

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

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GOVERNMENT OF INDIA

AERB SAFETY CODE

**RADIATION THERAPY SOURCES,
EQUIPMENT AND INSTALLATIONS**



ATOMIC ENERGY REGULATORY BOARD

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

**RADIATION THERAPY SOURCES,
EQUIPMENT AND INSTALLATIONS**

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FOREWORD

Activities concerning establishment and utilisation of nuclear/radiation 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 ensuring safety of members of the public and occupational workers as well as protection of 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, therefore, has undertaken a programme of developing safety codes, safety standards 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 standards are formulated on the basis of nationally and 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 shall be fulfilled to provide adequate assurance for safety. Safety guides and guidelines 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. The documents are revised when necessary, in the light of experience and feedback from users as well as new developments in the field.

The safety code for 'Telegamma Therapy Equipment and Installations', (AERB/SC/MED-1) and safety code for 'Brachytherapy Sources, Equipment and Installations', (AERB/SC/MED-3) were issued by AERB in 1986 and 1988 respectively. These codes specified mandatory requirements for radiation therapy facilities, covering the entire spectrum of operations ranging from the setting up of a facility to its ultimate decommissioning, including procedures to be followed during emergency situations. The codes also stipulated requirements of personnel and their responsibilities. With the advent of new techniques and equipment such as 3D-conformal radiation therapy, intensity modulated radiation therapy, image guided radiation therapy, treatment planning system, stereotactic radiosurgery, stereotactic radiotherapy, portal imaging, integrated brachytherapy and endovascular brachytherapy during the last two decades, AERB desires that these codes be revised and merged into a single code titled 'Radiation Therapy Sources, Equipment, and Installations'.

The revised Code is effective from the date of issue and supersedes all the earlier codes on the subject.

Appendices are an integral part of the document, whereas footnotes and bibliography are included to provide further information on the subject that might be helpful to the user.

Specialists in the field drawn from the Atomic Energy Regulatory Board, the Bhabha Atomic Research Centre and other consultants have prepared this code. It has been reviewed by experts and the Standing Committee on Radiation Safety Documents (SCRSD) and Advisory Committee on Radiological Safety (ACRS).

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.S. Bajaj)
Chairman, AERB

DEFINITIONS

Adequate Protection

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

Ambient Dose Equivalent

The quantity 'H*(d)' at a point in a radiation field, defined as the dose equivalent that would be produced by the corresponding aligned and expanded field in the ICRU sphere at a depth on the radius opposing the direction of the aligned field. A depth $d = 1$ cm is recommended for strongly penetrating radiation.

Brachytherapy

Branch of radiation therapy which relates to the uses of sealed sources for: (a) implants and intra-cavitary insertions, and (b) external mould/surface applications, in which the source to skin distance is not more than 5 cm.

Collimator Zone

The portion of the source/tube-housing of radiotherapy/radio-diagnosis equipment, which includes the mechanism for defining the useful beam.

Commissioning

The process during which 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 recognised by the Government of India for the purpose of the Rules promulgated under the Atomic Energy Act, 1962.

Contamination

The presence of radioactive substances in or on a material or in the human body or other place in excess of quantities specified by the competent authority.

Controlled Area

A delineated area to which access is controlled and in which specific protection measures and safety provisions are, or could be, required for

- controlling normal exposures or preventing the spread of contamination during normal working conditions; and
- preventing potential exposures or limiting their extent should they occur.

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.

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:

$$E = \sum_T W_T \cdot H_T$$

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.

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).

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 ionising radiation.

Handle

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

Implant (Source)

The procedure by which sources are applied to the body tissues or organs either manually or by an after-loading system.

Kerma, K

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).

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 to operate the above said facilities.

Penumbra (Teletherapy)

The zone of decreasing radiation intensity of the useful beam area, lying within the isodose boundaries defined by the 90% and 10% (telegamma beams) and by 80% to 20% (high energy photon beams) of the central axis dose, in a plane perpendicular to it and at a depth where the dose is maximum for the designated treatment distance.

Protective Barrier or Shielding (Radiation)

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

Quality

The totality of features and characteristics of an item or service that have the ability to satisfy stated or implied needs.

Quality Assurance

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

Quality Control (QC)

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

Radiation

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

Radiation Surveillance

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

Radioactive Material or Radioactive Substance

Any material or substance, which spontaneously emits radiation in excess of the levels prescribed by notification by the Central Government.

Radiological Safety Officer (or Radiation Safety Officer)

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, 2004.

Regulatory Constraints

Restrictions on radiation protection parameters specified by the regulatory body.

Sealed Source

Radioactive source material that is (a) permanently sealed in a capsule, or (b) closely bounded and in a solid form. The capsule or material of a sealed source shall be strong enough to maintain leak tightness under the conditions of use and wear for which the source was designed, as also under foreseeable mishaps.

Source

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

Source Housing

Shielding provided in any device containing a source, in order to : (a) define the useful beam; and (b) limit the radiation levels outside the useful beam to maximum permissible leakage levels, as specified by the competent authority.

Source Storage

A container of approved design in which the sealed sources are kept when not in use.

Source Transfer

Procedure by which the sealed source is transferred from the source housing to a shielded container and vice versa.

Stray Radiation

The sum of leakage and scattered radiations.

Supervised Area

Any area not designated as a controlled area but for which occupational exposure conditions are kept under review even though specific protective measures and safety provisions are not normally needed.

Teletherapy

Treatment with external radiation beam(s) where the distance from source to skin is greater than 5 cm.

Treatment Planning (Radiotherapy)

Planning of the techniques for radiation therapy, which may include treatment simulation and dosimetry.

Treatment Simulation

Methods by which the techniques and patient positioning for radiotherapy are simulated without delivering the therapy dose.

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

Part of the emergent radiation from a source housing, which is capable of being used for the purpose for which the equipment is intended.

SPECIAL DEFINITIONS (Specific for the Present Code)

Licensee

A person to whom licence is granted by the competent authority under the relevant Rules.

Operational Limits (Radiation)

Limits on levels of radiation or levels of contamination, as the competent authority may specify from time to time. However, in the case of diagnostic X-ray installation, contamination levels are not relevant.

Person

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

Radiation Installation

Any location or facility, including mobile facility, in which a radiation therapy 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 Worker

Any person, who is occupationally exposed to radiation.

Note: Words and expressions 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.

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1. INTRODUCTION

1.1 General

Radiation safety in the handling of radiation sources and radiation generating equipment which only covers sealed sources and particle accelerators is governed by sections 14, 16 and 17 of the Atomic Energy Act, 1962, and the Atomic Energy (Radiation Protection) Rules, 2004, issued under the Act. Radiation surveillance requirements and procedures for medical applications of radiation are specified for ensuring radiation safety of:

- (a) persons handling radiation generating equipment and sources for medical applications;
- (b) patients who undergo medical procedures for their health benefit;
- (c) persons connected with the patient, who are either living with him, or assisting him during the medical procedure; and
- (d) members of the public unrelated to the medical use of radiation.

1.2 Objective

The objective of this code is to stipulate the radiation safety requirements in the design, installation and operation of radiation therapy sources, equipment and installations in order to ensure:

- (a) that radiation workers and members of the public do not receive radiation dose in excess of the limits specified by the competent authority under the Atomic Energy (Radiation Protection) Rules, 2004, and the safety notifications/directives issued there under from time to time;
- (b) that radiation doses to workers and members of the public are optimised to levels as low as reasonably achievable; and
- (c) availability of appropriate instruments, tools and accessories, personnel and expertise, for safe handling of equipment and sources;
- (d) patient protection;
- (e) security, safe custody, transportation and disposal of sources;
- (f) timely detection and prompt rectification of malfunctions of radiation safety related equipment; and
- (g) initiation of appropriate actions to mitigate consequences of radiation emergencies.

1.3 Scope

This safety code titled ‘Radiation Therapy Sources, Equipment and Installations’ elaborates the safety provisions as applicable to radiation therapy practices. However, it does not cover unsealed sources and particle accelerators accelerating particles other than electrons.

In addition, regulations relevant to the use of radiation for medical purposes are contained in (a) Atomic Energy (Safe Disposal of Radioactive Waste) Rules, 1987 (b) AERB safety code for ‘Transport of Radioactive Materials’ (AERB/SC/TR-1, 1986) (c) AERB safety standard for ‘Testing and Classification of Sealed Radioactive Sources’ [AERB/SS/3, (Rev. 1) 2001] (d) Medical Electrical Equipment-part 2-11: Particular requirements for the safety of gamma beam therapy equipment, IEC 60601-2-11,1997, (e) Medical Electrical Equipment-part 2-1: Particular requirements for the safety of electron accelerators in the range 1MeV to 50 MeV, IEC 60601-2-1,1998, (f) Medical Electrical Equipment-part 2-17: Particular requirements for the safety of remote-controlled automatically-driven gamma ray after-loading equipment, IEC 601-2-17,1996, and (g) Medical Electrical Equipment-part 2-29: Particular requirements for the safety of radiotherapy simulators, IEC-60601-2-29,1999.

2. SAFETY SPECIFICATIONS FOR RADIOACTIVE SOURCES, RADIATION THERAPY EQUIPMENT AND PROTECTIVE DEVICES

2.1 General

2.1.1 Sealed Sources

2.1.1.1 Source Encapsulation Design

Sealed sources shall meet the specifications prescribed by the competent authority in respect of containment integrity, mechanical strength and source uniformity, so as to prevent release of radioactive material during the working life of the sealed sources. Each source shall pass relevant tests specified by the competent authority. The prescribed tests are given in Appendix-I.

2.1.1.2 Encapsulation Materials

The materials used for encapsulation shall be unaffected by ionising radiation and heat. In addition, the materials used for encapsulation of brachytherapy sources shall not be affected by body fluids and be non-toxic to body tissues.

2.1.1.3 Radioactive Materials

Radionuclides used in radiation therapy shall not be gaseous or have gaseous daughter products.

2.1.1.4 Source Identification

All sealed sources shall have appropriate identification of radionuclide and source strength. This information should be indelibly marked on the source-encapsulation. Wherever physically possible, the encapsulation of sealed sources and sealed container shall be durably and legibly marked with the information in the given order of priority: (a) mass number and chemical symbol of the radionuclide (b) serial number of the source (c) for neutron sources, the target element, and (d) manufacturer's name or logo.

2.1.1.5 Source Certificate

The certificate accompanying a source shall state its air kerma rate/dose rate (or the apparent activity) of the source measured under the reference conditions at specified distance. The certificate shall also provide dimensional details of the source, encapsulation and the tests that have been performed on the source to demonstrate integrity of encapsulation under normal and accident conditions. In the case of high dose rate remote after-loading brachytherapy equipment, the source certificate shall also specify the recommended useful life of the source.

2.1.2 Source Housing Integrity

The source housing of telegamma therapy, manual and remote after-loading brachytherapy equipment shall be so designed as to retain the integrity of the source and the shielding under all foreseeable accident conditions, including natural calamities likely to occur during their use.

2.1.3 Fail-Safe Mechanism

The beam control mechanism for teletherapy and source position control for remote after-loading brachytherapy equipment shall be so designed that in the event of a breakdown or malfunction of the actuating force, or in the event of inadvertent opening of the treatment room door, the source shall automatically and quickly be turned to OFF position and shall continue to remain so even if the force is restored, until the appropriate mechanism is operated from the control panel.

2.1.4 Conventional Safety

The equipment design shall comply with the mechanical, electrical, fire and environmental safety specifications, promulgated by State/Central Government from time to time, to prevent danger and/or personal injury.

2.1.5 Indication of Beam OFF/ON Conditions

Colour of the light indications for beam OFF or beam ON conditions, whether electrically operated or non-electrically operated, shall be as follows:

Status	Radiation Head		Treatment Control Panel	Elsewhere
	Electrical	Non-electrical		
Beam OFF	Green	Green	Green	Green
Intermediate Position	Red	Red	Red	Red
Beam ON	Red	Red	Yellow/Orange	Red

2.1.6 Radiation Warning Sign

The radiation housing shall be clearly and permanently marked on its outer surface with appropriate radiation warning sign [Appendix-II (A) and II(B)].

2.2 Teletherapy

2.2.1 Source Housing

Every source housing shall be so constructed that with the beam control mechanism (i) in the OFF position for telegamma therapy equipment, and (ii) in ON position for all teletherapy equipment, the dose rate from the leakage

radiation measured at specified distances from the source or the surface housing shall not exceed the limits specified by the competent authority (Appendix-III).

2.2.2 Collimator/Beam Limiting Device (BLD)

Collimator/BLD so constructed that the transmission of the radiation beam through it shall meet the specifications prescribed by the competent authority (Appendix-III).

2.2.3 Wedge Filters

Equipment which is supplied with a system of wedge filters shall be provided with interlocks to ensure that irradiation shall not be possible until:

- (a) selection of a specified wedge filter or no-wedge filter has been made and displayed at the treatment control panel; and
- (b) selected wedge filter is correctly positioned in the beam.

2.2.4 Penumbra

The penumbra width for a radiation field size of 10 cm x 10 cm at the designated treatment distance shall not exceed (i) 2.0 cm and 4.0 cm at the point of maximum ionisation for telegamma therapy equipment using Cobalt-60 and Caesium-137 sources, respectively, and (ii) 1.0 cm (photon beam) and 1.5 cm (electron beam) for electron accelerator.

2.2.5 Beam Rotation and Isocentre

The isocentre and the axis of rotation of collimator for various gantry positions shall be maintained within a sphere of 4 mm and 2 mm diameter, in the case of telegamma units and accelerators, respectively.

2.2.6 Systems Reliability and Accuracy

The teletherapy equipment shall have reliable systems and appropriate accessories for positioning and defining the useful beam and to enable accurate delivery of a pre-determined dose to the target volume in the intended manner. The treatment couch shall be considered as a part of the unit for this purpose.

2.2.6.1 Movements of Equipment Parts

- 2.2.6.1.1 It shall not be possible to operate motorised movements of equipment parts, which may cause physical injury to the patient, without personal action by the operator on two switches simultaneously. However, in case of power failure, it shall be possible to bring down the couch manually. Patient support system shall have provision of locking mechanically or electronically once the patient setup is completed.

- 2.2.6.1.2 It shall not be possible to adjust any movement parameter before completion of the treatment, without causing termination of irradiation.
- 2.2.6.1.3 Any interruption or termination of irradiation shall cause all equipment parts in motion to be stopped within designed limits.
- 2.2.6.1.4 Readily identifiable and accessible means shall be provided for emergency switching 'OFF' of all supply mains to the movement systems. When actuated, the system shall stop any movement within the designed limits.
- 2.2.6.1.5 If a hazardous situation arises from a change in the pressure of a system, used to provide power for movements, all movements shall stop forthwith.
- 2.2.6.1.6 For the motorised movements of both gantry and patient support system:
 - (a) at least one of the available rotation speeds of each movement shall not exceed 1° per second. No available speed shall exceed 7° per second; and
 - (b) angular distance between the position of the moving part, rotating at maximum speed, at the instant of control to stop the motion, and the final position shall not exceed 2°.

2.2.7 Relative Surface Dose

- 2.2.7.1 In case of electron accelerator, for a radiation field size of 30 cm x 30 cm or the largest available square field less than 30 cm x 30 cm, the relative surface dose on the radiation beam axis during X-radiation shall not exceed 70% of maximum depth dose for electron energies up to 5 MeV and 50% of maximum depth dose for electron energies greater than 5 MeV and up to 30 MeV.
- 2.2.7.2 In case of telegamma units, the relative surface dose on the radiation beam axis shall not exceed the following values:

- (a) Normal treatment distance not less than 30 cm

Cobalt-60	<ul style="list-style-type: none"> (i) 70% of the absorbed dose at the depth of 5 mm for 10 cm x 10 cm irradiation field size (ii) 90% of the absorbed dose at the depth of 5 mm for the largest irradiation field size available
Caesium-137	100% of the absorbed dose at the depth of 2 mm for the largest irradiation field size available

(b) Normal treatment distances between 10 cm and 30 cm

Cobalt-60	100% of the absorbed dose at a depth of 5 mm below the surface for the largest irradiation field size available
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(c) Normal treatment distances between 5 cm and 10 cm

Cobalt-60	130% of the absorbed dose at a depth of 5 mm below the surface for the largest irradiation field size available
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2.2.8 Retractable Radiation Beam Shield

Any retractable radiation beam shield shall be interlocked for correct position during irradiation.

2.2.9 Treatment Parameters Display

The radiation therapy equipment shall have appropriate visual features in treatment room to indicate the treatment distance, field size, collimator and gantry orientation and the treatment mode.

2.2.10 Control Panel (Console)

The control panel of the radiation therapy unit shall have reliable provisions to set and display all treatment parameters and hold at least the display of the elapsed time or balance time or an equivalent parameter, in the event of interruption of treatment.

2.2.11 Emergency Beam OFF

2.2.11.1 A clearly identifiable indicator for the beam OFF status shall be provided and it shall be coupled to the beam OFF/ON mechanism of the equipment.

2.2.11.2 In case of emergency, it shall be possible to make the telegamma beam OFF by mechanical means from inside the treatment room. It shall be possible to use mechanical means without the operator being exposed to the radiation beam. The mechanical means, if not an integral part of the telegamma unit, shall be located close to either the control panel, or the treatment room entrance.

2.2.12 Safety Locks

Teletherapy equipment shall be provided with locking mechanism to prevent unauthorised use. Further, it shall be possible to make the radiation beam ON from the control panel only.

2.2.13 Additional Requirements for Telegamma Unit

2.2.13.1 Beam OFF/ON Conditions

2.2.13.1.1 Electrically Operated Indications

Light shall be provided on, or close to, the radiation head to indicate whether the beam control mechanism is in the beam OFF or away from that position. The controlling switch shall be operated directly by the source carrier or shutter.

2.2.13.1.2 Non-electrical Indications

It shall be clearly indicated on the radiation head, the gantry or other parts, as to whether the source carrier or shutter is in the beam OFF position, beam ON position or between these two positions. The indicator shall be mechanically coupled to the source carrier or shutter.

2.2.13.2 Source Transfer Container/Flask

The design of the source transfer container/flask shall provide for adequate protection and safety in the form of appropriate shielding, double locking systems, features for mechanical handling, firm positioning and close compatible coupling with the source head during source transfer and related operations. The source transfer container shall be designed to meet the specifications of Type B(U)/(M) package and shall comply with the provisions of the Safety Code for 'Transport of Radioactive Materials', (AERB/SC/TR-1, 1986).

2.2.13.3 Radiation Source and Radiation Head

2.2.13.3.1 Telegamma therapy equipment shall be designed to permit the operation of transferring the telegamma source from the transport container to the radiation head of the equipment and its subsequent removal and transfer back to the transport container without exposing the personnel involved to an effective dose in excess of 1 mSv.

2.2.13.3.2 The telegamma source shall be secured within the radiation head in such a way that it shall not be detached during normal working conditions. Its removal shall only be possible using special tools.

2.2.13.3.3 The radiation head shall be clearly and permanently marked on its outer surface with radiation symbol (Appendix-II)

2.2.13.4 Equipment Documentation

Accompanying documents shall contain/specify:

- (a) detailed explanation of the function of all interlocks and other radiation safety devices;

- (b) recommended procedures to be observed by qualified personnel for the source transfer operation. These instructions shall include the procedures to be adopted in case of failure of the source carrier or shutter actuating means;
- (c) procedure to release the patient trapped during source stuck and normal use of the equipment due to the failure of powered movements of the gantry, source head or patient support assembly (treatment couch);
- (d) recommendations regarding inspection or replacement period for the specified parts of the equipment, including those affected by radiation, during the useful life of the equipment and, which in turn, could affect the safety of the patients and/or personnel;
- (e) the positions on the radiation head where swipe tests may be performed to detect any leakage of the radiation source; and
- (f) in case any radioactive material such as depleted uranium is used as shield in the construction of the source head (i) type and location of the radioactive material (ii) dose levels at exposed surfaces, if exceeding $0.1 \text{ mSv}\cdot\text{h}^{-1}$ (iii) whether swipe test be made to detect contamination resulting from this material, and (iv) results of the swipe tests undertaken, if any.

2.2.13.5 Movements of Equipment Parts

2.2.13.5.1 The distance between the position of radiation head, moving at its maximum speed at the instant of actuating a control to stop the motion and final position of the radiation head shall not exceed 10 mm.

2.2.13.5.2 At least one of the available speeds of each movement of vertical, lateral and longitudinal displacement of the table top shall not exceed 10 mm/s. No available speed shall exceed 50 mm/s.

2.2.13.6 Radiation Beam Interceptor/Shield

Where radiation beam interceptor is provided to reduce the structural shielding requirements, it shall transmit less than 0.5% of the radiation beam.

2.2.14 Additional Requirements for Electron Accelerator

2.2.14.1 Equipment Documentation

Accompanying documents shall contain:

- (a) detailed explanation of the function of all interlocks and other radiation safety devices;

- (b) cooling requirements for various parts and sub-assemblies of the medical electron accelerator, that need heat dissipation at a certain rate in order to function safely and correctly; and
- (c) procedure to release the patient trapped during treatment, due to the failure of powered movements of the gantry, source head or patient support assembly (treatment couch).

2.2.14.2 Movements of Equipment Parts

2.2.14.2.1 For equipment intended to be set up automatically, it shall not be possible to initiate or maintain movements associated with this condition without personal action of the operator simultaneously on the automatic set-up switch and a switch common to all movements.

2.2.14.2.2 For automatic set-up and for pre-programmed movements before treatment, speed shall be reduced prior to reaching 5° before a planned stop angle or at least 25 mm before a planned stopped position. The speed reduction shall be such that overshoot does not exceed 2° for rotational displacements and 5 mm for linear displacements.

2.2.14.2.3 The minimum speed available for linear displacements of collimator jaws and each movement of vertical, lateral and longitudinal displacement of the table top shall not exceed 10 mm.s^{-1} . No available speed shall exceed 100 mm.s^{-1} .

2.2.14.2 Dose Monitoring Systems

2.2.14.3.1 Two radiation detectors shall be provided in the radiation head, of which at least one shall be a transmission detector, centered on the radiation beam axis on the patient side of all field flattening and beam scattering filters. The detectors shall be of permanent type, removable only by using special tools.

2.2.14.3.2 The radiation detectors shall form part of two dose monitoring systems from which the absorbed dose at a reference point in the treatment volume can be calculated. It is imperative that

- (a) malfunctioning of one dose monitor shall not affect the correct functioning of the other system,
- (b) failure of any common element that could change the response of either dose monitoring system by more than 5% shall terminate the irradiation, and
- (c) when separate power supplies are used, failure of either supply shall terminate irradiation.

2.2.14.3.3 Dose monitoring systems shall be able to stop irradiation independently after pre-set dose has been delivered to the treatment volume.

- 2.2.14.3.4 Primary/secondary dose monitoring system combination shall be capable of terminating irradiation independently. It shall be ensured that in the event of the failure of primary dose monitoring system to terminate irradiation after pre-selected dose monitor units have been delivered, the secondary dose monitoring system shall terminate the irradiation when pre-selected monitor units have been exceeded by either 10% or by 0.25 Gy, whichever less, depending on design criteria used for the system.
- 2.2.14.3.5 Displays from both dose-monitoring systems should be placed close together and adjacent to the display of pre-selected number of dose monitor units at the control panel.
- 2.2.14.3.6 The dose monitor shall maintain the readings after interruption (due to power failure or any other cause) or termination (due to any reason) of the irradiation for at least 20 minutes, unless reset by the operator.
- 2.2.14.3.7 Initiation of new irradiation shall be possible only after reset of the previous display parameters and selection of the new irradiation parameters and dose monitoring units on the control panel.
- 2.2.14.3.8 To prevent gross distortion of absorbed dose distribution, the detectors in dose monitoring units shall monitor the radiation beam traversing through them, to detect symmetrical and unsymmetrical changes in the dose distribution.
- 2.2.14.3.9 Means shall be provided to terminate irradiation before an additional absorbed dose of 0.25 Gy is delivered when, at the depth specified for flatness measurements, either the absorbed dose distribution is distorted by more than 10%, or the signals from the radiation detectors indicate a change greater than 10%, in the absorbed dose distribution.
- 2.2.14.4 Safety in Patient Treatment
- 2.2.14.4.1 Equipment capable of producing both photon and electron beams shall comply with the following requirements to ensure proper and safe patient treatments:
- (a) irradiation shall not be possible until a selection of radiation type has been made;
 - (b) proper interlock shall ensure that the selected radiation type is only emitted;
 - (c) no irradiation shall be possible if any selection made in the treatment room does not match with the selection carried out at control panel;
 - (d) an interlock shall prevent X-radiation when accessories for electron irradiation, e.g. electron beam applicator, are fitted, and prevent electron irradiation when accessories for X-radiation, e.g. wedge filter, are in place;

- (e) an interlock shall prevent X-radiation when beam distributing or current control devices specified for electron irradiation are in position, e.g. electron beam scattering foils or scanners. Electron irradiation shall not be possible when beam distribution or current control devices specified for X-radiation are in place, e.g., X-ray field flattening filters, and
- (f) equipment capable of generating radiation beams of different energies shall display the selected energy at the control panel before and during irradiation.

2.2.14.4.2 For equipment capable of functioning in stationary mode and rotational mode of radiation therapy:

- (a) irradiation shall not be possible unless intended mode selection has been made on control panel;
- (b) an interlock shall terminate irradiation if equipment movement starts during stationary beam mode; or if movement does not start or stop, as intended, during moving beam treatments;
- (c) in moving beam radiation therapy, if a rotational movement can be performed from a selected start angle to a selected stop angle in either clockwise or counter-clockwise direction, a selection of the direction of rotation shall be required at the control panel. When clockwise rotation is selected, irradiation shall be terminated during counter-clockwise rotation, and vice versa;
- (d) an interlock shall terminate irradiation if the number of dose monitor units delivered in any 15° arc differs by more than 20% from the specified value; and
- (e) for moving beam radiotherapy, an interlock shall prevent the gantry moving more than 5° beyond the set limits; a similar interlock shall prevent movements of the treatment couch in excess of 5° or 10 mm beyond the limits selected.

2.2.14.4.3 Irradiation shall not be possible until a selection has been made, and displayed on the control panel or ensured by other means, for either field flattening filter or beam scattering foil.

2.2.14.4.4 Two independent interlocks shall be provided to prevent irradiation, if selected filter is not correctly positioned.

2.2.14.4.5 An interlock shall ensure that irradiation of patients is prevented until all external interlocks are in place and the specified combinations of radiation type, energy, stationary or moving beam radiotherapy, filters or control settings of other beam distributing systems, wedge filter and beam applicators have been selected.

2.2.14.5 Indication of Beam OFF/ON Conditions

Colours of the indicator lights used on the treatment control panel (TCP), or on other control panels, shall accord with the following:

- (a) Radiation beam ON - Yellow
- (b) Ready state - Green
- (c) Urgent action required in response to an unintended state of operation - Red
- (d) Preparatory state - Other colour

2.2.14.6 Radiation Beam Interceptor/Shield

2.2.14.6.1 Where the radiation beam interceptor is provided to reduce the structural shielding requirements in the electron accelerator, the manufacturer shall specify its transmission factor at each photon energy.

2.2.14.6.2 Any retractable radiation beam shield shall be interlocked for correct position during irradiation.

2.3 Brachytherapy

2.3.1 Source Storage

The design of the source storage shall be such as to provide adequate protection to the operating personnel, prevent unauthorised access to the sources and retain integrity of the sources under normal operations and envisaged accidental conditions, such as fire, flood, or mechanical impact, and shall have the approval of the competent authority. The leakage radiation levels shall comply with the limits for brachytherapy equipment (Appendix-III). The radionuclides and their activities shall be clearly indicated outside the source storage. A radiation symbol shall be posted permanently outside the storage.

2.3.2 L-Bench

The design of the L-bench (an L-shaped block of lead of appropriate dimensions and shielding fitted with lead glass of appropriate thickness and mirror arrangement for handling brachytherapy sources in a safe manner) shall be approved by the competent authority so as to provide adequate protection under normal working conditions. The L-bench shall be provided with a lead glass and a well-illuminated mirror arrangement for indirect viewing. The material(s) and thickness of such shield shall be indicated on it at a conspicuous place.

2.3.3 Handling Tools

All the tools used for handling the sources shall be provided with optimally long handles and firm grips such that the user will be able to benefit from adequate distance protection without hampering convenience and speed of operation.

2.3.4 Threader Block

Threader block where required shall be so designed that the active lengths of the available sources of various sizes shall be duly shielded when fully inserted in the holes provided in the block.

2.3.5 Mobile Shield

Mobile shield shall be so designed that it provides adequate protection to the persons under normal working conditions. The material(s) and thickness of such shield shall be indicated on it at a conspicuous place.

2.3.6 In-house Transport Container

The transport container used for the movement of the sources within the hospital premises shall be designed with due regard to the uniformity of shielding around the sources and convenience during actual transport conditions. A radiation symbol shall be clearly displayed on the exterior of the container. The container shall be provided with a suitable locking facility to prevent unauthorised access to the sources. The lead equivalence of the container shielding shall be clearly indicated on it at a conspicuous place. The limits of leakage radiation levels outside the container shall meet the specifications (Appendix-III).

2.3.7 Remote After-loading System

Remote after-loading system and equipment shall conform to the following additional safety specifications:

2.3.7.1 Source Storage

The source storage shall be so constructed as to retain the integrity of the sources and the shielding at normal and all envisaged accident conditions. It shall meet the specifications prescribed in subsection 2.3.1.

2.3.7.2 Temporary Storage Container

For temporary storage container/in-house storage container provided for the sources, the leakage radiation levels outside the container shall not exceed the limits (Appendix-III).

2.3.7.3 Systems Reliability and Accuracy

The equipment shall have reliable features and appropriate accessories for regulating the movement and accurate positioning of sources to deliver a prescribed dose to the target volume.

2.3.7.4 Safety Locks

The equipment shall be provided with two independent locking mechanisms, one of them key operated, to prevent unauthorised use and the other to actuate movement of the sources only from the control panel.

2.3.7.5 Control Panel Display

The equipment shall have appropriate visual features located in the control panel, to indicate the relevant treatment parameters. Clearly identifiable indicators shall be provided to show the OFF/ON status of each of the sources in use and the functional status of the safety related systems of the equipment.

2.3.7.6 Display on Interruption

The equipment shall permit a clear display of elapsed or balance treatment time, in the event of interruption of treatment for whatsoever reasons, for at least 10 hours from the time of interruption. The treatment shall be restarted only after selection of appropriate parameters at the control panel.

2.3.7.7 Colour of Indicator Lights

The colour of the indicator lights shall accord with the following:

2.3.7.7.1 Treatment Control Panel

- (a) immediate action required to terminate an unintended status of operation - Red
- (b) radioactive source(s) at the treatment positions - Yellow
- (c) radioactive source(s) in transit - Yellow (flashing)
- (d) ready state - Green
- (e) equipment switched on, but all the operations required to reach the ready state not yet carried out - White

2.3.7.7.2 Treatment Room

- (a) radioactive source(s) at the treatment positions - Red
- (b) radioactive source(s) in transit - Red

2.3.7.8 Source Transfer Mechanism

It shall not be possible to transfer the sources in case of imperfect coupling

on either end of the transfer/guide tube and/or fault in source drive cable mechanism.

2.3.7.9 Automatic Source Retraction

The sources shall automatically return to the source storage at the end of treatment and on interruption of treatment for whatsoever reasons. In case any source has failed to return to the storage, appropriate warning signals shall be actuated at the control panel. In addition, suitable means shall be available for manual retraction of sources to the storage container in the event of an emergency.

2.3.7.10 Door Interlocks

There shall be a door interlock provided in the treatment room for automatic interruption of the treatment and return of the sources to storage container of the equipment, in case the door is opened during irradiation.

2.3.7.11 Source Transfer/Emergency Storage Container

The design of the source transfer/emergency storage container used for loading/unloading of the sources shall provide adequate shielding, double locking system, mechanical handling features and compatible firm coupling with the source container during source transfer. The limits for leakage radiation levels outside the container are given in Appendix-III.

2.3.7.12 Conventional Safety

The design of the equipment shall comply with the mechanical, electrical, fire and environmental safety specifications (IEC 6061-1-1, IEC 6061-1-2, IEC 6061-1-3, IEC 6061-1-4).

2.3.7.13 Applicators

The material, thickness and dimensions of the applicator shall be specified by the vendor. The design shall be so as to facilitate easy loading and unloading of the sources and maintain their intended positions during treatment.

2.3.8 Manual After-loading System

In manual after-loading brachytherapy system, the sources are transferred from their storage to the treatment positions and back by manual operation using an appropriate mechanism for the source movement. Manual after-loading applicators or system shall conform to the safety specifications listed below:

2.3.8.1 Loading and Unloading

The design of the manual after-loading applicator or system shall ensure easy and quick loading and unloading of the sources. Source/source assemblies shall be easily identifiable.

2.3.8.2 Source Immobilisation

There shall be a suitable mechanism to keep the sources inside the applicators in their intended positions during treatment.

2.3.8.3 Applicator Immobilisation

The applicator shall be so designed that the loaded applicator remains in-situ during treatment.

2.3.9 Special Procedures

Appropriate safety measures specified by the competent authority shall be implemented for newer and special techniques and applications, such as intravascular, intraoperative, ophthalmic and image-guided brachytherapy applications.

2.4 Newer Treatment Techniques

2.4.1 Newer special techniques, such as 3D-conformal radiation therapy, intensity modulated radiation therapy, computer controlled and monitored operation, motorized autowedge, dynamic wedge, multileaf and micro multileaf collimators, record and verifying systems, portal imaging devices, image guided radiotherapy, stereotactic radiosurgery, intraoperative radiotherapy, helical tomotherapy and treatment planning systems shall meet regulatory requirements specified by the competent authority from time to time.

2.4.2 Approval for any new treatment protocol shall be sought only after clearance by the hospital ethics committee.

3. RADIATION THERAPY INSTALLATIONS

3.1 Siting of the Installation

Any radiation therapy equipment/installation shall be located in the hospital at a place where occupancy is the minimum and shall have the approval of the competent authority.

3.2 Layout of Installation

The rooms comprising a particular radiation therapy facility should be integrated at one place in a suitable, functionally efficient layout so that the entire treatment associated operations such as installation, source loading, commissioning, patient treatment, maintenance and decommissioning can be performed within the area with ease and safety.

3.3 Doors and Passages

The doors, passages and turnings of a radiation therapy installation shall permit safe and easy transport of the equipment, source transfer flask, and patients on wheel chairs and trolleys.

3.4 Shielding

Adequate structural shielding shall be provided for the walls, ceiling and, where appropriate, the floor of the treatment room, so that radiation doses outside the room shall not exceed the dose limits specified in Appendix-IV. The shielding for the radiation therapy installation shall be arrived at, taking into account the patient workload, use factor of the radiation beam and occupancy in the vicinity. The entry to the treatment room shall be of indirect type so as to minimise the shielding requirement at the entrance door.

3.5 Openings and Discontinuities

Service and dosimetry openings in the shielding shall be provided with shielded baffle or overlap of shielding, except in circumstances when such openings pose no significant radiation hazard under normal working conditions.

3.6 Safety Interlocks and Warning Lights

The treatment room in the case of teletherapy and remote after-loading brachytherapy equipment shall have appropriate door interlock and warning light at/or near the entrance to the treatment room so as to warn against inadvertent entry of persons during irradiation. The colour of the warning light shall be green when the beam is in the OFF position, red in the Transit position and yellow in the beam ON position.

3.7 Zone Monitor

A radiation zone monitor shall be provided at a location near the entrance to the treatment room of telegamma and brachytherapy facilities to monitor radiation level continuously.

3.8 Patient Monitoring

The control rooms for teletherapy and remote after-loading brachytherapy units and the nurses' station for the manual after-loading equipment shall be outside, but contiguous to the treatment room. An appropriate patient viewing facility shall be provided between these rooms. The control panel shall be so positioned that the patient undergoing treatment shall be observed by the operator clearly from the control room. If closed circuit TV system is provided to view the patient during treatment, an appropriate standby viewing system shall also be provided. Two-way communication system shall be provided between the patient and the treatment control panel and between the patient and the nurses' station in brachytherapy, as appropriate.

3.9 Ventilation and Air Conditioning

Treatment room shall have adequate provision for efficient ventilation and, where necessary, air conditioning.

3.10 Radiation Symbol

Radiation symbol as appropriate (Appendix– II), specified under Rule 14 of Atomic Energy (Radiation Protection) Rules, 2004, shall be posted conspicuously and prominently at the treatment room entrance and at the entrance of the controlled and supervised areas. A legend in Hindi and in English indicating radiation hazard and restricted entry, and an equivalent in local language shall also be posted near the radiation symbol.

3.11 Conventional Safety

The possibility of radiation therapy installation being flooded or being involved in a fire shall be considered and appropriate preventive measures taken. Suitable fire fighting systems shall be provided in consultation with the fire fighting personnel and manufacturers/suppliers of the radiation therapy equipment.

4. OPERATIONAL SAFETY

4.1 General

4.1.1 Commissioning

When a radiation therapy installation is newly established/re-established in a new location, or structural modification is carried out to an existing installation, or source handling equipment is subjected to major repairs, the installation shall not be commissioned for patient treatment, unless (i) quality assurance tests have been carried out by the medical physicist, (ii) radiological protection survey has been carried out by the radiological safety officer (RSO), and (iii) the commissioning of the installation is approved by the competent authority.

4.1.2 Contamination Check

Check for contamination of accessible areas of the telegamma equipment, as also remote after-loading brachytherapy equipment and its catheters and guide tubes in which the sealed sources move shall be checked at intervals not exceeding 6 months. Any sealed source showing contamination in excess of 200 Bq shall be considered as a leaky source. Leaky or contaminated sources shall not be used and shall be disposed as per regulatory requirements.

4.1.3 Source Transfer

4.1.3.1 Source transfer operations shall be carried out only by personnel duly authorised by the competent authority.

4.1.3.2 Effective dose during source transfer operation shall not exceed 1mSv.

4.1.4 Maintenance and Repair

4.1.4.1 Maintenance and repair of the teletherapy and remote after-loading brachytherapy equipment shall be undertaken only by persons authorised by the competent authority.

4.1.4.2 The licensee shall ensure that damaged sealed sources are not repaired locally. Such sources shall be promptly returned for safe disposal in consultation with the competent authority.

4.1.5 Emergency Preparedness

4.1.5.1 Devices and radiation monitoring instruments for use during an emergency shall be readily available in good working condition (i) in the control room for teletherapy and remote after-loading brachytherapy equipment, and (ii) near the source handling areas in case of manual brachytherapy.

4.1.5.2 Emergency procedures to be followed shall be established in the event of

- (i) failure of source movement mechanism of telegamma and remote after-loading brachytherapy equipment and posted conspicuously near the control panel of the equipment;
- (ii) loss of source in manual brachytherapy and posted conspicuously near the source storage and other appropriate location; and
- (iii) loss of source in other applications and posted conspicuously near the appropriate location.

4.1.6 Safety Systems

A protocol for each safety system such as fail-safe mechanisms, interlocks, timers, couplings, pneumatic systems and drive cable mechanism, shall be established in advance and adhered to in all periodic checks. The type of radiation therapy equipment in use shall determine the nature and periodicity of safety checks. In the event of detecting a defect in the equipment, it shall not be used till it is repaired. A separate log book shall be maintained for each radiation therapy equipment.

4.1.7 Personnel Monitoring

All personnel handling radiation therapy equipment and radioactive sources shall use personnel monitoring devices.

4.1.8 Dose Limits

All precautions shall be taken to ensure that the dose limits to radiation workers and members of the public prescribed are not exceeded (Appendix–IV).

4.1.9 Trainees

Persons undergoing training shall use personnel monitoring devices and work under the direct supervision of qualified personnel.

4.1.10 Disposal of Radioactive Material

Whenever the source is no longer in use, arrangement shall be made for its safe disposal. Safe disposal of radioactive sources and material shall be carried out only after obtaining authorisation from the competent authority.

4.2 Teletherapy

4.2.1 Calibration

4.2.1.1 When a teletherapy unit is newly commissioned or after major equipment repairs or a telegamma therapy unit is loaded with a replacement source, the radiation output shall be measured to an accuracy of $\pm 2\%$ by a properly calibrated dosimeter. Thereafter, the radiation output shall be checked every

week for one field (10 cm x 10 cm) to a constancy of $\pm 3\%$ and the records of measurements maintained. Any unexpected deviation in the measurements shall be investigated, appropriate corrective action taken before re-using the teletherapy unit, and a report sent to the competent authority.

4.2.2 Field Congruence

The congruence of radiation and optical fields with the collimator settings shall be checked at least once in a month. Further, this shall be checked whenever any repair is carried out on the collimator system including the optical field defining system.

4.3 Brachytherapy

4.3.1 Calibration

The reference air kerma rate at the specified distance of 1 meter from the brachytherapy source(s) shall be measured to an accuracy of $\pm 5\%$, using a properly calibrated instrument and verified annually, or earlier, in case the sources are changed or suspected to have suffered any damage. Any unexpected deviation in the measurements shall be investigated, appropriate corrective action taken before re-using the sources, and a report sent to the competent authority.

4.3.2 Source Storage

The arrangement of sources inside the storage safe shall be such as to permit easy handling with minimum exposure to personnel. Inventories of sources and dummies shall be maintained and verified at least once in a month. The safe shall be kept locked and the key shall be in the custody of the employer or his authorised representative. Stock of all brachytherapy sources shall be notified to the competent authority annually.

4.3.3 In-house Source Transport

The sources shall be appropriately tagged with individual identifications and transported in containers as specified in subsection 2.3.6. While transporting the radiation sources, the transport container shall not be left unattended.

4.3.4 Source Preparation

Appropriate protective equipment, such as shielded L-bench, shielded threaded blocks, lead pots, long handled tools and forceps, shall be used for handling the sources. In no case, the sources shall be handled with bare hands. Every individual source shall be identifiable either by coloured threads or any other suitable means. Activities of individual sources used in a clinical implant shall be verified. Calibrated radiation survey meter shall be used for monitoring source preparation area.

4.3.5 Mould Preparation

Mould is a device, shaped to keep radioactive sources in a specified arrangement at a short fixed distance from the region of treatment. In case mould is made for the patient, it shall be individually marked and identifiable. The sources shall be fixed properly in the mould to prevent their separation. Moulds shall be checked before application and after removal from the patient to account for the sources.

4.3.6 Source Checks

All radioactive sources handled shall be checked for integrity and uniformity of source distribution before initial use and re-checked at intervals not exceeding 6 months.

4.3.7 Source Application

Application of sources shall be done by, or under the direct supervision of, a qualified radiation oncologist. The sources shall be removed from the shielded container only when being applied to the patient. All sources shall be properly anchored or fixed to prevent their displacement. Detailed records of source application, treatment parameters, and source removal shall be documented and maintained.

4.3.8 Radiological Procedure

Personnel associated with the performance of a radiological procedure on the patient with sources in situ shall be informed of the presence of the sources to enable them to take appropriate safety precautions.

4.3.9 Removal of Sources

At the end of the scheduled time of treatment, the qualified radiation oncologist shall remove all sources and account them against patient application records before transfer to temporary storage container. The sources shall be transferred to the storage safe after requisite cleaning. The number and type of sources removed from the patient shall be checked once again against the issuance records before returning the sources to the safe.

4.3.10 Discharge of Patients with Sources

In case of discharge of patient with permanent implants, it shall be ensured that:

- (a) the dose rate from the patient implant site, shall not exceed the limits prescribed in Appendix-V at the time of discharge;
- (b) written instructions to the patient concerning contact with other persons and relevant precautions for radiation protection shall be provided, as necessary; and

- (c) the hospital shall maintain the record of the patient, giving details of the radionuclide, activity, dose rate, site of implant and shielding provided, if any, along with the copy of the instructions given to the patient.

4.3.11 Post-treatment Monitoring for Sources/Contamination

Patients, who have undergone brachytherapy, and also all equipment, clothing, linen and waste going out of the brachytherapy department as well as the radiation wards, shall be monitored appropriately to ensure neither loss of source(s) nor contamination.

5. QUALITY ASSURANCE

5.1 General

Radiation therapy equipment, including sources and accessories, shall be commissioned for patient treatment only after the entire prescribed acceptance tests have been performed and the results duly approved by the competent authority. The quality assurance tests shall be repeated at specified intervals and the records of the list of tests performed and their results maintained by the medical physicist in a logbook. It shall be clearly recognized that the functional performance of radiation therapy equipment can suddenly change due to electronic malfunctions; component failures; mechanical breakdowns; and deterioration and aging of the components. The licensee shall inform the competent authority if the results of tests show any unexpected deviation and corrective action taken.

Although the overall responsibility of quality assurance is assigned to medical physicist, it shall be noted that the quality assurance programme for the radiation therapy equipment is very much a team effort, and the responsibility of performing various tasks may be divided among medical physicists, dosimetrists, radiation oncologists, radiation therapy technologists and service engineers.

5.1.1 Objectives of Quality Assurance Programme

The objectives of quality assurance (QA) programme shall be:

- (a) to assure that all those planned and systematic actions necessary to provide adequate confidence that an equipment or treatment planning protocol/methodology satisfies stated or implied needs of the patient treatment;
- (b) continuing evaluation of adequacy and effectiveness of an equipment or treatment, with a view to initiate timely corrective measures and feedback, where necessary;
- (c) development of a framework for the analysis of a task, development of methods for evaluation of equipment or treatment; procedures and establishment of norms for test frequencies, base-line values and tolerance limits, for each task being evaluated;
- (d) validation of equipment design and functional performance; inspection and testing methods; and operational techniques employed to achieve intended objective of quality treatment; and
- (e) documentation for the test criteria and procedures, results of the QA measurements and periodic analysis of the test results to verify the

efficacy of the QA programme as an adequate instrument to realise the goal of the quality treatment.

5.1.2 Tolerance Values

It shall be ensured that:

- (a) tolerance values for each parameter for quality assurance programme shall be based on investigation for base-line standards at the time of acceptance and commissioning of the equipment;
- (b) the procedures for acceptance tests shall be followed to verify the manufacturers' specifications and to establish base-line performance values for new/refurbished equipment, and equipment following major repairs; and
- (c) if any of parameters exceed their tolerance value, action is required to bring the equipment into compliance.

5.1.3 Quality Assurance of Radiation Therapy Equipment

5.1.3.1 Test Criteria

Quality assurance test criteria shall be established and documented for each test performed during acceptance testing and commissioning measurements of the equipment.

5.1.3.2 Manufacturer's Prescribed Tests

Manufacturer's prescribed tests, for systems and sub-systems of the radiation therapy equipment, shall form an integral part of the quality assurance protocol, adopted for functional evaluation of the equipment.

5.1.3.3 Quality Assurance Protocol

Quality assurance protocol together with the tests specific to a particular radiation therapy equipment, shall be carried out to monitor the reference performance values of the radiation therapy equipment.

5.1.3.4 Periodicity of Equipment Tests

For an efficient performance of quality assurance test procedures and observed vulnerability of the test parameters, categorisation of the frequencies, such as daily, weekly, monthly and annual tests shall be established.

5.1.4 Responsibilities of the Employer/Licensee

The employer/licensee shall ensure that:

- (a) periodic quality assurance measurements are done on all systems and sub-systems of the equipment, including dosimetry devices and instruments;

- (b) regular preventive maintenance, and corrective actions where necessary, are carried out for the equipment; and
- (c) adequate test equipment, instruments and machine time are available to carry out the quality assurance tests and preventive maintenance.

5.2 Teletherapy

5.2.1 Telegamma

5.2.1.1 Periodicity of Procedures and Tests

- (a) Daily:
Door interlock, radiation room monitor, audio visual monitor, lasers and optical distance indicator
- (b) Weekly:
Check of source positioning
- (c) Monthly:
Output constancy, light/radiation field coincidence, field size indicator, gantry and collimator angle indicator, cross-hair centering, latching of wedges and trays, emergency off interlock and wedge interlock
- (d) Annual:
Output constancy, field size dependence of output constancy, central axis dosimetry parameter constancy (percentage depth dose, PDD/tissue air ratio, TAR), transmission factors constancy for all standard accessories, wedge transmission factor constancy, timer linearity and error, output constancy versus gantry angle, beam uniformity versus gantry angle, emergency off interlock, wedge interlock, collimator rotation isocentre, gantry rotation isocentre, couch rotation isocentre, coincidence of collimator, gantry and couch axes with isocentre, coincidence of radiation and mechanical isocentres, tabletop sag, vertical travel of table, field light intensity, and control panel systems.

5.2.1.2 Control Panel

It shall be ensured that the switches used to control the display of beam OFF/ON conditions at the treatment control panel shall be operated directly by the source carrier or the shutter.

5.2.2 Linear Accelerator

5.2.2.1 Periodicity of Procedures and Tests

- (a) Daily:
X-ray and electron output constancy, localisation lasers, optical distance indicator, door interlock and audio visual monitor.
- (b) Monthly:
Back-up monitor constancy, X-ray central axis dosimetry parameters (percentage depth dose, PDD and tissue phantom ratio, TPR), electron central parameters (PDD), X-ray beam flatness constancy, electron beam flatness constancy, X-ray and electron symmetry, emergency off switches, interlocks, wedge, electron cone interlocks, light/radiation fields coincidence, gantry/collimator angle indicators, wedge position, tray position, applicator position, field size indicator, cross-hair centering, treatment couch position indicators, latching of wedges, blocking trays, jaw symmetry and field light intensity.
- (c) Annual:
X-ray and electron output constancy, field size dependence of output constancy, output constancy for electron applicator, X-ray central axis parameters constancy (PDD and TPR), electron central parameters (PDD), off-axis factor constancy, transmission factor constancy for all treatment accessories, wedge transmission constancy, monitor chamber linearity, X-ray output constancy vs. gantry angle, electron output constancy vs. gantry angle, off-axis factor constancy vs. gantry angle, arc mode, safety interlocks, collimator rotation isocentre, gantry rotation isocentre, couch rotation isocentre, coincidence of collimator, gantry, couch axis with isocentre, coincidence of radiation and mechanical isocentre, table-top sag and vertical travel of table.

5.2.2.2 Control Console

- (a) It shall be ensured that the operation of a multi-modality accelerator does not permit dangerous combinations of beam current, target, and filter for photon and electron beams; and
- (b) the accuracy of software for a computer-controlled accelerator shall be validated periodically. Validation checks shall assure that the controlling software causes the accelerator to meet its: (i) operational specifications; (ii) safety specifications; and (iii) dosimetric specifications.

5.2.2.3 Multileaf Collimators

It shall be assured that a multileaf collimating system meets specifications and all applicable regulatory requirements. Items that shall be tested include,

but are not limited to: (i) actual leaf positions vs. programmed leaf positions for each leaf; (ii) time to reach position (a critical parameter for dynamic conformal therapy); (iii) radiation leakage through the leaves; (iv) radiation leakage between the leaves; and (v) beam contamination (caused by scattering from the leaves). These tests shall be repeated at several gantry angles to assure that the changes in mechanical stresses at different angles do not cause the system to function outside of its specifications.

5.2.2.4 Ancillary Equipment

Any ancillary equipment or software purchased with an accelerator shall be tested to assure that it meets the prescribed specifications. Such items include patient positioning lasers, electron beam mould kits and high dose rate therapy software (as an option to the computer control system).

5.2.2.5 Dosimetric and Spatial Accuracy

Overall dosimetric and spatial accuracy, for treatment, shall be within $\pm 5\%$ and ± 5 mm respectively, because these uncertainties are regarded as clinically acceptable and technically achievable.

5.2.2.6 Newer Innovations

Recent innovations in medical accelerator technology, such as computer controlled and monitored operation; motorized autowedge; dynamic wedge; intensity modulated radiation therapy (IMRT), micro-multileaf collimators; record and verify systems; total imaging devices; stereotactic radiosurgery; intraoperative radiotherapy, tomotherapy, and image guided radiotherapy shall meet applicable regulatory requirements of quality assurance.

5.3 Brachytherapy

Each brachytherapy source shall be calibrated and tested for leakage and contamination to ascertain that measured contamination, if any, is within the specified limits.

5.3.1 Periodicity of Procedures and Tests

5.3.1.1 Initial Procurement of Source

5.3.1.1.1 Long Half-life

Physical/chemical form, source encapsulation, radionuclide distribution and source uniformity, location of radionuclide, mean activity of batch and deviation from mean.

5.3.1.1.2 Short Half-life

Physical/chemical form and source encapsulation.

5.3.1.2 At every Use of Source

5.3.1.2.1 Long Half-life

Calibration verification.

5.3.1.2.2 Short Half-life

Mean activity of batch, deviation from mean and radionuclide distribution and source uniformity.

5.3.2 Specification of Source Strength

The specification of the brachytherapy source strength shall be expressed as reference air kerma rate at specified distance of one meter as far as possible. However, air kerma strength shall be determined at a distance where the source approximates a point source. Measurement of reference air kerma rate and air kerma strength shall be measured using an appropriate, calibrated ionisation chamber.

5.3.3 Tolerance Variation for Individual and Batch of Sources

When a large number of identical sources are in use, the deviation between the manufacturer and the institution calibrations for the mean of a batch of sources shall not exceed 3%. However, for individual source, deviation from the mean shall not exceed 5%.

5.3.4 Applicator

It shall be ensured that:

- (a) applicator positions the source(s) where they are intended to be localised; and
- (b) any part of the structures which is used to attenuate the radiation (e.g. rectal and bladder shields) has not shifted.

5.3.4.1 Periodicity of Procedures and Tests

(a) Initial Use or Following Malfunction and Repairs

Source location and location of shields for intracavitary applicators by radiography, and coincidence of dummy and active sources for intracavitary and interstitial applicators.

(b) Annual

Source location for intracavitary applicators by radiography.

5.3.5 Remote After-loading Unit

5.3.5.1 Periodicity of Procedures and Tests

(a) Each Treatment Day

Door interlocks, lights and alarms, console functions, switches, batteries, printer, visual inspection of indicators on the control console, treatment unit and the entrance to treatment room, source guides, and verification of accuracy of ribbon preparation.

(b) Weekly

Accuracy of source and dummy loading (dummies used for spacing and/or simulation/verification), and source positioning.

(c) At Each Source Change or Quarterly

Calibration, timer function, accuracy of source guides and connectors, and mechanical integrity of applicators.

(d) Annual

Dose calculation algorithm, simulation of emergency conditions, and verification of source inventory.

5.3.5.2 Back-up Power Supply

It shall be ensured that a battery-powered back-up power supply system is incorporated to withdraw the sources in the event of unplanned power failure.

5.3.5.3 Verification of Source Position

The accuracy and reproducibility of source positioning within the applicator and the sequence of active sources or dwell positions shall be checked at the time of commissioning the unit and periodically thereafter.

5.3.5.4 Electronic Timer

Accuracy, linearity and reproducibility of the electronic timer shall be verified.

5.3.5.5 End or Transit Dose

End or transit dose effect on dose delivery shall be verified.

5.4 Measuring Equipment

5.4.1 Local Standard Instrument and its Traceability

- (a) Local standard instrument shall have a calibration directly traceable to accredited secondary standards dosimetry laboratory and shall, preferably, be used for calibration of field instruments only.

- (b) Periodicity of calibration for dosimetric equipment and for protection level instruments shall be as stated in the calibration certificate issued by the accredited secondary standards dosimetry laboratory. However, the periodicity of calibration shall not exceed two years for dosimetric equipment and five years for protection level instruments.

5.4.1.1 Periodic Checks

Periodic checks shall be carried out on local standard instrument to evaluate the deviations from baseline values for linearity, venting, extra-cameral signal (stem effect), chamber leakage, recombination, collecting potential, polarity effect, and redundancy.

5.4.2 Checks for Field Instruments

Field instruments shall be subjected to periodic checks to ensure the validity of initial calibration for linearity, leakage, venting, stem leakage, recombination, and collecting potential.

5.4.3 Routine Dosimetry Measurements

Routine dosimetry measurements shall be carried out using field instruments, which have been duly calibrated against local standard instrument.

5.4.4 Output Checks

Output measurements with field instrument shall be compared, once a month, against the value measured using local standard dosimeter.

5.4.5 Relative Dose Measurements

The accuracies of ion chamber, film, TL dosimeter and diode used for relative dose measurements shall be verified; in particular, ion chamber for linearity and stem leakage; film for dose response characteristics; densitometer linearity; processor uniformity and reproducibility; TLD for calibration and linearity; and diodes for energy dependence; stem effect and linearity; and records maintained.

5.4.6 Calibration of Accessories

Calibrations shall be checked for barometer once in three months; and thermometer and measuring scales, prior to their initial use.

5.5 Treatment Planning System

In order to ensure that the objectives of treatment planning are met, the following tests/checks shall be performed on the treatment planning system (TPS):

- 5.5.1 Hardware and Software Platforms
Hardware and software platforms used for TPS shall be verified for their adequacy and accuracy.
- 5.5.2 Accuracy and Linearity of all Input/Output Devices
Accuracy and linearity of all input/output devices shall be evaluated.
- 5.5.3 Anatomical Data
Input of anatomical data to treatment planning system shall be checked for its correctness and proper linkage to appropriate patient file.
- 5.5.4 Contour Input
Contour input, through digitiser or film scan, and the relative coordinates of the planes in which contours are drawn shall be checked for accuracy and orientation.
- 5.5.5 TPS Reconstructed Images
In order to verify the correct identification of anatomical structures and to match the adjacent fields, geometry, orientation and grey-scale representation of TPS reconstructed images shall be checked to establish geometry and orientation.
- 5.5.6 TPS Beam Definition
TPS beam definition protocol shall provide acceptable degree of agreement with specific treatment machine beam definitions in respect of geometry, scales and output.
- 5.5.7 TPS Errors and Inaccuracies
TPS users shall guard against software implementation errors; inaccuracies in algorithms and models; errors due to inaccurate or wrong model parameters; deficiencies of computer peripherals, such as printer and plotter; intentional or unintentional changes in data or software files; and errors introduced during the software upgrade process.
- 5.5.8 Warnings and Messages
TPS shall provide adequate warnings and messages for input beyond the design ranges.
- 5.5.9 TPS Functionalities
TPS functionalities such as move beam, oppose beam, z-coordinate, shift block, copy block, read block from beam's eye view (BEV) file, BEV beam position, and BEV-lateral, longitudinal and rotational movements, shall be

verified for their accuracy in the patient coordinate system and the consistency between results of movements.

5.5.10 Input Beam/Source Data

Input beam/source data-set shall be consistent and accurate for correct modelling of the dose calculation algorithm. Adequacy and accuracy of the modelling algorithm employed by the system shall be verified.

5.5.11 TPS Calculation Accuracy/Anatomical Data

TPS calculation accuracy shall be verified against test data sets measured for actual treatment conditions (both simple and complex). The test data sets shall be designed to evaluate the efficacy, adequacy and accuracy of the computational models and algorithms employed by the treatment planning system.

5.5.12 TPS Functional Capabilities and Computational Pathways

All functional capabilities and computational pathways of TPS shall be verified against a realistic test criteria designed, by both the manufacturer and user, to establish the correctness of TPS specifications and determine its clinical range of applications.

5.5.13 Constraints in TPS Design

TPS design shall ensure that it shall not be possible to:

- (a) perform treatment planning calculations using an incomplete treatment unit or incomplete patient anatomy model;
- (b) specify beam limiting devices or beam modifiers other than those allowed by the unit model;
- (c) specify customised blocking devices and beam modifiers as being in a position, relative to the beam source, other than those allowed by the treatment unit model; and
- (d) specify a beam size (or position):
 - (i) outside the pre-defined range of the beam limiting device (or applicator) for a selected unit model, or
 - (ii) larger than the maximum size for a particular beam modifier (e.g., wedge filter).

5.6 Treatment Planning Process

Treatment planning process begins with the patient data acquisition and is followed by definition of planning treatment volume and organs-at-risk; graphical planning; plan evaluation, implementation and verification; and

dose delivery in accordance with the prescription. The data pertaining to treatment planning process shall be complied with so as to ensure that the objectives of quality treatment are met.

5.6.1 Patient Position

Patient position shall be comfortable and reproducible during imaging and treatment set-ups and patient shall maintain same position during imaging and treatment.

5.6.2 Immobilisation Technique

Quality assurance of immobilisation technique shall be established and implemented to ensure treatment position in accordance with the prescription and correct dose delivery.

5.6.3 Imaging Device

Imaging device used for patient data acquisition shall be checked periodically to evaluate its functional characteristics and to ensure the correctness and adequacy of the data generated.

5.6.4 Contouring Device

Contouring device and associated accessories shall be checked to verify their accuracy.

5.6.5 Data Transfer Device

Data transfer device shall be checked to verify linearity of the device (e.g. digitiser) and integrity of the data transferred. The tests shall be designed to check transfer errors.

5.6.6 Treatment Volume Definition

Treatment volume definition shall be constrained to allow for uncertainties associated with exact determination of tumour mass, extent of occult spread of the disease, and safety margin requirements to compensate for organ motions, set-up errors and other inherent technical limitations of the imaging modality.

5.6.7 Input/Output Devices

Accuracy of hardware input/output devices shall be checked, before their use in treatment planning.

5.6.8 Calculation Accuracy

Treatment planning calculation accuracy shall be verified using test data sets for actual clinical treatments, both simple and complex.

5.6.9 Treatment Plans

Treatment plans shall be evaluated, for their correctness and accuracy, prior to clinical implementation.

5.6.10 Treatment Prescription

Written, signed and dated clinical treatment prescription shall be used for all treatments.

5.6.11 Treatment Time/Monitor Unit Calculation

Treatment time/monitor unit calculation, performed using treatment planning system, shall be checked using an alternative method of computation such as manual method.

5.6.12 Blocks and Beam Modifiers

Production of the blocks and beam modifiers shall be subject to relevant quality control test procedures.

5.6.13 Port Film

Port film reviews shall be undertaken to ascertain placement errors, if any, of all ancillary devices positioned in accordance with the prescription in radiation beam.

5.6.14 In-vivo Dosimetry

In-vivo dosimetry shall be carried out, wherever practically feasible, to identify major deviation in treatment dose delivery and to verify the dose to critical organs.

5.7 Imaging Devices Used in Radiation Therapy

5.7.1 Simulator

5.7.1.1 Mechanical and Electrical Checks

Simulator shall be designed to reproduce the geometric conditions of radiation therapy equipment and it shall be subjected to same mechanical and electrical checks applicable to therapy units.

5.7.1.2 Leakage Radiation

Leakage radiation levels for simulator tube-head shall comply with the safety requirements for a diagnostic X-ray unit at maximum operating tube potential.

5.7.1.3 Radiography/Fluoroscopy Checks

In order to assure image quality, all checks pertaining to diagnostic radiography equipment, having fluoroscopy and image intensifier facility,

including exposure rate measurement, tabletop exposure with fluoroscopy, kV_p and mAs calibrations, high and low contrast resolution, and film processor sensitometry shall be performed and compliance ensured with the baseline values, within tolerance limits.

5.7.1.4 Field Symmetry

Field symmetry at different collimator and gantry rotation angles shall be verified.

5.7.1.5 Congruence Between Optical and Radiation Fields

Congruence between optical and radiation fields shall be checked.

5.7.1.6 Lasers and Optical Distance Indicators

Localising lasers and optical distance indicator shall be checked for their accuracy.

5.7.1.7 Coincidence - Collimator, Gantry, Couch Axes and Isocentre

Coincidence between collimator, gantry, couch axes and isocentre shall be checked.

5.7.1.8 Isocentre

Isocentre shall be checked for all orientations of collimator, gantry and couch rotations.

5.7.1.9 Focal Spot - Axis Indicator

Focal spot - axis indicator shall be checked for all positions of the X-ray tube for linear and/or rotational movements.

5.7.2 Computed Tomography (CT) Scanner

5.7.2.1 Leakage Radiation

CT scanners shall comply with the leakage radiation levels prescribed for diagnostic X-ray units at maximum operating tube potential.

5.7.2.2 Periodic Checks

Periodic checks shall be carried out based on established and standard QA protocols, and their accuracies determined using appropriate phantom for mechanical alignment of CT; slice thickness determination; noise; uniformity index; low contrast detectability; spatial resolution; CT number to electron density conversion; and patient doses during typical CT procedures.

5.7.2.3 Motion Artefacts

Effects of motion artefacts caused by patient motion during CT scan, resulting in incorrect imaging information due to distorted CT images and altered linear attenuation coefficients shall be carefully studied and documented to quantify treatment planning errors.

5.7.2.4 Temporal and Spatial Resolutions

Temporal and spatial resolutions of reconstructed radiographs shall be checked to ensure accuracy of the information content.

5.7.2.5 Virtual Simulation Accuracy

Virtual simulation accuracy shall be checked, by comparing digitally reconstructed radiographs against simulator films obtained during actual clinical procedures.

5.7.2.6 Patient Data Transfer

Patient data transfer accuracy of CT scanner, whether on-line or otherwise, networked to the other treatment-related facility, shall be verified.

5.7.2.7 CT Data Storage and Transfer Protocol

CT data storage and transfer protocol shall conform to internationally accepted standards, such as digital imaging communications in medicine (DICOM), to facilitate data manipulation mechanisms at user end. This capability of scanner shall be evaluated carefully, as treatment planning accuracy depends critically on the correct volumetric information regarding patient.

6. PATIENT PROTECTION

6.1 Quality Assurance

Prior to commissioning of radiation therapy equipment, including sources and accessories for patient treatment, the entire prescribed acceptance tests shall be performed. It shall be ensured that the results of the tests are within tolerance limits. Records of list of tests performed and their results shall be maintained by the medical physicist in a logbook. Quality assurance tests shall be repeated at specified intervals and records of the list of tests performed and their results maintained by the medical physicist in a logbook. The licensee shall inform the competent authority if the results of the tests show any unexpected deviation and corrective action taken.

6.2 Equipment and Accessories

Appropriate equipment and accessories, as required shall be made available for measuring source strength and for performing dosimetry, treatment planning, treatment simulation and quality assurance tests. These shall be maintained in good working condition.

6.3 Calibration of Dosimetry Instruments

The dosimetry instruments shall be calibrated at specified intervals and the dose measurements shall have accuracy within $\pm 3\%$. These calibrations shall be traceable to national/international standard laboratories and as per internationally accepted dosimetry protocols.

6.4 Dose Delivery

6.4.1 For both teletherapy and high dose rate brachytherapy patients, the radiation therapy technologist shall keep a close watch to ensure that the treatment is terminated at the intended time.

6.4.2 In the case of brachytherapy patients, the positions of the applicator/sources in/on the patient shall be verified with the help of appropriate imaging systems. It shall be ascertained that, as far as possible, the positions of the sources are retained in the same way throughout the treatment, unless planned otherwise.

6.5 Patient Treatment Chart

A patient treatment chart shall be maintained for each patient as per institution's requirement. The chart shall be signed by the members of the radiation oncology team. The modifications, if any, in the treatment schedule shall be recorded in the chart. The chart shall also be reviewed at regular intervals, at least once a week, by the radiation oncology team, signed and dated by the reviewers.

6.6 Misadministration

6.6.1 Misadministration of doses resulting in accidental medical exposures involving:

- (a) any treatment given to either the wrong patient or the wrong site, or using the wrong radioisotope, or wrong type of radiation, or with a dose or dose fractionation differing substantially from the values prescribed by the radiation oncologist or that may lead to undue acute secondary effects, and
- (b) any equipment failure, accident, error, mishap, miscalculation or other unusual occurrence with the potential for causing a patient dose significantly different from that intended

shall be promptly investigated by the employer/licensee.

6.6.2 A report of the investigation, including

- (a) calculation or estimation of the doses received and their distribution within the patient,
- (b) corrective measures required to prevent recurrence of such an accident; and
- (c) method to implement any corrective measures

shall be promptly sent to the competent authority by employer/licensee.

6.7 Treatment Records

The licensee shall maintain treatment records of each patient for at least 15 years, including source configurations in case of brachytherapy, to facilitate unambiguous and correct post-treatment follow-up.

7. MANAGEMENT OF RADIATION EMERGENCY

7.1 Radiation Emergency Action Plan

7.1.1 The purpose of the radiation emergency action plan shall be to mitigate the consequences, and manage any emergency situation. The intervention, if any, shall aim at limiting external exposure.

7.1.2 Foreseeable Emergencies

Licensee shall prepare emergency action plans, consisting of a set of procedures to be implemented for all foreseeable emergencies, including the following:

- (a) Radioactive source failing to return to the safe shielding position
- (b) Damage to, or dislodge/loss/theft of radioactive source at the installation during use, storage, transport, loss of source shielding or natural calamities such as fire, flood, or earthquake
- (c) Death of patient, with sources *in situ* ; and
- (d) Teletherapy emergencies such as, selection of wrong treatment mode, selection of wrong beam modifiers and wrong dose delivery.

7.1.3 Display of Emergency Procedures

Emergency procedures to be followed in the event of failure of beam control mechanism, source movement mechanism, dislodgement and damage or loss of the source, shall be established and posted conspicuously near the control panel in the case of teletherapy and remote after-loading brachytherapy equipment, and near the source storage and other appropriate locations in the case of manual brachytherapy system.

7.1.4 Identification and Training of Emergency Handling Personnel

The emergency action plan shall:

- (a) identify personnel for handling radiation emergencies and make them familiar with the responsibilities and functions, line of authority and most direct and alternate lines of communication;
- (b) provide for initial training and drills, and periodic retraining and drills, in their respective tasks to ensure effectiveness of the plans;
- (c) provide for training needed to recognise abnormal exposures, as well as formal procedures, and for prompt communication to the RSO;
- (d) provide for appropriate tools, radiation monitoring instruments and personnel monitoring devices to be kept and maintained in working condition; and

- (e) specify the authorities to be contacted at the initial phase, during progress, and at termination of an emergency.
- 7.1.5 The licensee shall ensure that all workers are familiar with the emergency action plan.
- 7.1.6 Release of Dead Bodies

Any dead body containing sources in situ shall not be handed over to the claimants until all the sources have been removed and accounted for, and the body duly monitored by the RSO to confirm removal of all the sources.
- 7.2 Reporting of Radiation Emergency**
- 7.2.1 RSO shall:
 - (a) report to the licensee immediately on any emergency situation, initiate necessary remedial actions, and endorse a copy of the report to the competent authority; and
 - (b) carry out prompt investigation on causes of the emergency, evolve means to prevent recurrence and submit a detailed report to the competent authority.
- 7.2.2 Licensee shall:
 - (a) report to the employer immediately and to the competent authority regarding the incident within 24 hours of its occurrence.
 - (b) submit to the competent authority a detailed report on the emergency/unusual occurrences, which have hazardous consequence or potential to cause hazardous consequences. This report shall include (i) date and time of occurrence, (ii) brief description of the incident, (iii) action taken, (iv) probable causes of the incident, and (v) steps taken to avoid recurrence of such incidents in future.
 - (c) arrange to carry out prompt investigation on any emergency situation, including:
 - (i) any equipment failure, accident, mishap, miscalculation or other unusual occurrence with the potential for causing a patient dose significantly different from that intended, and
 - (ii) any therapeutic treatment delivered to either the wrong patient, or the wrong tissue, or using wrong source, or with a dose or dose fractionation differing substantially from the value prescribed by the radiation oncologist, or that may lead to undue acute secondary effects.

7.2.3 The employer shall:

- (a) report to the competent authority regarding the incident within 24 hours of its occurrence; and
- (b) lodge a written complaint with the police in case of loss or theft of the radioactive sources, if they are not traced within 24 hours.

8. RADIATION PROTECTION PROGRAMME

8.1 General

8.1.1 Radiological Safety Officer

The Radiological Safety Officer (RSO) shall instruct all radiation workers on relevant safety measures; educate and train new entrants; implement all radiation surveillance measures; control storage and movement of sources; conduct periodic radiation protection surveys; maintain proper records of personnel doses; and take appropriate local measures, including clear administrative instructions in writing to deal with radiation emergencies. All radiation workers shall be trained by the RSO in the management of radiation emergencies.

8.1.2 Monitoring Instruments

Appropriate monitoring instruments, such as personnel monitoring devices, radiation survey meters and contamination monitors, shall be made available to the RSO. The monitoring instruments shall be calibrated to an accuracy better than $\pm 20\%$.

8.1.3 Accident Management

In the event of an accident, every possible care shall be taken to save human life, minimise radiation doses to personnel, patient and public, and take such further remedial steps as considered necessary. The competent authority shall be consulted at the earliest to restore normal conditions.

8.1.4 Source Transport

Radiation therapy sources shall be transported only with prior approval of the competent authority, and in accordance with the provisions of the AERB safety code for the 'Transport of Radioactive Materials' (AERB/SC/TR-1).

8.1.5 Disposal of Decayed/Unused Sources

Disposal of decayed/unused radioactive sources, including prescribed material like depleted uranium, shall be undertaken by the licensee only in accordance with the procedures prescribed by the competent authority.

8.2 Brachytherapy

8.2.1 Source Inventory

Records of sources such as date of procurement/sale/transfer/loss/disposal/damage, type and specifications and details of the acceptance tests carried out shall be maintained. A chart indicating the location, type and activity of

the various sources in storage shall be displayed in the vicinity of the storage safe. Records of sources with comparatively short half-lives, such as ^{125}I and ^{192}Ir , shall be updated in the chart at suitable intervals.

8.2.2 Source Issuance

A logbook shall be maintained by the licensee in which information shall be entered regarding movement of the sources from, and to, the storage, including:

- (a) the type, number and activity of sources required,
- (b) the name and signature of the person receiving the sources, with time and date,
- (c) name, hospital identification number and address of the patient, site of treatment and name and number of sources used, and location(s) of use in the hospital,
- (d) proposed time and date of start and termination of treatment; and
- (e) the time and date of actual return of the sources to storage, along with signatures of persons returning and receiving the sources.

8.2.3 Integrity of Sources

Integrity of the sources shall be checked at periodic intervals and records maintained. Sources, which are leaky, damaged, or otherwise unsatisfactory, shall not be used. Sources contaminated, but not leaky, shall not be used before proper decontamination.

8.2.4 Loss of Sources

In case any source is reported missing, the RSO shall immediately initiate appropriate actions to locate and recover the same. The movement of personnel, patients, public and all hospital waste and use of toilets and washbasins, etc, shall be stopped in the suspect areas and the likely escape routes of the lost sources shall be monitored. Audio/beep type sensitive radiation monitors are useful to locate the sources. All occupied areas in and around the hospital shall be monitored to confirm radiation-free conditions before declaring their free use. The competent authority shall be informed forthwith of any loss of sources.

8.2.5 Radiation Emergency Management

In the event of an accident, every possible care shall be taken to prevent radiation injury, e.g. direct contact with unshielded brachytherapy sources. In case of release of contamination, the affected area shall be isolated and its use permitted only after proper decontamination. The internal contamination of affected personnel shall be assessed to initiate remedial measures, as appropriate.

8.2.6 Release of Dead Bodies

Any dead body containing sources in-situ shall not be handed over to the claimants until all the sources have been removed and accounted for and the body duly monitored by the RSO to confirm removal of all sources. Post-mortem examination, if any, should not be performed unless all sealed sources have been removed from the body and accounted for. In bodies with permanent implant, efforts shall be made to remove the implanted sources.

9. PERSONNEL REQUIREMENTS AND RESPONSIBILITIES

9.1 Safety Personnel

A radiation therapy facility shall have a Radiological Safety Officer (RSO) having qualifications as prescribed and approved by the competent authority (Appendix-VI).

9.2 Operating Personnel

A radiation therapy facility shall have adequate number of qualified radiation oncologists, medical physicists, dosimetrists, where available, and radiation therapy technologists as prescribed in Appendix-VI and Appendix-VII.

9.3 Qualifications and Experience

The operating personnel and safety personnel in a radiation therapy facility shall possess the minimum qualifications and experience prescribed by the competent authority (Appendix-VI).

9.4 Licence Conditions

The licensee shall ensure due compliance with the terms and conditions of the licence issued to him by the competent authority.

9.5 Responsibilities of Personnel in Radiation Therapy Facility

The radiation therapy team comprising of radiation oncologist, medical physicist, dosimetrist, where available, and radiation therapy technologist shall carry out radiation therapy with due regard to patient protection and operational safety in handling the radiation therapy sources and equipment. The responsibilities of the personnel in radiation therapy facility are given in Appendix-VIII.

9.6 Responsibilities of the Vendor

The vendor shall:

- (i) make available along with the radiation therapy equipment, manuals for installation, operation and maintenance, and detailed procedures for equipment-specific quality assurance tests;
- (ii) provide the user with a representative set of (a) central axis depth dose data and isodose curves in case of beam therapy, and (b) source specification and encapsulation information in case of brachytherapy;
- (iii) provide the necessary gadgets and accessories for the normal operation of the radiation therapy equipment and for handling emergency situations;

- (iv) ensure that the equipment is serviced and maintained by service engineer certified by the competent authority (Appendix-VI); and
- (v) ensure the availability of essential spare parts of the radiation therapy equipment for its useful life.

10. REGULATORY CONTROLS

10.1 Licence

Radiation therapy sources and equipment shall be handled only in accordance with the terms and conditions of the licence issued by the competent authority. Licence shall be in the form of a licence, authorisation, registration or consent.

- (a) Licence: Licence shall be issued for sources and practices associated with the operation of (i) telegamma unit and accelerator used in radiotherapy, (ii) computed tomography (CT) unit for simulation purpose, (iv) such other source or practice as may be notified by the competent authority, from time to time.
- (b) Authorisation: Licence shall be an authorisation for sources and practices associated with the operation of (i) brachytherapy, (ii) deep X-ray units, superficial and contact therapy X-ray units, and (iii) such other source or practice as may be notified by the competent authority, from time to time.
- (c) Registration: Licence shall be a registration for sources and practices associated with the operation of (i) therapy simulator, and (ii) such other source or practice as may be notified by the competent authority, from time to time.
- (d) Consent: Licence shall be a consent for (i) approval for siting, design, construction, commissioning and decommissioning of a radiation installation, (ii) approval for sealed sources, radiation generating equipment and equipment containing radioactive sources, for the purposes of manufacture and supply, (iii) approval for package design for transport of radioactive material, (iv) approval for shipment of radioactive consignments, and (v) such other source or practice as may be notified by the competent authority, from time to time.

Compliance with the specifications of this Code is a prerequisite for the issuance of the said licence by the competent authority.

10.2 Design Certification

Every radiation therapy source and equipment shall meet the design safety specifications stipulated in this Code. The manufacturer/vendor shall obtain design certification from the competent authority prior to marketing, manufacturing the therapy source and equipment.

10.3 Type Approval/No Objection Certificate

10.3.1 Indigenously Made Radiation Therapy Equipment/Radioactive Source

Prior to marketing the radiation therapy equipment/radioactive source, the local manufacturer shall obtain a No Objection Certificate (NOC) or a type approval certificate from the competent authority for supply of radiation therapy equipment or radioactive source respectively. Type approval certificate shall be issued only if the equipment/radioactive source satisfies the safety specifications prescribed in the applicable Standard and this Code. The local manufacturer shall demonstrate type approval testing and performance verification of the equipment/radioactive source to representatives of competent authority for type approval. Based on the satisfactory demonstration of type approval testing and performance verification, type approval certificate for such equipment/radioactive source shall be issued by the competent authority. Only type approved equipment shall be used in the country.

10.3.2 Imported Radiation Therapy Equipment/Radioactive Source

Vendor shall obtain a No Objection Certificate (NOC) from the competent authority, for import of one such equipment for obtaining type approval, prior to marketing. NOC for such equipment/radioactive source shall be issued only if the equipment/radioactive source satisfies the safety specifications of the prescribed standards applicable for the equipment/radioactive source. Upon import and installation of the equipment in the country, the vendor shall demonstrate type approval testing and performance verification of the equipment to representatives of competent authority for type approval. Based on the satisfactory demonstration of type approval testing and performance verification, type approval certificate for such equipment shall be issued by the competent authority. Only type approved equipment shall be used in the country.

10.4 Approval of Building Design and Layout of the Proposed Rooms for Housing Radiation Therapy Equipment/Radioactive Source

The drawings of building design and the layout of the proposed rooms for housing radiation therapy equipment/radioactive source shall be submitted as stipulated by the competent authority. Room housing radiation therapy equipment/radioactive source shall not be constructed unless the competent authority approves the building and the layout drawing of the proposed room housing radiation therapy equipment/radioactive source from radiation safety standpoint. Any change in the approved building and the layout design shall be carried out only with the prior approval of the competent authority.

10.5 Authorisation for Procurement of Equipment/Radioactive Source

Prior authorisation shall be obtained from the competent authority for procurement of radiation therapy equipment/or/and radioactive source.

10.6 Security of Sources

The employer/licensee shall make adequate provisions for the security of sources during all stages of handling, as required by the competent authority.

10.7 Commissioning

Room housing radiation therapy equipment/radioactive source shall be commissioned only with prior approval and as per the terms and conditions specified by the competent authority.

10.8 Notifications/Directives

The employer/licensee shall ensure that persons handling radiation therapy equipment/radioactive source shall abide by the provisions of this Code and their further elaboration in the various notifications/directives, issued by the competent authority from time to time. The employer/licensee shall also ensure that other measures of radiation safety stipulated by the competent authority are promptly implemented.

10.9 Inspection

The radiation therapy installation, equipment and radioactive source shall be made available for inspection to the representative of the competent authority to verify the compliance with the regulatory requirements including the provisions of this code.

10.10 Transport of Radioactive Source

Radioactive source shall not be transported in public domain without prior approval of the competent authority. The requirements that shall be complied with for transport of radioactive materials are given in the AERB safety code for 'Transport of Radioactive Materials' (AERB/SC/TR-1, 1986).

10.11 Change of Premise/Location

Radiation therapy equipment/radioactive source shall be used only in the approved premise/location and the same shall not be taken out of the approved premise/location for any purpose without the prior approval of the competent authority.

10.12 Transfer of Radioactive Source

The employer/licensee shall not lend, gift, transfer, sell or dispose off radioactive source without the prior approval of the competent authority.

10.13 Decommissioning and Disposal

When the radiation therapy unit or radioactive sources is no longer to be used, the employer/licensee shall:

- (i) submit a proposal to competent authority to undertake decommissioning of radiation therapy installation/equipment or disposal of radioactive sources to obtain approval;
- (ii) remove the radioactive sources, contaminated materials, if any, and depleted uranium, if present, and return them to the supplier/disposal agency for safe disposal;
- (iii) upon completion of decommissioning and disposal, submit to the competent authority a detailed report on (a) decommissioning operations, (b) safe disposal of the radioactive material and (c) personnel doses received during these operations.

10.14 Approval of RSO

The employer shall designate a qualified person from his employment to function as RSO in a radiotherapy installation with the approval of competent authority. The nomination in the prescribed application shall be submitted to the competent authority for first approval as well as renewals.

10.15 Radiation Therapy Technologist

The employer/licensee shall employ only qualified radiation therapy technologist in a radiotherapy installation as prescribed (Appendix-VI).

10.16 Certification of Radiation Therapy Service Engineer

The employer/licensee shall employ vendors who have qualified service engineers as prescribed (Appendix-VI). Each such vendor shall obtain a certificate for their service engineers in the prescribed format from the competent authority.

10.17 Penalties

Any employer/licensee who contravenes the provisions of the Atomic Energy Act, 1962, and/or Atomic Energy (Radiation Protection) Rules, 2004, or as elaborated in this Code, or any other terms or conditions of a licence issued to him by the competent authority, is punishable under Sections 24, 25 and 26 of the Atomic Energy Act, 1962. The punishment may include imprisonment, or fine, or both.

APPENDIX-I

PERFORMANCE REQUIREMENTS FOR RADIATION THERAPY SEALED SOURCES

The following tests are intended to simulate the environment of conventional accidents in order to demonstrate the ability of a radiation therapy source to withstand the adverse temperature, external pressure, impact, vibration and puncture conditions likely to prevail. The manufacturer shall demonstrate, either by performing the prescribed tests or by equivalent analytical methods, that the integrity of the actual source capsule will not be impaired on undergoing these tests i.e. the capsule will not develop a leak demonstrable by any radioactive test method showing removable contamination in excess of 200 Bq (~ 5 nCi). In case non radioactive test method is employed, the sealed source is considered to be leak-tight, if the actual standard helium leakage rate is less than $1 \mu \text{ Pa} \cdot \text{m}^3 \cdot \text{s}^{-1}$ for non-leachable and $10^{-2} \mu \text{ Pa} \cdot \text{m}^3 \cdot \text{s}^{-1}$ for leachable or gaseous contents. The sealed sources used in telegamma therapy, brachytherapy interstitial and intracavitary appliances and surface applicators shall meet the requirements of sealed source classification designation C/E 53524, 53211 and 43312 of AERB safety standard titled 'Testing and Classification of Sealed Radioactive Sources' [AERB/SS/3(Rev.1), 2001].

SEALED SOURCE PERFORMANCE REQUIREMENTS FOR TYPICAL USAGE AND CLASSIFICATION

Sealed Source Usage	Sealed Source Test Requirements					
	Temperature	Pressure	Impact	Vibration	Puncture	Bend
Gamma teletherapy	-40°C (20 minutes) + 600°C (1 h) and thermal shock 600°C to 20°C	25 kPa absolute to 2 MPa absolute	5 kg from 1 m	3 times for 10 minutes 25 to 500 Hz at 49 m.s ⁻² (5 g) ¹	50 g from 1 m	---
Interstitial and intracavitary appliances	-40°C (20 minutes) + 600°C (1 h) and thermal shock 600°C to 20°C	25 kPa absolute to 2 MPa absolute	50 g from 1 m	No test	No test	---
Surface applicators	-40°C (20 minutes) +400°C (1 h) and thermal shock 400°C to 20°C	25 kPa absolute to 2 MPa absolute	200 g from 1 m	No test	1 g from 1 m	---

1 Peak acceleration amplitude

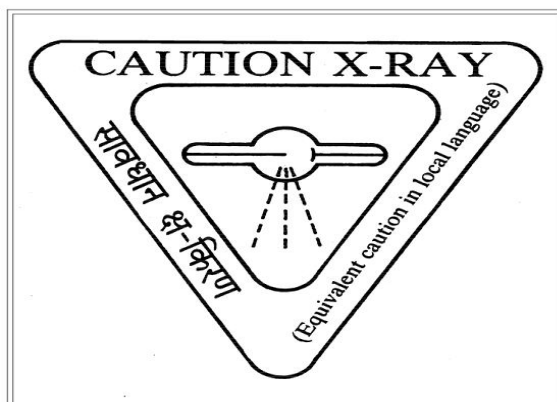
APPENDIX-II

RADIATION SYMBOL

A. RADIOACTIVE MATERIAL SYMBOL



B. X-RAY SYMBOL



APPENDIX-III

LIMITS OF LEAKAGE RADIATION LEVELS FOR RADIATION THERAPY EQUIPMENT AND ACCESSORIES

Radiation therapy equipment installed subsequent to the issuance of this Code shall meet the following requirements of radiation leakage levels:

A Teletherapy

A1 Telegamma

A1.1 Leakage Radiation through the Beam Limiting Devices during Irradiation

<p>(a) With the beam control mechanism set in the beam ON position, for all radiation beam sizes, the adjustable and interchangeable beam limiting devices shall attenuate the radiation such that the absorbed dose at normal treatment distance (NTD) anywhere in the area protected by the beam limiting device.</p>	<p>shall not exceed 2% of the maximum absorbed dose for a 10 cm x 10 cm radiation field measured on the radiation beam axis at the same distance.</p>
<p>(b) In addition, for equipment in which the maximum field size of the radiation beam exceeds 500 cm² at NTD, the additional limits of leakage through beam limiting devices (BLD) shall apply for square fields of any size so that the product of the average absorbed dose due to leakage radiation through the beam limiting devices and the maximum area able to be protected by the beam limiting devices</p>	<p>shall not exceed 1/10th of the product of the maximum absorbed dose on the radiation beam axis and the area of the radiation beam for a field size of 10 cm x 10 cm.</p> <p>All the values of absorbed dose and the area are referred to the NTD.</p>

A1.2 Leakage Radiation Outside the Maximum Radiation Beam

<p>(a) Beam control mechanism in the beam ON condition:</p> <p>(i) In a plane circular surface of radius 2 m centered on and perpendicular to the radiation beam axis at normal treatment distance (NTD) and excluding the area defined by the geometrical projection of distal end of the beam limiting device(BLD), the absorbed dose due to leakage radiation</p> <p>(ii) The absorbed dose rate due to leakage radiation measured at a distance of 1 m from the radiation source</p> <p>(b) Beam control mechanism in transition from the beam OFF to the beam ON condition and vice versa:</p> <p>The absorbed dose outside the maximum cross-section of the radiation beam at 1 m from the radiation source</p>	<p>shall not exceed: (i) a maximum of 0.2%, and (ii) an average of 0.1% of the maximum absorbed dose measured at the point of intersection of radiation beam axis and the plane surface for a 10 cm x 10 cm radiation field.</p> <p>shall not exceed 0.5% of the maximum absorbed dose rate on the radiation beam axis measured at distance of 1 m from the radiation source</p> <p>shall not exceed 0.5% of the maximum absorbed dose rate on the radiation beam axis measured at a distance of 1 m from the radiation source</p>
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A1 3 Stray Radiation in the Beam OFF Condition

<p>With the beam control mechanism in the OFF position, the protective shielding shall attenuate the radiation such that for the maximum rated activity of the source, the absorbed dose rate due to stray radiation measured:</p>	
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(a) at distance of 1 m from the source	shall not exceed 0.02 mGy.h ⁻¹
(b) at any readily accessible position 5 cm from the surface of the protective shielding	shall not exceed 0.20 mGy.h ⁻¹

Note: Measurements, for assessing compliance with the requirements of leakage radiation levels for source housings shall be averaged over an area not greater than 100 cm² at a distance of 1 m from the source, or 10 cm² at a distance of 5 cm from the source housing, as the case may be.

A2 Linear Accelerator

A2.1 Leakage Radiation through the Beam Limiting Devices

(a) Each beam limiting device shall attenuate the X-radiation such that the absorbed dose anywhere in the area defined by the geometrical projection of the distal end of the beam limiting device, excepting any residual radiation field, which must adequately be covered by at least two TVL's of the shielding material to avoid any contribution to the transmission measurement.	shall not exceed 2% of the maximum absorbed dose measured on the radiation beam axis at normal treatment distance (NTD) in a 10 cm x 10 cm field.
(b) For radiation fields of any size, the average absorbed dose, due to leakage radiation through the beam limiting devices in the area defined in A2.1(a) above	shall not exceed 0.75% of the maximum absorbed dose on the reference axis at NTD in a 10 cm x 10 cm radiation field.
(c) Leakage radiation through the parts of a multi-element beam limiting device (e.g. MLC) that project into the rectangular radiation field formed by automatically adjustable leafs	shall not exceed 5% of the maximum absorbed dose measured on the reference axis at NTD distance in a 10 cm x 10 cm radiation field.

A2.2 Leakage Radiation Outside the Beam Limiting Device

In a plane circular surface of radius 2 m centred on and perpendicular to the radiation beam axis at normal treatment distance (NTD) and excluding the area defined by the geometrical projection of distal end of the beam limiting device (BLD), the absorbed dose due to leakage radiation	shall not exceed: (i) a maximum of 0.2%, and (ii) an average of 0.1% of the maximum absorbed dose measured at the centre of the plane in a 10 cm x 10 cm radiation field.
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A2.3 Leakage Radiation Outside the Patient Plane

Outside the area defined in A.2.2, the absorbed dose due to leakage radiation at 1 m from the path of the electrons between electron gun and the target or electron window, and the reference axis	shall not exceed 0.5% of the maximum absorbed dose measured on the radiation beam axis in a 10 cm x 10 cm radiation field at NTD
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A2.4 Stray X-radiation During Electron Irradiation

The percentage absorbed dose on the reference axis due to X-radiation at a depth of 100 mm beyond the practical electron range	shall not exceed 4% for electron energies up to 6 MeV, 5% between 6 and 15 MeV and 10% beyond 15 MeV up to 30 MeV.
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A2.5 Neutron Leakage

(a) Neutron leakage radiation outside the BLD (in the patient plane)	At electron energy exceeding 10 MeV, the neutron dose in the plane defined in A.2.2	shall not exceed a maximum of 0.05% and an average of 0.02% of the maximum absorbed dose in a 10 cm x 10 cm radiation field at the point of intersection with the radiation beam axis.
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(b) Neutron leakage radiation outside the patient plane	except in areas defined in A.2.2 and under the same conditions, at electron energy exceeding 10 MeV, the neutron dose	shall not exceed 0.05% of the maximum absorbed dose due to electron or X-radiations.
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A2.6 Induced Radioactivity

When the energy of the electrons at the target or electron window exceeds 10 MeV, the following limits for induced radioactivity shall apply.

(a) Ambient equivalent dose due to ionising radiation from the equipment at the end of 4 h series of irradiation of 4 Gy at the maximum specified absorbed dose rate, separated by off periods of 10 minutes. OR	shall not exceed the following values when accumulated over a period of 5 minutes starting 10 s after the final termination of irradiation: (i) 10 μSv at any readily accessible position 5 cm from the surface of the enclosure, and (ii) 1 μSv at 1 m from the surface of the enclosure.
(b) Ambient equivalent dose rate due to ionising radiation from the equipment at the end of 4 h series of irradiation of 4 Gy at the maximum specified absorbed dose rate, separated by off periods of 10 minutes.	shall not exceed the following values when measured during the period starting 10 s after final termination of irradiation and not extending to more than 3 minutes from that time: (i) 200 $\mu\text{Sv}\cdot\text{h}^{-1}$ at any readily accessible place 5 cm from the surface of the enclosure, and (ii) 20 $\mu\text{Sv}\cdot\text{h}^{-1}$ at 1 m from the surface of the enclosure.

A2.7 Adventitious Ionising Radiation

For equipment parts not intended to produce ionising radiation for radiotherapy and which form part of the electron accelerator, ionising radiation emitted by thermionic valves excited by voltages exceeding 5 kV	shall not produce an ambient dose exceeding 5 μSv in 1 h at a distance of 5 cm from any accessible surface.
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B. BRACHYTHERAPY

Brachytherapy source storage, emergency storage and in-house transport container shall meet the following limits for leakage radiation levels, with the maximum rated radioactivity in the source storage:

Equipment	Leakage Radiation Dose Rate ($\mu\text{Gy}\cdot\text{h}^{-1}$)	
	5 cm from surface of storage	1 m from source
(a) Remote after-loading system		
(i) Unrestricted access	10	1
(ii) Restricted access	100	10
(b) Manual after-loading system/emergency storage container/ in-house transport container		
(i) Portable	500	20
(ii) Mobile	1000	50

Note: To meet the compliance with the requirements of the above limits of leakage radiation levels, measurements shall be averaged over an area not greater than (i) 100 cm² at 1 m from source, or (b) 10 cm² at 5 cm from the surface of the source housing, as the case may be.

APPENDIX-IV

DOSE LIMITS¹

The limits on effective dose apply to the sum of effective doses from external and internal sources excluding the exposures due to natural background radiation and medical exposures and the calendar year shall be used for dose limitation purposes.

Workers

The occupational exposure of any worker shall be so controlled that the following limits are not exceeded:

- (a) an effective dose of 20 mSv/y averaged over five consecutive years (calculated on a sliding scale of five years);
- (b) an effective dose of 30 mSv in any year;
- (c) an equivalent dose to the lens of the eye of 150 mSv in a year;
- (d) an equivalent dose to the extremities (hands and feet) of 500 mSv in a year
- (e) an equivalent dose to the skin of 500 mSv in a year; and
- (f) limits given above apply to female workers also. However, once pregnancy is declared the equivalent dose limit to embryo/fetus shall be 1 mSv for the remainder of the pregnancy.

Trainees

The occupational exposure of apprentices and trainees between 16 and 18 years of age shall be so controlled that the following limits are not exceeded:

- (a) an effective dose of 6 mSv in a year;
- (b) an equivalent dose to the lens of the eye of 50 mSv in a year ;
- (c) an equivalent dose to the extremities (hands and feet) of 150 mSv in a year; and
- (d) an equivalent dose to the skin of 150 mSv in a year.

Note : Apprentices and trainees in radiation facility, if any, shall be of age above 16 years only.

Public

The estimated average doses to the relevant members of the public shall not exceed the following limits:

- (a) an effective dose of 1 mSv in a year;
- (b) an equivalent dose to the lens of the eye of 15 mSv in a year; and
- (c) an equivalent dose to the skin of 50 mSv in a year.

¹ The dose limits shall be applicable as per the directives issued by the competent authority from time to time.

APPENDIX-V

DOSE RATE LIMITS FOR DISCHARGE OF PERMANENT IMPLANT PATIENTS

Radionuclide	Dose rate at 1 m from the Body Surface (mSv.h ⁻¹)
¹⁹⁸ Au	0.21
¹²⁵ I	0.01
¹⁰³ Pd	0.03

APPENDIX-VI

MINIMUM QUALIFICATIONS AND EXPERIENCE REQUIRED FOR PERSONNEL IN RADIATION ONCOLOGY FACILITY

1. Radiation Oncologist

A radiation oncologist shall have:

- (i) a basic degree in medicine from a recognised university; and
- (ii) a post-graduate degree in radiation therapy/radiation oncology or an equivalent qualification.

2. Medical Physicist/Radiation Physicist/Radiological Physicist

A medical physicist/radiation physicist/radiological physicist shall have:

- (i) a post graduate degree in Physics from a recognised university;
- (ii) a Post M.Sc. diploma in radiological/medical physics from a recognised university; and
- (iii) an internship of minimum 12 months in a recognised well-equipped radiation therapy department.

OR

- (i) a basic degree in science from a recognized university, with physics as one of the main subjects;
- (ii) a post graduate degree in radiological/medical physics from a recognised university; and
- (iii) an internship of minimum 12 months in a recognised well-equipped radiation therapy department.

3. Radiological Safety Officer

A radiological safety officer shall have:

- (i) minimum qualifications required for a Medical Physicist/Radiation Physicist/Radiological Physicist as mentioned above; and
- (ii) an approval from the competent authority to function as Radiological Safety Officer.

4. Dosimetrist

A dosimetrist shall have:

- (i) a basic degree in science from a recognised university, with physics as one of the subjects; and
- (ii) a minimum of 2 years experience in dosimetry in a recognised well-equipped radiation therapy department .

5. Radiation Therapy Technologist

A radiation therapy technologist shall have:

- (i) 10 + 2 or equivalent with science subjects from a recognised board; and
- (ii) two years' radiation therapy technologists' course, or equivalent, based on the minimum course content prescribed by the competent authority, from a recognised institution with in-field training in radiotherapy.

6. Radiation Therapy Service Engineer

A radiation therapy service engineer shall have:

- (i) basic degree/diploma in electrical/electronic/biomedical/mechanical engineering from a recognised university; and
- (ii) certification from the competent authority for handling radiation therapy equipment.

APPENDIX-VII

MINIMUM PERSONNEL REQUIREMENTS FOR RADIATION ONCOLOGY FACILITY

S.No.	Category	Staffing
1	Radiation Oncology (i) Chief Radiation Oncologist (ii) Radiation Oncologist	One per centre One additional, for each 400 patients treated annually. No more than 40 patients under treatment by a single physician per day
2	Medical Physics Medical Physicist/Radiation Physicist/Radiological Physicist	One per Centre, for up to 500 patients treated annually, additional in ratio of 1 per 500 patients treated annually.
3	Radiological Safety Radiological Safety Officer	One per centre
4	Radiation Therapy Technology (i) Chief Radiation Therapy Technologist (ii) Radiation Therapy Technologist (iii) Technologist (Simulator) (iv) Technologist (Brachytherapy)	One per centre 2 per teletherapy unit up to 40 patients treated daily, 4 per teletherapy unit up to 80 patients treated daily. 2 for every 500 patients simulated annually As needed
5	Treatment Planning and Execution (i) Dosimetrist/ Physics Assistant (ii) Technologist (Mould Room)	One per 500 patients treated annually One per 600 patients treated annually
6	Auxiliary (i) Nurse (ii) Social Worker (iii) Dietician (iv) Physiotherapist (v) Occupational Therapist (vi) Psychologist (vii) Maintenance Engineer	May be employed as per requirement ” ” ” ” ” ”

APPENDIX-VIII

RESPONSIBILITIES OF PERSONNEL IN RADIATION ONCOLOGY FACILITY

1. Employer

The employer shall have responsibilities listed in Rule 20 of the Atomic Energy (Radiation Protection) Rules, 2004 including those to:

- 1.1 ensure that the provisions of the Atomic Energy (Radiation Protection) Rules, 2004 or modified thereafter, are implemented by the licensee, RSO and workers;
- 1.2 provide adequate manpower for the functioning of the radiation therapy facilities;
- 1.3 provide adequate facilities and equipment to the licensee, RSO and workers to carry out their functions effectively;
- 1.4 inform the competent authority if the licensee, RSO, or any other worker leaves the employment;
- 1.5 be the custodian of radiation sources in his possession and shall ensure physical security of the sources at all times; and
- 1.6 inform the competent authority, within twenty four hours of any accident involving a source or loss of source of which he is the custodian.

2. Licensee

The licensee shall have responsibilities listed in Rule 21 of the Atomic Energy (Radiation Protection) Rules, 2004 including those to:

- 2.1 ensure that the provisions of the Atomic Energy (Radiation Protection) Rules, 2004, or modified thereafter, are implemented;
- 2.2 responsibility for ensuring radiation safety, developing suitable emergency plans, availability of qualified personnel and providing them requisite facilities to discharge their duties and functions;
- 2.3 ensure due compliance with the terms and conditions of the license issued to him by the competent authority;
- 2.4 provide all necessary facilities to the RSO to discharge his duties and functions to ensure adequate protection;
- 2.5 inform the employer and the competent authority of any loss of source;

- 2.6 conduct or arrange for quality assurance tests of structures, systems, components and sources and related equipment and maintain records;
- 2.7 inform the competent authority if the RSO or any worker leaves the employment; and
- 2.8 inform the competent authority when he leaves the employment.

3. Radiological Safety Officer (RSO)

The RSO shall have responsibilities listed in Rule 22 of the Atomic Energy (Radiation Protection) Rules, 2004 including those to:

- 3.1 ensure that the provisions of the Atomic Energy (Radiation Protection) Rules, 2004 or modified thereafter, are implemented;
- 3.2 establish and maintain an effective radiation protection programme to ensure safety of workers, patients and public;
- 3.3 instruct all workers on relevant safety measures;
- 3.4 assist the licensee in developing suitable emergency plans to deal with accidents and ensuring appropriate emergency preparedness;
- 3.5 provide adequate training in radiation protection and safety methodologies to all workers;
- 3.6 implement all radiation surveillance measures;
- 3.7 conduct periodic radiation protection surveys to verify compliance with the regulatory requirements;
- 3.8 ensure safe work practices during procedures, such as source transfer and target replacement;
- 3.9 carry out personnel monitoring and maintain records thereof;
- 3.10 ensure periodic calibration of radiation measuring and associated instruments;
- 3.11 submit periodic reports to the competent authority giving details such as safety status of the installation and inventory of sources; and
- 3.12 inform the competent authority when he leaves the employment.

4. Radiation Oncologist

The radiation oncologist shall have the sole responsibility for the overall care of the patient. He/She shall ensure that the provisions of the Atomic Energy (Radiation Protection) Rules, 2004, or modified thereafter, are implemented. The responsibilities shall include:

- 4.1 consultations with the patient, clinical evaluation of the disease and the justification for the proposed line of treatment;
- 4.2 establishment of treatment plan, including dose prescription;
- 4.3 executions of treatment and participation in it on a regular basis;
- 4.4 on-treatment evaluations and patient monitoring;
- 4.5 preparation of treatment summary at the end of the treatment procedure; and
- 4.6 evaluation of the treatment and follow-up.

5. Medical Physicist/Radiation Physicist/Radiological Physicist

The medical physicist/radiation physicist/radiological physicist shall ensure that the provisions of the Atomic Energy (Radiation Protection) Rules, 2004, or modified thereafter, are implemented. The responsibilities of the medical physicist/radiation physicist/radiological physicist shall include:

- 5.1 facility design and planning calculations, in accordance with the requirements of the installation that meets the regulatory stipulations of radiation protection and safety;
- 5.2 preparations of specifications for treatment and dosimetric equipment;
- 5.3 acceptance testing, commissioning and quality assurance (including calibration of therapy equipment);
- 5.4 periodic calibration of the dosimetric equipment, traceable to national standards laboratory;
- 5.5 measurement and analysis of beam data; and tabulation of beam data for clinical use;
- 5.6 evaluation and optimisation of treatment planning;
- 5.7 development of QA protocols and procedures in radiation therapy regarding delivery of radiation treatment, radiation safety and control and regulatory compliance; and
- 5.8 supervision of radiation therapy equipment servicing and maintenance of records.

6. Dosimetrist/Physics Assistant

Dosimetrist/Physics Assistant shall ensure that the provisions of the Atomic Energy (Radiation Protection) Rules, 2004, or modified thereafter, are implemented. The responsibilities of the Dosimetrist/Physics Assistant shall include:

- 6.1 carrying out necessary procedures to initiate treatment planning process, in consultation with the radiation oncologist and medical physicist;
- 6.2 carrying out manual/computer generated dose calculations and participation in the review of patient chart;
- 6.3 maintaining accurate documentation of all facets of the treatment plan and communication of the same to the radiation oncology team;
- 6.4 assisting the medical physicist in clinical dose measurement and machine calibration;
- 6.5 assisting in brachytherapy source loadings; and
- 6.6 assisting the medical physicist in clinical dose measurements, machine calibrations, quality assurance procedures and radiation protection surveys.

7. Radiation Therapy Technologist

Radiation therapy technologist shall ensure that the provisions of the Atomic Energy (Radiation Protection) Rules, 2004, or modified thereafter, are implemented. The responsibilities of the radiation therapy technologist shall include:

- 7.1 patient set-up strictly in accordance with the prescription chart;
- 7.2 selection of treatment parameters on the machine and the treatment control panel as defined in the prescription chart;
- 7.3 delivery of correct dose to the planning treatment volume;
- 7.4 stopping the treatment, when a fault condition develops;
- 7.5 intimating the licensee/RSO immediately regarding the incident;
- 7.6 ensuring that no further treatment is given to the patient, unless the RSO certifies, in writing, that the fault condition has been rectified, and it is safe to commence the treatment after re-setting of the treatment parameters on the control panel; and
- 7.7 following the radiation safety instructions, specified by the RSO from time to time.

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LIST OF PARTICIPANTS

COMMITTEE FOR REVIEW OF SAFETY CODES ON RADIATION THERAPY INSTALLATIONS (CRSCRI)

Dates of meeting:

January 17, 2003	August 5, 2003	April 23, 2004	July 19, 2005
January 30, 2003	August 18, 2003	May 7, 2004	July 25, 2005
March 12, 2003	September 5, 2003	August 16, 2004	July 26, 2005
March 24, 2003	September 24, 2003	August 23, 2004	September 6, 2005
April 3, 2003	October 1, 2003	January 25, 2005	September 9, 2005
April 7, 2003	October 14, 2003	January 27, 2005	September 23, 2005
April 16, 2003	October 22, 2003	February 10, 2005	October 5, 2005
April 23, 2003	November 11, 2003	February 16, 2005	October 25, 2005
May 5, 2003	December 12, 2003	February 17, 2005	November 3, 2005
May 20, 2003	January 2, 2004	March 1, 2005	May 12, 2006
May 28, 2003	February 9, 2004	March 2, 2005	May 17, 2006
June 16, 2003	February 16, 2004	March 18, 2005	May 22, 2007
June 20, 2003	February 24, 2004	April 1, 2005	May 30, 2007
June 25, 2003	March 3, 2004	April 6, 2005	December 19, 2007
July 1, 2003	March 15, 2004	April 7, 2005	January 3, 2007
July 9, 2003	March 19, 2004	April 8, 2005	January 4, 2007
July 14, 2003	April 6, 2004	April 21, 2005	
July 18, 2003	April 20, 2004	April 26, 2005	

Members of CRSCRI:

Dr. P.S. Iyer (Chairman)	:	BARC (Former)
Dr. S.K. Shrivastava	:	TMC, Mumbai
Shri A.M. Pendse	:	P.D. Hinduja National Hospital and Research Centre, Mumbai
Shri V.K. Sathyanarayana	:	P.D. Hinduja National Hospital and Research Centre, Mumbai
Shri U.B. Tripathi	:	BARC (Former)
Dr. R.M. Nehru (Member Secretary) (Till October 6, 2005)	:	AERB
Smt. Kanta Chhokra (Member Secretary) (From October 7, 2005)	:	AERB (Former)

**STANDING COMMITTEE ON RADIATION SAFETY
DOCUMENTS (SCRSD)**

Dates of meeting : March 6, 2006
March 7, 2006
April 17, 2006
April 18, 2006
March 21, 2007

Members of SCRSD:

Dr. A.R. Reddy (Chairman) : DRDO, New Delhi (Former)
Dr. P.S. Iyer : BARC (Former)
Shri R.J. Pardikar : BHEL, Thiruchirappalli
Dr. B.C. Bhatt : BARC (Former)
Dr. D.N. Sharma : BARC
Shri P.K. Nema : BARC
Dr. U.N. Nayak : BARC
Shri T.K. Jayakumar* : BRIT, Mumbai
Dr. A.N. Nandakumar : AERB (Former)
Shri K.D. Pushpangadan : AERB (Former)
(Member-Secretary)

*Shri V.G.R. Subramanian was the Former member of the committee.

**ADVISORY COMMITTEE ON RADIOLOGICAL SAFETY
(ACRS)**

Date of meeting : March 22, 2007

Members of ACRS:

Dr. U.C. Mishra (Chairman) : BARC (Former)

Dr. A.R. Reddy : DRDO, New Delhi (Former)

Dr. Gursharan Singh : BARC

Dr. B.C. Bhatt : BARC (Former)

Dr. S.K. Shrivastava : TMC, Mumbai

Dr. (Smt.) Meera Venkatesh : BARC (Former)

Shri S.P. Agarwal (Member-Secretary) : AERB (Former)

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

S. No.	Safety Code No.	Titles
1.	AERB/RF-MED/ SC-1 (Rev. 1)	Radiation Therapy Sources, Equipment and Installations, Mumbai, India, 2011.
2.	AERB/RF-MED/ SC-2 (Rev. 2)	Nuclear Medicine Facilities, Mumbai, India, 2011.
3.	AERB/SC/MED-2 (Rev. 1)	Medical Diagnostic X-ray Equipment and Installations, Mumbai, India, 2001.
4.	AERB/SS-5	Design and Manufacture of X-ray Analysis Equipment, Mumbai, India, 1992.
5.	AERB/SG/MED-1	Medical Management of Persons Exposed in Radiation Accidents, Mumbai, India, 1990.
6.	AERB/SM/MED-1	Atlas of Reference Plans for Medical Diagnostic X-ray Installations, Mumbai, India, 1988.
7.	AERB/SM/MED-2	Handbook for Medical Management of Persons Exposed in Radiation Accidents, Mumbai, India, 1989.

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