AERB SAFETY CODE NO. AERB/SC/MED-2 (Rev. 1)

SAFETY CODE FOR MEDICAL DIAGNOSTIC X-RAY EQUIPMENT AND INSTALLATIONS

Approved by the Board on October 5, 2001

This document is subject to review, after a period of one year from the date of issue, based on the feedback received.

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FOREWORD

Widespread utilisation of ionising radiation for multifarious applications in medicine, industry, agriculture, research etc. has brought in its wake the need for exercising regulatory controls to ensure safety of users, members of the public and the environment. The Atomic Energy Regulatory Board (AERB), constituted under the Atomic Energy Act, 1962 by the Government of India, is entrusted with the responsibility of developing and implementing appropriate regulatory measures aimed at ensuring radiation safety in all applications involving ionising radiation. One of the ways to meet these responsibilities is to develop and enforce specific codes and standards dealing with radiation safety aspects of various applications of ionising radiation to cover the entire spectrum of operations, starting from design of radiation equipment, their installation and use to decommissioning/disposal.

In view of the fact that regulatory standards and requirements, techniques of radiation safety engineering and type of equipment change with time, it becomes necessary to review and revise codes and standards from time to time to incorporate these changes.

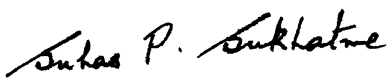
In addition to the safety of workers and members of the public, it is of utmost importance to ensure radiological safety of the patient in medical (diagnostic and therapeutic) uses of radiation. Diagnostic radiology facilities are widely available in the country and a large number of persons undergo diagnostic X-ray procedures every year. It is therefore imperative that adequate attention to safety is paid with regard to this widespread practice.

The first "Safety Code for Medical Diagnostic X-ray Equipment and Installations, AERB/SC/MED-2" was issued by AERB in December 1986. This Code has been revised by a task group (Task Group II) constituted by AERB. The revised Safety Code for "Medical Diagnostic X-ray Equipment and Installations" has considered all changes in the recommendations of ICRP and has incorporated all the latest regulatory requirements relevant to medical X-ray diagnostic practice.

The Standing Committee for Review and Revision of AERB's Radiation Safety Documents constituted by Chairman, AERB has undertaken the scrutiny and

finalisation of this Code. The revised Code, approved for issuance on October 5, 2001 by the Atomic Energy Regulatory Board, is effective from its date of approval, and replaces the earlier Code dated December 30, 1986.

AERB wishes to thank all individuals and organisations for help in the revision of the Code. The names of individuals who participated in the preparation of both the first Code and its present revision are listed for information, along with their affiliations.



(Suhas P. Sukhatme)
Chairman, AERB

DEFINITIONS

Annual Limit of Intake (ALI)

The intake by inhalation, ingestion or through skin of a given radionuclide in a year by the Reference Man which would result in a committed dose equal to the relevant dose limit. The ALI is expressed in units of activity.

Attenuation

A reduction in intensity of radiation passing through matter due to processes such as absorption and scattering.

Beam Hardening

The process of filtration of an X-ray beam by the preferential absorption of lower energy photons, thereby increasing the average energy of the beam.

Collimator or Field-Limiting Diaphragm

A device used for limiting the size and shape of the primary radiation beam.

Commissioning

The process during which structures, systems and components of a facility, having been constructed, are made operational 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 recognised by the Government for the purpose of the Rules promulgated under the Atomic Energy Act, 1962.

Decommissioning

The process by which a 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.`

Dose

A measure of the radiation received or 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. The modifying terms are used when they are necessary for defining the quantity of interest.

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, defined as a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor.

$$E = \sum_T W_T \,.H_T$$

where H_T is the equivalent dose in tissue T and W_T is the tissue weighting factor for tissue T. The unit of effective dose is joule per kilogram ($J.kg^{-1}$), termed sievert (Sv).

Equivalent Dose

The quantity $H_{T,R}$ defined as:

$$H_{T,R} = D_{T,R} \,.W_R$$

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 different values of W_R, the equivalent dose is defined as:

$$H_T = \sum_R D_{T,R} \,.W_R \,.$$

The unit of equivalent dose is joule per kilogram ($J.kg^{-1}$), termed sievert (Sv).

Employer

Any person with recognised responsibility, commitment and duties towards a worker in his or her employment by virtue of a mutually agreed relationship (A self-employed person is regarded as being both a worker and employer).

Filter

A radiation attenuating material incorporated in the path of the radiation beam to absorb preferentially the less penetrating components of the useful 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 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;

Gantry Aperture

The physical opening in the CT scanner through which the patient is moved for the X-ray examination.

Grid

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, import, transport, or dispose of.

Kerma

The quantity K, defined as:

$$K = dE_{tr} / dm$$

where, dE_{tr} is the sum of the initial kinetic energies of all charged ionising particles liberated by uncharged ionising particles in a material of mass dm. The SI unit of kerma is the joule per kilogram ($J.kg^{-1}$), termed gray (Gy).

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/tube housing, except the useful beam or primary beam.

Light Beam Collimator or Light Beam Diaphragm

The mechanism to collimate and indicate the radiation field by optical means.

Milliampere-seconds (mAs)

The product of the current through X-ray tube in mA and the duration of the exposure in seconds.

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.

Radiation

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

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 Radiation Protection Rules, 1971.

Safety

Protection of all persons from undue radiological hazards.

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 the useful beam so as not to exceed the radiation leakage levels as prescribed by the competent authority.

Type Approval

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

Useful Beam or 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.

Worker

Any person, who works, whether full-time, part-time or temporarily, for an employer, and who has recognised rights and duties in relation to occupational radiation protection. (A self-employed person is regarded as having the duties of both an employer and worker).

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

SPECIAL DEFINITIOINS

Beam Shaping (Flattening) Filter or Bowtie Filter

An X-ray beam filter composed of a material such as graphite, teflon or aluminium, which, when placed in the X-ray tube, more heavily attenuates peripheral portions of the X-ray beam which pass through the thinner portions of the patient. The term bowtie refers to the shape of the filter.

Cone

A device by which X-ray beam is confined to a specified area, size or dimension.

Detector

A device element of a detector unit or array 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.

Focus

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

Kilovolt Peak (kVp)

The peak kilo-voltage applied across an X-ray tube.

Mobile Equipment or Portable Equipment

Equipment intended to be moved or carried from one location to another between periods of use.

Modulation Transfer Function (MTF)

A curve plotting spatial frequency on the horizontal axis against a modulation transfer value on the vertical axis. This curve indicates how well an image

represents the true spatial frequencies with an object at each spatial frequency. The maximum value of the modulation transfer function is 1.0. The curve "function" indicates the degree of accuracy of "transfer" of the modulation (spatial frequency) from an object to the image at different spatial frequencies within the image.

Milliampere (mA)

A measure of the electric current through X-ray tube (also called tube current).

Noise

A point-to-point variation in image density that does not contain useful information.

Permanent Filter

See "filter".

Person

Person includes:

(a) any individual, corporation, association of persons, whether incorporated or not, partnership, estate, private or public institution, group, government agency, or any state or any political subdivision thereof, or any political entity within the state, any foreign government or nation, or any political subdivisions of any such government or nation or other entity.

(b) any legal successor, representative or agent of each of the foregoing.

Protective Barrier or Shielding

A barrier of radiation-attenuating material used to reduce radiation levels.

Scan Incrementation

The movement of the patient couch to a different slice level during a computed tomography (CT) examination.

Signal-to-Noise Ratio

The ratio of strength of the signal for information content in the image-to-noise level.

X-ray Equipment or X-ray Unit

The integrated assembly consisting of X-ray tube along with its housing, supporting structures, associated accessories necessary for proper operation, and inclusive of built-in radiation safety devices.

CONTENTS

1. INTRODUCTION

1.1 Purpose

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

(a) ensure that radiation workers and members of the public are not exposed to radiation in excess of limits specified by the competent authority under the Radiation Protection Rules, 1971, and by safety directives issued from time to time;

(b) reduce radiation exposures below these limits to levels as low as reasonably achievable;

(c) ensure availability of appropriate equipment, personnel and expertise for safe use of the equipment and for patient protection; and

(d) ensure timely detection and prompt rectification of radiation safety-related defects or malfunctioning of the equipment.

1.2 Scope

Radiation safety in handling of radiation generating plants is governed by section 17 of the Atomic Energy Act, 1962, and the Radiation Protection Rules (RPR), G.S.R. - 1601, 1971 issued under the Act. The "Radiation Surveillance Procedures for Medical Applications of Radiation, G.S.R. - 388, 1989", issued under rule 15 specify general requirements for ensuring radiation protection in installation and handling of X-ray equipment. This Code elaborates the safety requirements contained in the Atomic Energy Act, 1962, the Radiation Protection Rules, 1971 and the Radiation Surveillance Procedures relevant to medical diagnostic X-ray equipment and installations and their use. Guidance and practical aspects on implementing the requirements of this Code are provided in various guides issued under this Code.

2. SAFETY SPECIFICATIONS FOR MEDICAL DIAGNOSTIC X-RAY EQUIPMENT AND PROTECTIVE DEVICES

2.1 General Purpose Radiographic Equipment

2.1.1 Tube Housing

Every 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 cm^2 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 X-ray target when the tube is operating at the maximum rated kVp and for the maximum rated current at that kVp. There shall be a distinctly visible mark on the tube housing to indicate the plane of focus.

2.1.2 Beam Limiting Devices

Tube housing for stationary and mobile diagnostic X-ray units shall be provided with light beam collimators. These collimators shall comply with the leakage radiation level prescribed for tube housing.

2.1.3 Beam Filtration

(a) The minimum total filtration in useful beam for maximum rated operating tube potential shall be as given in the following table:

TABLE: MINIMUM TOTAL FILTRATION FOR X-RAY TUBES

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

(b) Total filtration shall be indicated on the tube housing. The total permanent filtration in the tube shall be not less than 1.5 mm Al.

2.1.4 Tube Positioning

X-ray unit shall have facilities for tube positioning, target-to-film distance selection, useful beam centring and angulation, positioning of the patient and the X-ray film for exposure in the desired manner, and appropriate features to display the same.

2.1.5 Locking Devices

Tube housing and tube support shall have appropriate locking devices to immobilise the tube in the desired location and orientation.

2.1.6 Bucky Alignment

X-ray table shall have provisions for correct positioning of the grid, the bucky tray and the film cassette in proper alignment with the useful beam and for their locking in the desired position.

2.1.7 Cable Length

X-ray unit shall be provided with electrical cables of sufficient length so that the control panel/operation switch can be located and operated from a minimum distance of 3 m from the nearest position of the X-ray tube. For mobile/portable X-ray equipment the cable length shall be not less than 2 m.

2.1.8 Control Panel

Control panel shall be provided with means to indicate and control exposure parameters, including tube potential, time of exposure, tube current, and integral exposure in milliampere-seconds (mAs). It shall also provide facilities for technique selection and the engagement of the bucky mechanism. A clearly marked and identifiable indicator shall be provided at the control panel to show whether the X-ray beam is 'ON' or 'OFF'. For portable/mobile units appropriate indication of exposure parameters shall be provided.

2.1.9 Common Station

When more than one tube can be operated from a single control panel, there shall be indication at or near the tube housing and on the control panel showing which of the tubes is being operated.

2.1.10 Exposure Switch

Control panel shall have provision to terminate X-ray exposure automatically after a pre-set time or manually at any moment before this time by removing pressure from it. When mechanical timers are provided, repeated exposures shall not be possible without resetting the timer. The timer shall be capable of accurately reproducing short exposure of 0.05 second and its maximum range of exposure shall not exceed 5 second. The exposure device shall be so arranged that inadvertent exposure is not possible.

2.1.11 Radiation Leakage from Transformer

Radiation levels at 5 cm from the transformer surface of the X-ray unit shall not exceed 5 μGy in any one hour.

2.2 Dental X-Ray Equipment

2.2.1 Tube Housing

Tube housing shall conform to leakage radiation levels prescribed for radiography equipment in 2.1.1.

2.2.2 Beam Filtration

Beam filtration requirements shall be the same as given in 2.1.3.

2.2.3 Focus-to-Skin Distance

(a) 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 the following table:

TABLE: MINIMUM FOCAL SPOT TO SKIN DISTANCES FOR DENTAL X-RAY ASSEMBLIES

Maximum rated tube potential (kVp)	Minimum focus-to-skin distance (cm)
Between 50 and 60	10
Above 60 and up to and including 75	20
Above 75	30

(b) In case of orthopan tomography (OPG) equipment for dental panoramic tomography, the focus-to-skin distance shall be not less than 15 cm.

2.2.4 Dental Cones

(a) X-ray tube shall be provided with such cones that will limit the beam diameter to less than 7.5 cm at the distance specified at the cone end. Interchangeable cones with built-in diaphragm shall be marked with the diameter of cross-section of the useful beam at FSD. The cone shall provide the same degree of protective shielding as specified for leakage from housing in 2.1.1.

(b) In case of OPG, the protective shielding to attenuate the transmitted radiation shall form an integral part of the equipment.

2.2.5 Control Panel

Control panel shall be provided with means to indicate and control the exposure parameters such as tube potential (kVp), tube current (mA), and beam "ON" and "OFF".

2.2.6 Cable Length

X-ray unit shall be provided with an electrical cable, which shall be connected to the operating switch at its end. Its length shall be such that the operating switch can be operated from a minimum distance of 2 m from the nearest position of X-ray tube.

2.3 Mammography X-Ray Equipment

2.3.1 Tube Housing

Tube housing shall be so constructed that leakage radiation averaged over an area of 100 cm^2, with no linear dimension greater than 20 cm and located at 5 cm from any point on the external surface of X-ray tube housing, does not exceed 0.02 mGy in any one hour.

2.3.2 Beam-Limiting Devices

Tube housing shall be provided with such removable beam-limiting device that at any target-to-receptor distance specified for the unit, the beam size shall not exceed that of the image receptor next to the chest wall by 2% of the target-to-receptor distance and shall also not exceed beyond any other edge of the receptor. The beam-limiting device shall be provided with sufficient shielding to reduce the radiation level of primary beam as specified for the tube housing in 2.3.1. The image receptor support shall be such that transmitted dose, when operated at the maximum rated kVp and the maximum rated current at that kVp, is less than 1 μGy per exposure at 5 cm beyond the support with no breast present. The device shall bear on its external surface clearly visible permanent markings stating the image receptor size and the target-to-receptor distance for which the device is designed.

2.3.3 Beam Filtration

The total filtration in the useful beam shall be not less than 0.03 mm of molybdenum for screen-film mammography for Mo-W alloy target type and 0.5 mm of aluminium for xeromammography for W-target X-ray tubes. If an edge filter is used, the attenuation equivalent shall be given for the low energy side of absorption edge. The total permanent filter and attenuation equivalent shall be indicated on the tube housing.

2.3.4 Tube Positioning

Sub-section 2.1.4 shall apply.

2.3.5 Locking Devices

Sub-section 2.1.5 shall apply.

2.3.6 Cable Length

X-ray unit shall be provided with an electrical cable of sufficient length so that the control panel/operation switch can be located and operated from a minimum distance of 3 m from the nearest position of X-ray tube.

2.3.7 Control Panel

Control panel shall be provided with means to indicate control and exposure parameters including tube potential, exposure time and tube current/integral exposure in mAs. A clearly marked and identifiable indicator shall be provided at the control panel to show whether the X-ray beam is "ON" or "OFF".

2.3.8 Exposure Switch

Control panel shall have provision to terminate X-ray exposure automatically after a pre-set time or manually at any moment before this time by removing pressure from it. Pre-set time shall be such that it shall assure a net optical density (OD) within ± 0.15 OD on the films necessary for a clear X-ray of breast. When mechanical timer is provided, repeated exposures shall not be possible without resetting the timer. The timer shall be capable of accurately reproducing short exposure of 0.05 s and its maximum range of exposure shall not exceed 5 s. The exposure device shall be so arranged that inadvertent exposure is not possible.

2.3.9 Radiation Leakage from Transformer

Sub-section 2.1.11 shall apply.

2.3.10 Breast Compression Device

A device for maintaining firm breast compression shall be provided to assure uniform thickness of the compressed breast. The degree of

compression shall be smoothly adjustable and shall remain at the set level during exposure. The compression plate shall not attenuate the beam by more than 2 mm tissue equivalent material.

2.4 Photofluorographic X-Ray Equipment (MMR)

2.4.1 Tube Housing

Sub-section 2.1.1 shall apply.

2.4.2 Beam-Limiting Device

Tube housing of X-ray equipment designed for a fixed image receptor size and fixed target-to-fluorescent screen distance shall be provided with such beam limiting device that the equipment becomes inoperative if a part of the useful beam at the plane of fluorescent screen extends beyond the area of fluorescent screen. When the photofluorographic equipment is designed for a variable image receptor size and variable target-to-receptor distance, the collimator shall be adjustable and shall give a rectangular beam.

2.4.3 Protective Flaps

Protective flaps of 0.25 mm lead equivalence shall be provided on the bracket attached to the bottom of fluorescent screen mounting such that it can be swivelled into place to protect against scattered radiation.

2.4.4 Tube-Screen Alignment

Means shall be provided to ensure that the beam axis will be perpendicular to the plane of the screen and pass through the centre of screen.

2.4.5 Beam Filtration

Sub-section 2.1.3 shall apply.

2.4.6 Tube Positioning

Sub-section 2.1.4 shall apply.

2.4.7 Locking Devices

Mass miniature radiography X-ray unit shall be provided with an interlock arrangement on the film holder mechanism such that it shall not be possible to take more than one film exposure without resetting each time.

2.4.8 Cable Length

Sub-section 2.1.7 shall apply.

2.4.9 Control Panel

Sub-section 2.1.8 shall apply.

2.4.10 Exposure Switch

Sub-section 2.1.10 shall apply. Further, a back-up or safety timer shall also be provided to safeguard against failure of the phototimer. There shall also be a visual/aural indicator device to alert the operator in case phototimer fails to terminate the exposure.

2.4.11 Radiation Leakage from Transformer

Sub-section 2.1.11 shall apply.

2.5 Computed Tomography (CT) Unit

2.5.1 Tube Housing

Sub-section 2.1.1 shall apply.

2.5.2 Beam-Limiting Devices

The tube housing shall be provided with beam-limiting devices so that unattenuated primary beam at the plane of detector shall not exceed the useful dimension of detector by more than 20%.

2.5.3 Beam Filtration

Tube housing shall be provided with filter for both beam-hardening and beam-flattening (bow-tie filter).

2.5.4 Scan Plane Visualiser

A scan plane visualisation device shall be provided to indicate directly or indirectly the position of slice plane(s) (tomographic plane or a reference plane offset from the tomographic plane) on the patient within ± 2 mm.

2.5.5 Couch Position Accuracy

The accuracy of positioning of the patient couch shall be ± 2 mm and independent of the direction of motion of the couch.

2.5.6 Beam-ON Indicators

Visual indicators shall be provided on the control console and on the gantry of the scanning system to indicate whether X-ray scanning is in progress. Indicators on the gantry housing of the scanning mechanism shall be discernible from any point external to the patient side of the gantry.

2.5.7 Scan Increment Accuracy

The deviation of indicated scan increment from actual scan increment shall not exceed ± 0.5 mm with a weight of 100 kg simulating a human body on the patient couch.

2.5.8 Gantry Aperture Clearance

Gantry aperture clearance at the extremes of tilt shall permit the scanning of at least a 50 cm thick patient.

2.5.9 Image Receptor

Housing and supporting plates of image receptor of a CT system shall provide shielding equivalent to at least 2 mm lead for 100 kVp. From 100 to 150 kVp an additional lead equivalent of 0.01 mm per kVp shall be required. The lead equivalence shall be clearly stated on the equipment.

2.5.10 Visual Indicators

CT conditions of operation to be used during a scan or scan sequence shall be indicated prior to initiation sequence. For equipment having all or some of these conditions of operation at fixed values, this requirement shall be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

2.5.11 Timers

Means shall be provided to terminate X-ray exposure automatically as soon as the selected scan has been completed or in the event of equipment failure affecting data collection. Means shall also be provided so that the operator can terminate the X-ray exposure at any time during a scan or a series of scans under X-ray system control of greater than 0.5 second duration. A visible signal shall indicate when the X-ray exposure has been terminated through these means, and manual resetting of the CT conditions of operation shall be required prior to initiation of another scan. A back-up timer or device shall also be provided to monitor equipment function, and if the timer fails, it shall terminate the exposure at 110 percent of set value of total scan time.

2.5.12 Warm-up Conditions

Initiation of an exposure shall not be possible if the scanning motor fails to start, unless warm-up conditions are met or a localisation exposure has been selected. If the warm-up facility is provided on a CT system, there shall be a clear indication on the control panel when the warm-up mode has been selected, and there shall be a device which de-energises the X-ray tube on completion of the desired warm-up phase.

2.6 Fluoroscopy X-Ray Equipment

2.6.1 Fluoroscopy Tube Housing and Filtration

Tube housing shall conform to leakage radiation levels prescribed for radiography equipment in 2.1.1. The useful beam shall have a total filtration of not less than 2.0 mm aluminium for general fluoroscopy.

2.6.2 Protective Lead Glass

Protective lead glass covering of the fluorescent screen shall have a lead equivalent thickness of 2.0 mm for units operating up to 100 kVp. For units operating at higher kilovoltages the lead equivalence shall be increased at the rate of 0.01 mm per kVp.

2.6.3 Lead Rubber Flaps

X-ray table and fluoroscopy screen shall be provided with means of adequate protection for the radiologist and other staff against scattered X-rays. Protective flaps having lead equivalence of not less than 0.5 mm and sufficient dimensions to protect the radiologist shall be so provided that they are suspended (a) from the bottom of the screen such that the flaps overlap the fluoroscopic chair in vertical fluoroscopy, and (b) from the edge of the screen, nearest to the radiologist, such that the flaps extend down to the table top in case of horizontal fluoroscopy. The 'bucky-slot' shall be provided with a cover of 0.5 mm lead equivalence on the radiologist's side.

2.6.4 Tube-Screen 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.

2.6.5 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 unilluminated 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.

2.6.6 Focus-to-Table Top Distance

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

2.6.7 Fluoroscopy Timer

The unit 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.

2.6.8 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 panel when the beam is “ON”.

2.6.9 Table-Top Exposure

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 min.

2.6.10 Control Panel

Sub-section 2.3.7 shall apply.

2.7 Image Intensifier Television System X-Ray Equipment

2.7.1 Tube housing

Sub-section 2.1.1 shall apply.

2.7.2 Primary Protective Barrier

Fluoroscopic equipment shall be so constructed that, under conditions of use for patients, a primary protective barrier permanently incorporated into the equipment shall limit the entire section of the beam. The exposure shall automatically terminate when this barrier is removed from the beam. The kerma rate due to transmission through the primary barrier, combined with scatter from an attenuation block in the useful beam, shall not exceed 20 μGy per h at 10 cm from any accessible surface beyond the plane of the image receptor for each 1 cGy per min of block entrance kerma.

2.7.3 Beam Limiting Device

An adjustable collimator shall be provided to restrict the size of the beam to the area of interest. Collimators shall be so arranged that for spot film radiography, the shutters shall automatically change to the required field size before each exposure.

2.7.4 Beam Filtration

Sub-section 2.1.3 shall apply.

2.7.5 Tube-Receptor Alignment

X-ray tube and collimating system shall be so linked with the image receptor assembly that the beam is centred on the image receptor assembly. The beam shall be confined within the useful receptor area at all source-image receptor distances.

2.7.6 Focus-to-Skin Distance

Sub-section 2.6.6 shall apply.

2.7.7 Bucky Slot Closure

When the X-ray tube is permanently located under a table, the table shall be provided with a bucky slot closure having lead equivalence of 0.5 mm to attenuate all scattered radiation originating under the table.

2.7.8 Table Top Exposure

The kerma rate, measured in air at the position where the centre of the useful beam enters the patient, shall be less than 5 cGy per min for units without automatic brightness control (ABC) and less than 10 cGy per min for units with ABC.

2.7.9 Entrance Exposure

For photofluorographic spot film cameras, the entrance kerma at image intensifier for maximum tube potential and current shall not be greater than 3.0 μGy per exposure. For cine-fluorography, the entrance kerma to the image intensifier shall not be more than 0.3 μGy per frame.

2.7.10 Area of X-ray Beam

The length and width of X-ray field in the plane of the image receptor shall not exceed the corresponding distances of the image receptor by more than 3% of source-to-image distance (SID). The sum of excess length and width shall be not greater than 4% of SID.

2.8 Digital Subtraction Angiography X-Ray Equipment

Sub-sections 2.8.1 to 2.8.10 shall be the same as sub-sections 2.7.1 to 2.7.10 respectively.

2.8.11 Image Intensifier

Image intensifier shall have an intrinsic resolution of at least 4 line pairs

(lp) per mm at a modulation transfer function value of 0.1.

2.8.12 Video Camera

Video camera shall have a signal-to-noise ratio equal to or greater than 500 : 1 and shall employ a progressive read-out.

2.9 Radiation Protection Devices

2.9.1 Protective Barrier

The protective barrier between operator/control panel and X-ray tube/ patient shall be of appropriate size and design to shield the operator adequately against leakage and scattered radiation. It shall have a minimum lead equivalence of 1.5 mm. A viewing window of approximately 1.5 mm lead equivalence shall be provided on the barrier. Lead equivalence shall be indicated on the barrier as well as on the viewing window.

2.9.2 Fluoroscopy Chair

Fluoroscopy chair shall have a minimum of 1.5 mm lead equivalence and its design shall ensure adequate protection to the radiologist against scattered radiation.

2.9.3 Protective Aprons

Protective aprons shall have a minimum lead equivalence of 0.25 mm and their size/design shall ensure adequate protection to the torso and gonads of the radiologist against scattered radiation.

2.9.4 Protective Gloves

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

2.9.5 Gonad Shield

Gonad shields shall have a minimum lead equivalence of 0.5 mm.

2.9.6 Cassette Pass Box

The cassette pass box intended for installation in the X-ray room wall shall have a shielding of 2.0 mm lead equivalence. The design shall be such that the pass box can be opened from one side at a time.

2.9.7 Temporary Film Storage

The box intended for temporary storage of undeveloped films shall have not less than 2.0 mm lead equivalence all around.

2.9.8 Vehicle-Mounted X-ray Equipment

X-ray units installed in a mobile van or vehicle, e.g. for medical surveys/ clinics in remote areas, 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.

2.9.9 Shielding Continuity

Appropriate overlap of shielding materials shall be provided at the joints or discontinuities so as to ensure minimum prescribed shielding all over the surface of all radiation protection devices. Care shall be taken to ensure that lead or any other shielding material does not creep or flow, resulting in reduction of shielding in any location.

2.9.10 Markings

Lead equivalence of shielding incorporated in radiation protection devices shall be marked conspicuously and indelibly on them.

2.9.11 Immobilisation

Facilities for immobilisation of patients, especially children, shall be provided so as to minimise holding of patients during X-ray examinations.

2.9.12 Miscellaneous Accessories

Additional radiation protection devices, which would be necessary for specialised radiological investigations, shall have a minimum of 0.5 mm lead equivalence.

2.9.13 Conventional Safety

Appropriate equipment shall be available to prevent/manage conventional hazards such as fire, flooding and electrical emergencies. Electrical lines to the X-ray unit shall be separated from lines to other utilities. Fire alarms and all electrical features shall comply with the safety regulations outlined in IS-7620 Parts 1 and 2.

3. ROOM LAYOUT FOR AN X-RAY INSTALLATION

3.1 Location of X-Ray Installation

Rooms housing diagnostic X-ray units and related equipment shall be located as far away as feasible from areas of high occupancy and general traffic, such as maternity and paediatric wards and other departments of the hospital that are not directly related to radiation and its use. In case the installation is located in a residential complex, it shall be ensured that (i) wall(s) of the X-ray rooms on which primary X-ray beam falls is (are) not less than 35 cm thick brick or equivalent, (ii) walls(s) of the X-ray room on which scattered X-ray fall is (are) not less than 23 cm thick brick or equivalent, and (iii) there is a shielding equivalent to at least 23 cm thick brick or 1.7 mm lead in front of the door(s) and windows of the X-ray room to protect the adjacent areas, either used by general public or not under possession of the owner of the X-ray room.

3.2 Layout

The layout of rooms in an X-ray installation shall be such that the number of doors for entry to the X-ray rooms shall be kept to the minimum. The unit shall be so located that it shall not be possible to direct the primary X-ray beam towards dark room, door, windows, and control panel, or areas of high occupancy.

3.3 Room Size

The room housing an X-ray unit shall be not less than 18 m^2 for general purpose radiography and conventional fluoroscopy equipment. The size of room housing the gantry of the CT unit shall not be less than 25 m^2. Also, not more than one unit of any type shall be installed in the same room, and no single dimension of these X-ray rooms shall be less than 4 m.

3.4 Shielding

Appropriate structural shielding shall be provided for walls, doors, ceiling and floor of the room housing the X-ray unit so that doses received by

workers and the members of public are kept to the minimum and shall not exceed the respective annual effective doses as prescribed by the competent authority. Appropriate shielding shall also be provided for the dark room to ensure that the undeveloped X-ray films are not exposed to more than 10 μGy per week. The important dose limits are given in Appendix-I.

3.5 Openings and Ventilation

Unshielded openings in an X-ray room for ventilation or natural light shall be located above a height of 2 m from the finished floor level outside the X-ray room.

3.6 Illumination Control

Rooms housing fluoroscopy equipment shall be so designed that adequate darkness can be achieved conveniently, when desired, in the room.

3.7 Control Panel

The control panel of diagnostic X-ray equipment operating at 125 kVp or above shall be installed in a separate room located outside but contiguous to the X-ray room and provided with appropriate shielding, direct viewing and oral communication facilities between the operator and the patient. In case of X-ray equipment operating up to 125 kVp, the control panel can be located in the X-ray room. The distance between control panel and X-ray unit/chest stand shall be not less than 3 m for general purpose fixed X-ray equipment.

3.8 Waiting Areas

Patient waiting areas shall be provided outside the X-ray room.

3.9 Warning Light and Placard

A suitable warning signal such as red light shall be provided at a conspicuous place outside the X-ray room and kept “ON” when the unit

is in use to warn persons not connected with the particular examination from entering the room. An appropriate warning placard as indicated in Appendix-II shall also be posted outside the X-ray room.

3.10 Dark Room

The dark room shall be located adjacent to the X-ray room such that no primary or secondary X-rays reach inside the dark room.

4. RADIATION PROTECTION AND WORK PRACTICE

4.1 Occupancy in X-Ray Room

No person other than those specifically concerned with a particular X-ray examination shall stay in the X-ray/CT gantry room during radiological examinations. The X-ray room shall be kept closed during the radiation exposure.

4.2 Assistance to Patients

Holding of children or infirm patients for X-ray examination shall be done only by an adult relative or escort of the patient and not by a staff member. Such persons shall be provided with protective aprons and gloves. No pregnant women shall hold the patient during X-ray examination. Immobilisation devices shall be used to prevent movement of children during exposure. In no case shall the film or X-ray tube be held by hand.

4.3 Foetal Protection

Notice in local language shall be displayed in the X-ray department at a conspicuous place asking every female patient to inform the radiographer or radiologist whether she is likely to be pregnant. Examination of women known to be pregnant shall be given special consideration.

4.4 Organ Shields

Gonad shields shall be employed to shield the reproductive organs of the patient unless it would interfere with the information desired. Eye shields shall be provided to protect the eyes of patients undergoing such special examinations as carotid angiography. Thyroid shields shall be used where necessary.

4.5 Mobile Equipment

A mobile X-ray unit shall be used with appropriate safety measures to

protect the public in the vicinity. Minimum occupancy and maximum distance from occupied areas and temporary shields shall be employed for the purpose. Fluoroscopy shall not be carried out with mobile equipment.

4.6 Servicing of Unit

Only persons certified by the competent authority on the basis of their experience and radiation protection background to undertake this job safely shall undertake servicing of X-ray equipment. The service personnel shall use appropriate radiation survey meters and direct reading dosimeters, in addition to personnel monitoring devices, for on-the-spot verification of radiation levels.

4.7 Personnel Monitoring

All radiation workers shall use appropriate personnel monitoring devices, as instructed by the employer.

4.8 Storage of Radiation-Sensitive Materials

Storage of undeveloped X-ray films and personnel monitoring devices when not in use shall be done appropriately in areas protected from X-rays and other radiation sources in the installation.

4.9 Serial Changers

Automatic serial changers shall be used where the volume of work demands such specialised equipment.

4.10 Optimisation of Dose

To ensure minimum possible dose to the patient, the field size shall be restricted to the minimum that is consistent with the diagnostic requirement. Particular attention shall be paid to restricting field size in paediatric radiology. Gonads, unless required, shall not be exposed to primary beam.

5. PERSONNEL REQUIREMENTS AND RESPONSIBILITIES

5.1 Requirements

5.1.1 Safety Personnel

Every X-ray department shall have a Radiological Safety Officer (RSO) having qualifications as prescribed in Appendix-III and approved by the competent authority. The RSO may either be the employer himself/herself or a consultant or a full/part-time employee to whom the employer shall delegate the responsibility of ensuring compliance with appropriate radiation safety/regulatory requirements applicable to his/her X-ray installation.

5.1.2 Radiologist

All installations having more than two X-ray units, or even a single X-ray unit with fluoroscopy facility, and all establishments performing special procedures, shall have the services of a qualified radiologist. The qualifications and experience shall be as given in Appendix-III.

5.1.3 X-ray Technologist

All X-ray installations shall have either a radiologist or a qualified X-ray technologist to operate the X-ray unit. The minimum qualifications and experience for X-ray technologist shall be as given in Appendix-III.

5.2 Responsibilities

5.2.1 Manufacturer

The manufacturer or supplier of X-ray equipment shall make available to the actual user detailed procedures for routine quality assurance tests, exposure charts, operating manuals and a copy of safety/regulatory documents as may be issued by the competent authority from time to time. The manufacturer or supplier shall provide appropriate servicing

and maintenance facilities during the useful life-time of X-ray equipment. In case of CT, the manufacturer shall provide the required phantoms for dosimetry and image quality checks.

5.2.2 Service Engineer

Persons undertaking servicing of X-ray equipment shall immediately report to the competent authority any equipment no longer safe for use according to this Code, furnishing brief description of the equipment, its location/address, the name and address of the employer/owner and the nature of defects that make the equipment hazardous. The minimum qualifications and experience for service engineer shall be as given in Appendix-III.

5.2.3 Employer

(a) In any diagnostic X-ray installation the ultimate responsibility of ensuring radiation safety, availability of RSO and qualified personnel for handling of X-ray equipment, and providing them requisite equipment and facilities to discharge their duties, shall rest with the employer. The employer shall also be responsible for ensuring that personnel monitoring devices are made available to the radiation workers. He/she shall inform the competent authority of any change in equipment or staff including RSO.

(b) The employer shall ensure that persons handling medical X-ray diagnostic equipment duly abide by the provisions of this Code. In so doing they should obtain technical guidance from various guides issued by the competent authority from time to time. He/she shall also ensure that these documents are made available to them. Further, the employer shall also implement any other measures of safety as the competent authority may stipulate at any time in each individual case, without delay.

5.2.4 Radiologist

The radiologist shall undertake an X-ray examination on the basis of medical requirement. He/she shall so conduct the examination as to

achieve maximum reduction in radiation dose to the patient while retaining all clinically important information.

5.2.5 X-ray Technologist

X-ray technologist and other attending staff shall ensure appropriate patient protection, public protection and operational safety in handling X-ray equipment and other associated facilities.

5.2.6 Student/Trainee

Medical students/trainees shall not operate X-ray equipment except under direct supervision of authorised operating personnel and shall not receive an effective dose in excess of 6 mSv in any one year.

5.2.7 Radiological Safety Officer (RSO)

RSO shall assist the employer in meeting the relevant regulatory requirements applicable to his/her X-ray installation. He/she shall implement all radiation surveillance measures, conduct periodic radiation protection surveys, maintain proper records of periodic quality assurance tests, and personnel doses, instruct all workers on relevant safety measures, educate and train new entrants, and take local measures, including issuance of clear administrative instructions in writing, to deal with radiation emergencies. RSO shall ensure that all radiation measuring and monitoring instruments in his/her custody are properly calibrated and maintained in good condition. Suitable records of such surveys, including layout drawings, dose mappings, deficiencies noticed and remedial actions taken, shall be maintained for future follow-up.

6. REGULATORY CONTROLS

6.1 Design Certification

Every medical diagnostic X-ray equipment shall meet the design safety specifications stipulated in this Code. The manufacturer/vendor shall obtain design certification from the competent authority prior to manufacturing the X-ray equipment.

6.2 Type Approval / No Objection Certificate

Prior to marketing the X-ray equipment the manufacturer shall obtain a Type Approval Certificate from the competent authority for indigenously made equipment. For equipment of foreign make, the importing/vending agency shall obtain a No Objection Certificate (NOC) from the competent authority, prior to marketing the equipment. Type Approval/NOC shall be issued only if the equipment satisfies the safety specifications of this Code and the standards in force, as demonstrated by actual type testing of the equipment. Only type-approved and NOC-validated equipment shall be marketed and used in the country. Format of application for NOC/Type Approval is given in Appendix-IV.

6.3 Approval of Layout

No X-ray unit shall be commissioned unless the layout of the proposed X-ray installation is approved by the competent authority. The application for approval shall be made by the person owning responsibility for the entire X-ray installation, in the format given in Appendix-V.

6.4 Registration of X-ray Equipment

Acquisition of an X-ray equipment, by purchase, transfer, gift, leasing or loan, shall be registered with the competent authority by the person acquiring the equipment. Registration shall be done only after the installation is approved from radiation safety viewpoint.

6.5 Commissioning of X-ray Equipment

No X-ray equipment shall be commissioned unless it is registered with the competent authority.

6.6 Inspection of X-ray Installations

The diagnostic X-ray installations shall be made available by the employer/owner for inspection, at all reasonable times, to the competent authority or its representative, to ensure compliance with this Code.

6.7 Decommissioning of X-ray Installations

Decommissioning of X-ray equipment shall be registered with the competent authority immediately by the employer/owner of the equipment/ installation.

6.8 Certification of RSO

Any person accepting consultancy assignment to discharge the duties and functions of RSO in diagnostic X-ray installations shall do so only after obtaining certification from the competent authority for the purpose. Such certification shall be granted on the basis of adequacy of the person's qualifications, experience and testing/survey/dosimetry equipment available. Formats of application for obtaining approval of RSO are given in Appendix-VI. RSO shall be of at least Level-I.

6.9 Certification of Service Engineers

Only persons holding a valid certificate from the competent authority shall undertake servicing of X-ray equipment. Certification shall be granted on the basis of qualifications, training, experience, and safety record of such person and availability of servicing facilities. Format of application for obtaining approval of service engineers is given in Appendix-VII.

6.10 Penalties

Any person who contravenes the provisions of the Radiation Protection Rules, 1971, elaborated in this Code, or any other terms or conditions of the license/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 fine, imprisonment, or both, depending on the severity of the offence.

APPENDIX-I

DOSE LIMITS

Workers

1. The cumulative effective dose over a block of five years shall not exceed 100 mSv.

2. The effective dose in any calendar year during a five-year block shall not exceed 30 mSv.

3. (a) The equivalent dose in any calendar year to the lens of the eye shall not exceed 150 mSv;

   (b) The equivalent dose in any calendar year to the skin, the hands and feet shall not exceed 500 mSv.

4. In case of a woman worker of reproductive age, once pregnancy has been estabilished, the conceptus shall be protected by applying a supplementary equivalent dose limit to the surface of the woman's abdomen (lower trunk) of 2 mSv for the remainder of the pregnancy. Internal exposures shall be controlled by limiting intakes of radionuclides to about 1/20 of ALI. The employment shall be of such type that it does not carry a probability of high accidental doses and intakes.

Trainees

The effective dose in any calendar year shall not exceed 6 mSv.

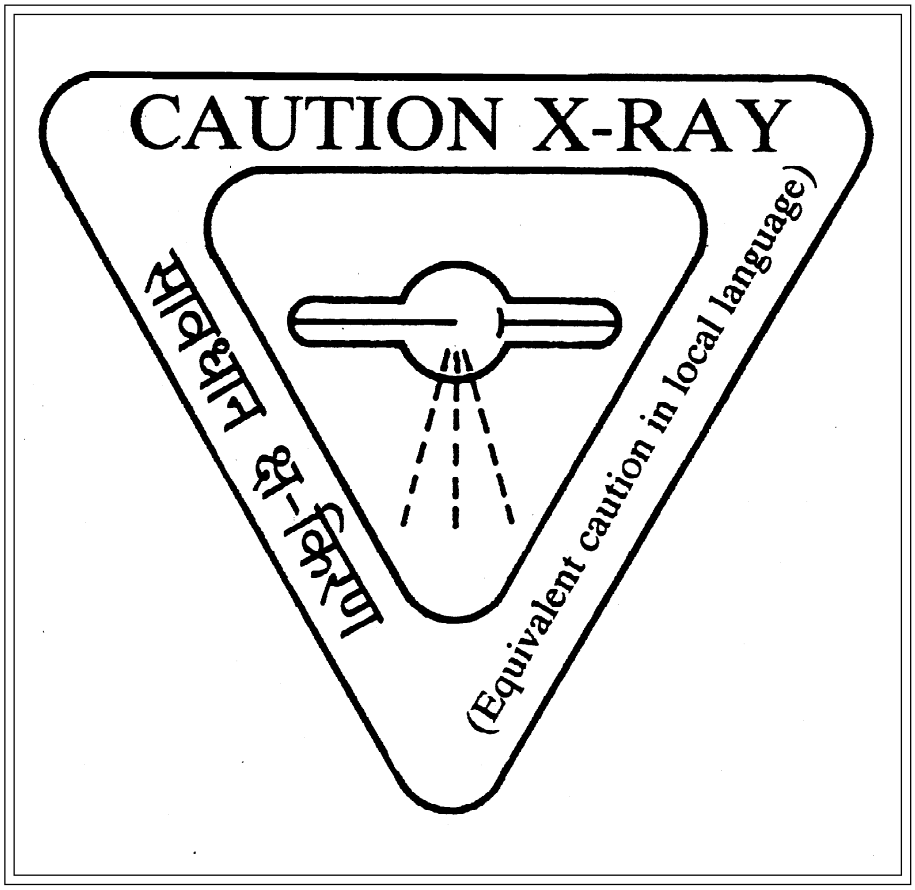
Public

1. The effective dose in any calendar year shall not exceed 1 mSv.

2. In special circumstances, a higher value of effective dose is allowed in a single year, provided that the effective dose averaged over a five year period does not exceed 1 mSv/y.

APPENDIX-II

THE X-RADIATION WARNING SIGN



APPENDIX-III

MINIMUM QUALIFICATION AND EXPERIENCE REQUIRED FOR PERSONNEL

1. Radiologist

(i) An M.B.B.S. degree from a recognised university or an equivalent qualification; and

(ii) A post-graduate degree/diploma in radiodiagnosis from a recognised university.

2. X-ray Technologist

(i) 10+2 or equivalent examination passed with science subjects from a recognised board; and

(ii) Radiographer's/X-ray technologist's course of minimum one year duration (including in-field training in diagnostic radiology) passed from a recognised institution.

3. Radiological Safety Officer

A certification from the competent authority to the effect that the RSO designate is capable of fulfilling the duties and functions of an RSO as laid down in this Code.

4. Service Engineer

(i) A degree/diploma in electrical/electronic engineering or in an associated discipline; and

(ii) A certification from the competent authority.

APPENDIX-IV

Government of India
Atomic Energy Regulatory Board
Niyamak Bhavan, Anushaktinagar,
Mumbai-400094.

FORMAT OF "APPLICATION FOR NOC/TYPE APPROVAL OF MEDICAL RADIOGRAPHY/FLUOROSCOPY/CT/MAMMOGRAPHY/DENTAL X-RAY EQUIPMENT"

To be submitted by the manufacturer/assembler to the Chairman, Atomic Energy Regulatory Board, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with a copy to the Head, Radiological Physics and Advisory Division, Bhabha Atomic Research Centre, CT&CRS Building, Anushaktinagar, Mumbai-400094

Separate form should be submitted for each type of medical diagnostic X-ray equipment

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A. Details of applicant

1. (a) Name and address of the applicant/local supplier with PIN code (in block letters):

(b) Mode of communication:

Telephone with STD code													
Fax													
Telex													
Telegram													

2. (a) Name and address of the manufacturer with PIN code:

(b) Mode of communication:

Telephone with STD code													
Fax													
Telex													
Telegram													
E-Mail													

3. Person to be contacted regarding this application:

Telephone with STD code													

4. Model name and type of equipment which is to be type approved:

5. State whether the equipment is for radiography/fluoroscopy/combined/mammography/ CT/ dental/special:

6. This application is for:

Type approval/NOC			
Renewal of type approval/NOC	Ref No.:	Date:	Valid till:

7. Place where the unit is to be type tested for type approval:

B. Details of equipment specification

1. Name of the model of the unit:

2. Type of unit : Radiography/Fluoroscopy/Dental/CT/ Mammography/Special Mobile/Portable/Fixed/ Any other (specify)

3. Additional facilities for special examination if any :

4. Maximum rating of the unit

   (a) Kilovolt :
   (b) Milliampere :
   (c) Exposure time (in seconds) :

5. Number of X-ray tubes :

6. Year and country of manufacture of the equipment :

C. Details of X-ray tube

1. Name of manufacturer :

2. Type/Model - S.No. :

3. Nominal maximum voltage in kV :

4. Nominal continuous current rating in mA :

5. Type of anode : Stationary/Rotating

6. Anode heat capacity :
   (Please enclose cooling curves)

7. Method of cooling the anode :

8. Target material used and target angle :

9.	Number of focal spots, focal spot size and location (specify the accuracy of the marking on the tube housing)	:	One/two Small :.....mm × .....mm Large :.....mm × .....mm Accuracy :..... mm
10.	Inherent filtration provided in mm and material used	:	
11.	Year and country of manufacture	:	

D. Details of generator

1.	Nominal voltage	:	
2.	Type of rectification	:	Half wave/Full wave/Multipulse
3.	Mains power requirements	:	

E. Details of X-ray tube housing

1.	Material of X-ray tube housing (shielding) and thickness. If the material used is other than lead, specify its lead equivalence	:	
2.	Leakage radiation from the tube housing (measured at maximum rating and measured values to be averaged over an area of 100 cm^2 at a distance of 1 m from the target) for maximum number of radiographs in one hour	:	

F. Details of beam-limiting devices and filtration

1.	Type of beam limiting device/devices used	:	Light beam diaphragm/Cone/ Collimator/Any special arrangements
2.	Leakage radiation through beam limiting devices under condition specified in E.2	:	..... μGy/h
3.	Light beam and radiation beam congruence (attach a radiograph)	:	Within .....mm
4.	Dimensions of cones provided	:	Dental/Radiography

5. Filtration provided

(a) Inherent/permanent filtration : ..... mm Al

(b) Added filtration : ..... mm Al

(c) Total (in mm of Al equivalent) : .....

G. Details of radiation output

1. X-ray beam output at 80 kVp for $20 \times 20 cm^2$ field at 1m from target : ..... μGy/mAs

2. Exposure rate at table top for fluoroscopy for .... kV ..... mA (specify target-to-table top distance) : ..... μGy/min

3. Exposure rate on the surface of the florescence screen with $30 \times 30 \times 30 cm^3$ water phantom (tissue equivalent phantom) : ..... μGy/h

4. Radiation level at diaphragm control knobs for fluoroscopy machines at maximum technique factors with the water phantom : ..... μGy/h

H. Details of fluoroscopy machines

1. Minimum target-to-table top distance : .....cm

2. Lead glass backing of fluorescent screen (lead equivalence in mm) :

3. Tube to screen alignment at maximum field size and FSD (specify the margin left all around the screen) :

4. Shutter movement mechanism :

5. Type of "ON"-"OFF" switch provided : Continuous/Dead man type

6. Lead rubber flaps — Size — Lead equivalence

(a) Below the screen : ..... ×.....cm^2 .....mm

(b) Sides of the screen : .....×.....cm^2 .....mm

7. Automatic exposure termination device : Yes/No

8. Material used for table top and aluminium: equivalence of table top

I. Details of image intensifier

1. Screen size :

2. High contrast resolution :

3. Low contrast resolution :

4. Automatic brightness control :

5. Provision for reading kV, mA and pulse repetition rate :

J. Any other relevant information you may like to furnish

K. Specify the National Standards **:** Bureau of Indian Standards/Any other(specify)

I certify that all the information furnished by me is correct to the best of my knowledge and belief.

Place :
Date :

Signature :
Name :
Designation :

(Seal of the institution)

APPENDIX-V

Government of India
Atomic Energy Regulatory Board
Niyamak Bhavan, Anushaktinagar
Mumbai-400094.

FORMAT OF "APPLICATION FOR APPROVAL OF X-RAY INSTALLATION LAYOUT"

1. Name of owner and address of the institution:

2. Address of proposed X-ray installation:

3. Address for correspondence:

4. Name and address of supplier:

5. Details of the X-ray unit to be commissioned:

(i) Model number :

(ii) Make :

(iii) Type approval certificate No. :

(iv) Maximum operating voltage :

(v) Maximum operating current :

(vi) Name and address of manufacturer :

6. Expected work load:

S.No	Type of examination	Number of examinations	mAs per examination
1			
2			
3			
4			
5			

7. The layout plan (scale 1:50) showing the location of X-ray unit, chest stand, doors, control panel, mobile protective barrier, windows, ventilation, waiting areas and type of occupancy around including above ceiling and below floor is enclosed. The thickness of walls and distances of doors, control panel and windows from the X-ray machine/ chest stand are also indicated.

Place: Signature :
Date: Name :
Designation :

(Seal of the institution)

APPENDIX-VI

Government of India
Atomic Energy Regulatory Board
Niyamak Bhavan, Anushaktinagar,
Mumbai-400094.

FORMAT OF "APPLICATION FOR APPROVAL OF NOMINATION OF RADIOLOGICAL SAFETY OFFICER LEVEL-I"

To be submitted by the applicant to the Chairman, Atomic Energy Regulatory Board, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with a copy to the Head, Radiological Physics and Advisory Division, Bhabha Atomic Research Centre, CT&CRS Building, Anushaktinagar, Mumbai-400094. The application for renewal of nomination should be submitted at least two months prior to the expiry of approval

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Part-1: Particulars of the Institution

1. Name and address of the institution with PIN code (in block letters):

2. Name, designation and address of the head of the institution (the applicant) with PIN code (in block letters):

2. Mode of communication:

Telephone with STD code													
Fax													
Telex													
Telegram													
E-Mail													

4. This application is for:

First time RSO approval			
Renewal of RSO approval	Ref No.:	Date:	Valid till:

5. Details of equipment available at the institution:

S.No.	Name of the manufacturer	Model No.	Type*	Operating parameters		Date of installation
				kVp (max.)	mA (max.)	
1						
2						
3						
4						
5						

* Please indicate R for Radiography, F for Fluoroscopy, C for Combined, D for Dental, CT for Computed Tomography, M for Mammography, Any others (specify)

6. Details of unusual occurrences that have taken place in the past including any radiation emergencies:

S.No. Date of	incident	Radiation equip-ment or source involved	Nature of incident	Details of action taken	Number of persons involved	Maximum dose received by an individual as a result of the incident

7. Radiation workers in the institution:

S.No.	Name of employee and date of birth	Designation	Responsibilities and functions	Date of commencement of radiation work	Personnel monitoring service number

Part-2: Particulars Of The RSO-designate

1. Name (with initials expanded) of the persons to be designated as RSO (in block letters):

PLEASE AFFIX A RECENT PASSPORT SIZE PHOTOGRAPH

2. Present designation of the nominee:

3. Address of the nominee:
Office address:

Telephone with STD code																		

Residential address:

Telephone with STD code																		

Permanent home address:

Telephone with STD code																		

4. Academic qualifications and training in radiation safety:

Qualifications	S.No.	University/Examining body	Degree/ Diploma	Year of passing	Subject(s) of study
Academic	1.				
	2.				
Training course in radiation safety	1.				
	2.				

5. Experience in radiation work:

S.No.	Year(s) of work	Name of institution and address	Radiation equipment, sources handled	Maximum activity handled if any	PMS number

6. Radiation equipment/radioactive materials (if any in the institution) for which RSO will be responsible:

Radiation Equipment	
Radioactive Material	

7. Additional responsibilities proposed to be assigned to RSO:

8. In case the application is for renewal of nomination of RSO, give details of functions and responsibilities handled by the RSO since his approval. (Include functions such as tests and safety checks, training of radiation workers in the institution, reporting on safety status and unusual occurrences to AERB and RP&AD, BARC and any other functions relating to radiation safety in the institution)

9. (a) I hereby certify that the information furnished above is correct to the best of my knowledge and belief;

(b) I undertake to abide by the conditions stipulated by the competent authority from time to time and follow guidelines in discharging the duties and responsibilities as RSO; and

(c) I further undertake to inform the Atomic Energy Regulatory Board immediately in case I am relieved of my services as RSO.

Date :

Signature of RSO-designate

10. (a) I hereby certify that all statements made in this application are correct to the best of my knowledge and belief;

(b) I hereby undertake to provide all necessary facilities to RSO to discharge his/her duties and functions effectively; and

(c) I further undertake to inform the Atomic Energy Regulatory Board immediately in case the RSO is relieved of his duties.

Place :

Signature of the head of the institution (the Applicant)

Date :

(Seal of the institution)

APPENDIX-VII

Government of India
Atomic Energy Regulatory Board
Niyamak Bhavan, Anushaktinagar
Mumbai-400094.

FORMAT OF "APPLICATION FOR APPROVAL OF SERVICE ENGINEER"

To be submitted by the applicant to the Chairman, Atomic Energy Regulatory Board, Niyamak Bhavan, Anushaktinagar, Mumbai-400094 with a copy to the Head, Radiological Physics and Advisory Division, Bhabha Atomic Research Centre, CT&CRS Building, Anushaktinagar, Mumbai-400094. The application for renewal of approval of service engineer should be submitted at least two months prior to the expiry of the approval

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1. Name and address of the institution with PIN code (in block letters):

2. Name, designation and address of the Service Engineer with PIN code (in block letters):

3. Date of birth:

4. Mode of communication:

Telephone with STD code													
Fax													
Telex													
Telegram													
E-Mail													

5. This application is for:

First time approval			
Renewal of approval	Ref No.:	Date:	Valid till:

6. Academic qualifications and training in radiation safety:

S.No:	Degree/Diploma	University/Examination body	Year of passing	Subjects of study
1				
2				
3				
4				

7. Names of radiation monitoring instruments handled:

8. Details of work done with X-ray units:

Name of institution where the work was done	Type of X-ray unit serviced	Nature of job carried out	Exposure received (during each job)

9. I undertake to abide by the conditions stipulated by the competent authority from time to time and follow the guidelines in carrying out the service of X-ray machines.

Place : Signature of the Service Engineer
Date :

10. (a) I hereby certify that all statements made in the application are correct to the best of my knowledge;

(b) I hereby undertake to provide all necessary radiation monitoring instruments/badges and protective devices for servicing of X-ray machines; and

(c) I further undertake to inform AERB immediately in case the service engineer leaves the job.

Place: Signature of the Head of institution
Date :

(Seal of the institution)

BIBLIOGRAPHY

1. Atomic Energy Act, No. 33 of 1962.

2. Radiation Protection Rules, G.S.R.-1601, September 13, 1971.

3. Atomic Energy Regulatory Board - Its Powers and Functions: Constitution Order by Government of India (Order No. 25/2/83-ER dt. 15.11.83), (S.O. - 4772), No.53, Part-II, Section 3, Sub-section (ii) December 31, 1983.

4. Radiation Surveillance Procedures for Medical Applications of Radiation, G.S.R.-388, March 29, 1989.

LIST OF PARTICIPANTS

ADVISORY COMMITTEE ON CODES AND GUIDES FOR MEDICAL APPLICATIONS OF RADIATION

Membership of the Committee (1986):

Dr. S.M. Sharma (Chairman)	:	Bhabha Atomic Research Centre, Mumbai
Dr. M.P. Jain	:	Institute of Nuclear Medicine and Allied Sciences, Delhi
Dr. U. Madhvanath	:	Bhabha Atomic Research Centre, Mumbai
Shri P.S. Negi	:	Post Graduate Institute of Medical Education and Research, Chandigarh
Dr. T.P. Ramachandran	:	Regional Cancer Centre, Trivandrum
Shri S. Ramaswamy	:	Peico Electronics & Electricals Ltd, Madras
Dr. I.S.S. Rao	:	Atomic Energy Regulatory Board, Mumbai
Shri Masood Ahmad* (Member-Secretary)	:	Atomic Energy Regulatory Board, Mumbai

* Author of the initial draft of the first Code issued in 1986.

TASK GROUP II

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

Members of the Task Group:

Dr. M.S.S. Murthy (Convenor)	:	Bhabha Atomic Research Centre, Mumbai (Formerly)
Dr. Masood Ahmad	:	Atomic Energy Regulatory Board, Mumbai
Dr. D. Balasubrahmanian	:	BARC Hospital, Mumbai (Formerly)
Shri G. Janaki Raman	:	Bhabha Atomic Research Centre, Mumbai
Dr. A. Sankaran	:	Bhabha Atomic Research Centre, Mumbai (Formerly)
Shri. J.B. Sasane	:	Bhabha Atomic Research Centre, Mumbai
Shri V.K. Shirva	:	Bhabha Atomic Research Centre, Mumbai
Shri V.K. Bhargava (Member-Secretary)	:	Atomic Energy Regulatory Board, Mumbai (Formerly)

STANDING COMMITTEE FOR REVIEW AND REVISION OF AERB'S RADIATION SAFETY DOCUMENTS (SCRCG)

Members participating in the meeting:

Shri A. Nagaratnam (Chairman)	:	Defence Research and Development Organisation, Hyderabad (Formerly)
Shri E.B. Ardhanari	:	Walchandnagar Industries Limited, Walchandnagar (Formerly)
Shri P.K. Ghosh	:	Atomic Energy Regulatory Board, Mumbai
Dr. P.S. Iyer	:	Bhabha Atomic Research Centre, Mumbai, (Formerly)
Dr. S.K. Mehta	:	Bhabha Atomic Research Centre, Mumbai (Formerly)
Dr. B.K.S. Murthy	:	Bhabha Atomic Research Centre, Mumbai (Formerly)
Dr. A.R. Reddy	:	Defence Research and Development Organisation, Delhi
Dr. I.S.S. Rao	:	Atomic Energy Regulatory Board, Mumbai (Formerly)
Shri P.S. Viswanathan	:	Apollo Cancer Hospitals, Chennai (Formerly)
Dr. B.C. Bhatt (Co-opted Member, since 1-9-1997)	:	Bhabha Atomic Research Centre, Mumbai
Shri J.S. Bisht (Co-opted Member)	:	Bhabha Atomic Research Centre, Mumbai (Formerly)
Dr. M.S.S. Murthy (Co-opted Member, till 31-8-1997)	:	Bhabha Atomic Research Centre, Mumbai (Formerly)
Dr. A.N. Nandakumar (Co-opted Member)	:	Bhabha Atomic Research Centre, Mumbai
Shri K.D. Pushpangadan (Member-Secretary)	:	Atomic Energy Regulatory Board, Mumbai