Aluminum (mm) or Equivalent
110	3.9
120	4.3
130	4.7
140	5.0
150	5.5

* For ray requirement of minimum total filtration is as given in Table-1B.

other type of X-equipment the

TABLE-1B: TOTAL FILTRATION Vs TUBE POTENTIAL [Ref: IS 7620]

Maximum Rated Tube Potential (kVp)	Minimum Total Filtration (mm Al)
Less than 70	1.5
70 to and including 100	2.0
Above 100	2.5

I.2.2 : Mammography

I.2.2.1 The total filtration in mammography equipment with Mo-Mo target filter combination shall not be less than 0.03 mm Mo. For any other target filter combination the values of first HVL given in Table-2 will apply. The minimum total filtration equivalent to first HVL shall be provided.

TABLE -2: FIRST HVL Vs TUBE POTENTIAL [Ref: IS 7620]

Applied Tube Potential (kVp)	First HVL
30	≥ 0.3 mm Al
40	≥ 0.4 mm Al
50	≥ 0.5 mm Al

I.3 Automatic Exposure Control (AEC)

AEC shall be designed such that the transmitted dose shall not vary by more than 20% for all phantom thicknesses.

I.4 Couch

The couch used with the X-ray equipment shall not have attenuation of more than 1.2 mm Aluminum equivalent. The couch shall have markings in the centre for patient positioning.

I.5 Table-top (where applicable) Exposure Rate

The Air Kerma Rate measured at table top for the minimum focus-to-table top distance shall be as low as possible, and in any case shall not exceed 10 cGy per minute.

I.6 Additional Specifications for Dental Equipment

I.6.1 Dental Intra Oral X-ray Equipment

I.6.1.1. Dental X-ray assemblies for use with intra-oral films shall be provided with dental cones ensuring the minimum focal spot to skin (FSD) distance as given in following table:

TABLE-3: MINIMUM FOCUS TO SKIN DISTANCE Vs TUBE POTENTIAL

Maximum Rated Tube Potential	Minimum Focus-to-skin Distance
Above 60 kVp and up to and including 75 kVp	20 cm
Above 75 kVp	30 cm

I.6.2 Panoramic X-ray Equipment such as Ortho Pan-Tomography (OPG) and Dental Cone Beam Computed Tomography (CBCT)

I.6.2.1 A face positioning device shall be provided to limit the minimum focal spot to skin distance not less than 15 cm.

I.6.2.2 Provision for tube locking shall be provided such that the primary radiation beam is fully intercepted during the complete cycle and no part of the beam shall be outside the image receptor area.

I.6.2.3 The cassette carrier shall be interlocked such that exposure is not possible, unless a film cassette is in the cassette carrier.

I.7 Additional Specifications for Fluoroscopy Equipment

I.7.1 Protective Lead Glass

Protective lead glass (for conventional fluoroscopy) covering of the fluorescent screen shall have a lead equivalent thickness of 2.0 mm for equipment operating up to 100 kVp. For equipment operating at higher kilo-voltages the lead equivalence shall be increased at the rate of 0.01 mm per kVp.

I.7.2 Built-in Protective Device

The 'bucky-slot' shall be provided with protective flaps of 0.5 mm lead equivalence for protection of radiation worker.

I.7.3 Tube- image Receptor Alignment

X-ray tube and fluoroscopic screen shall be rigidly coupled and aligned so that both move together synchronously and the X-ray beam axis passes through the centre of the screen in all positions of the tube and screen. The beam shall be confined within the useful receptor area at all source-image receptor distances.

I.7.4 Field Limiting Diaphragm

Tube housing shall be provided with a field-limiting diaphragm. Its control mechanism shall be so mechanically restricted that even when the diaphragm is fully opened and the screen is at the maximum distance from the table, there is still an un-illuminated margin of at least 1 cm all along the edges of the screen. The diaphragm control knobs shall be located on the frame of the fluorescent screen and provided with local shielding of at least 0.25 mm lead equivalence.

I.7.5 Focus-to-Table Top Distance

The focus-to-table top distance shall not be less than 30 cm for fluoroscopy equipment.

I.7.6 Table-top Exposure Rate

The Air Kerma Rate measured at table top for the minimum focus-to-table top distance shall be as low as possible, and in any case shall not exceed 5 cGy per minute for conventional fluoroscopy and 10 cGy per minute for pulsed fluoroscopy

I.7.7 Fluoroscopy Timer

The equipment shall have a cumulative timer and its maximum range shall not exceed 5 minutes. There shall also be provision for an audible signal at the end of the pre-set time.

APPENDIX -II
DESIGN SPECIFICATIONS FOR RADIATION PROTECTION DEVICES

II.1 Radiation Protection Devices

II.1.1 Protective Barrier (Fixed/Mobile)

The protective barrier between operator/control console and X-ray tube/patient shall be of appropriate size and design to shield the operator adequately against stray radiation. It shall have a minimum lead equivalence of 1.5 mm. The protective barrier shall have a viewing window as specified in II.1.2.

In case of mammography equipment, the protective barrier between operator/control console and X-ray tube/patient shall be of appropriate size and design to shield the operator adequately against stray radiation. It shall have a minimum lead equivalence of 0.25 mm. The protective barrier shall have a viewing glass with minimum lead equivalence of 0.25 mm.

II.1.2 Protective Lead Glass Viewing Window

The protective glass viewing window provided with barrier or control room shall be of adequate size and design. It shall have a minimum lead equivalence of 1.5 mm.

II.1.3 Ceiling Suspended Protective Glass

The ceiling suspended protective glass shall be of appropriate size and design. It shall have a minimum lead equivalence of 0.5 mm.

II.1.4 Couch Hanging Protective Flaps

The couch hanging protective flaps shall be of adequate size and design. It shall have a minimum lead equivalence of 0.5 mm.

II.1.5 Protective Door

All the doors to X-ray room shall have lead (equivalent) lining of 1.7 mm.

II.1.6 Protective Aprons

Protective aprons shall have minimum 0.25 mm lead equivalence and their size/design shall ensure adequate protection to the torso and gonads.

II.1.7 Protective Gloves

Protective gloves shall have a minimum 0.25 mm lead equivalence and the design shall ensure adequate protection against scattered radiation reaching the hands and wrists and shall permit easy movements of hands/fingers.

II.1.8 Thyroid Shield

Protective thyroid shield shall have minimum 0.25 mm lead equivalence and their size/design shall ensure adequate protection to the thyroid.

II.1.9 Protective Goggles

Protective goggles shall have minimum 0.25 mm lead equivalence and their size/design shall ensure adequate protection to the lens of the eye.

II.1.10 Gonad Shield

Protective gonad shield shall have minimum 0.25 mm lead equivalence and their size/design shall ensure adequate protection to the gonad.

ANNEXURE-I

RADIATION SAFETY OF PATIENTS

Radiation safety of patients is ensured by compliance to requirements given in this safety code. Though medical exposures have no 'dose limits' all referring physicians, doctors and X-ray technologists should be aware of radiation protection aspects like justification and optimization of radiation exposure of patients.

For ensuring radiation protection during medical exposures the hospital/ centre should:

- (a) set and follow the standard exposure protocols for adult as well as paediatric patients as per the image quality required for clinical diagnosis;
- (b) have in place a quality control protocol which should ensure the right procedure to the right patient and correct reporting. The quality control protocol should be reviewed periodically; and
- (c) provide the patient, dose records for future reference.

For patients who are pregnant or likely to be pregnant, the following aspects should be considered in addition to the above.

- (a) A woman presenting herself for X-ray examination should be asked about the possibility of pregnancy.
- (b) Radiography of areas away from the foetus such as chest, skull, extremities should be carried out with proper beam limitation and shielding of abdomen and with low dose protocols.

Paediatric Patients

The following practices are deemed unjustified and should be avoided:

- (a) Following adult exposure protocols for children
- (b) Using automatic exposure control systems in imported equipment, which are not customized to Indian population before use.
- (c) Radiographs taken by unqualified personnel.
- (d) Not considering alternate means of diagnosis (MRI, USG etc).
- (e) Not asking for previous X-ray records, for the same ailment.
- (f) Expecting best quality images, even if there is no additional gain in terms of diagnosis.

In addition to the requirements mentioned, for paediatric patients the following measures should be followed:

- (a) X-ray beam should be carefully collimated to the area of interest, excluding other regions, especially gonads, breast, thyroid and eyes.
- (b) Anti-scatter grid should be used judiciously for children, when high image quality is of prime concern.
- (c) For the desired X-ray tube current and time product (mAs), should use shortest exposure time.
- (d) Additional filters if provided by design should be used.

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July 15, 2013
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SAFETY DOCUMENTS (SCRRRS D)**

Dates of meeting : December 09, 2014

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ADVISORY COMMITTEE ON RADIOLOGICAL SAFETY (ACRS)

Dates of meeting: **March 13, 2015**
 March 25, 2015

Chairman and Members of ACRS:

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**LIST OF REGULATORY SAFETY DOCUMENTS ON MEDICAL FACILITIES
INVOLVING RADIATION**

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AERB/RF-MED/SG/MED-1 (Rev. 1)	Medical Management of Persons Exposed in Radiation Accidents (Under preparation)
AERB/RF/SM/G-3	Regulatory Inspection and Enforcement in Radiation Facilities