CODE NO. AERB/RF/SC

GOVERNMENT OF INDIA

AERB SAFETY CODE

RADIATION SOURCES, EQUIPMENT AND INSTALLATIONS

ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY CODE No: AERB/RF/SC

RADIATION SOURCES, EQUIPMENT AND INSTALLATIONS

Atomic Energy Regulatory Board
Mumbai -400094
India

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Order for this Code should be addressed to:

The Chief Administrative Officer
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Niyamak Bhavan
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FOREWORD

The Atomic Energy Regulatory Board (AERB) was constituted in 1983, to carry out certain regulatory and safety functions envisaged under Section16, 17 and 23 of the Atomic Energy Act, 1962. AERB has powers to lay down safety standards and frame rules and regulations with regard to the regulatory and safety requirements envisaged under the Act. The Atomic Energy (Radiation Protection) Rules, 2004, provides for issue of requirements by the Competent Authority for radiation installations, sealed sources, radiation generating equipment and equipment containing radioactive sources, and transport of radioactive materials.

With a view to ensuring the protection of occupational workers, members of the public and the environment from harmful effects of ionizing radiations, AERB regulatory safety documents establish the requirements and guidance's for all stages during the lifetime of nuclear and radiation facilities and transport of radioactive materials. These requirements and guidance's are developed such that the radiation exposure of the public and the release of radioactive materials to the environment are controlled; the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation is limited, and the consequences of such events if they were to occur are mitigated.

The Regulatory documents apply to nuclear and radiation facilities and activities giving rise to radiation risks, the use of radiation and radioactive sources, the transport of radioactive materials and the management of radioactive waste.

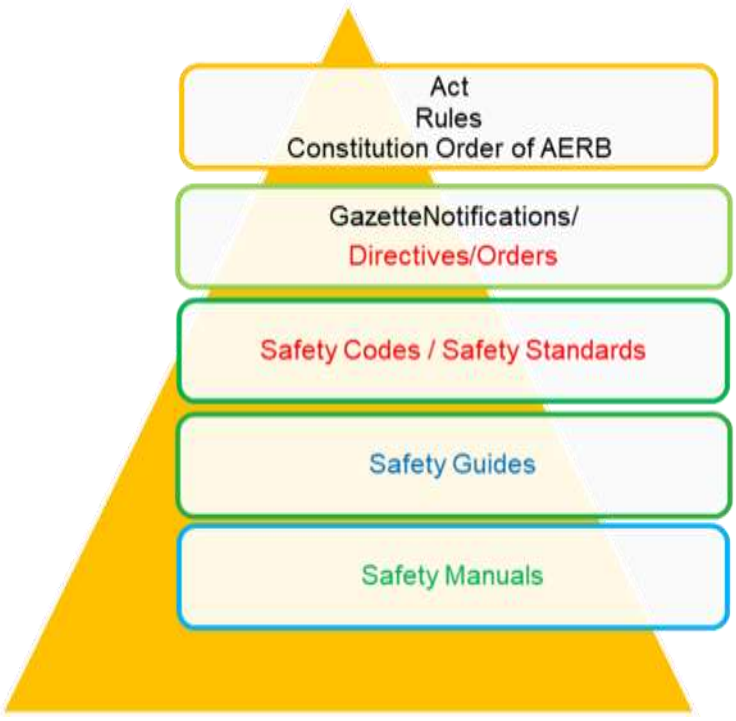

Fig. 1 Hierarchy of Regulatory Documents

Safety codes establish the objectives and set requirements that shall be fulfilled to provide adequate

assurance for safety. Safety Standards provide models and methods, approaches to achieve those requirements specified in the safety codes. Safety guides elaborate various requirements specified in the safety codes and furnish approaches for their implementation. Safety manuals detail instructions/safety aspects relating to a particular application. The hierarchy of Regulatory Documents is depicted in Figure.1.

The recommendations of international expert bodies, notably the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA) are taken into account while developing the AERB Regulatory safety documents.

The principal users of AERB regulatory safety documents are the applicants, licensees, and other associated persons in nuclear and radiation facilities including members of the public. The AERB regulatory safety documents are applicable, as relevant, throughout the entire lifetime of the nuclear and radiation facilities and associated activities. The AERB regulatory safety documents also form the basis for AERB's core activities of regulation such as safety review and assessment, regulatory inspections and enforcement.

The existing safety codes (5 nos.) for radiation applications, being practice-specific, have certain prescriptive requirements for specific practices. A 'new' practice-specific safety code was required to accommodate technological advancement and emerging new practices. Also, some inconsistences in the regulatory requirements among these safety codes were noticed. Therefore, with an aim to establish consolidated, generic and unambiguous requirements across various practices, AERB has developed a 'single' safety code titled 'Radiation Sources, Equipment and Installations', AERB/RF/SC, to accommodate technological advancement and emerging new practices besides ensuring coherency among the regulatory requirements. This safety code is issued in exercise of provisions under Rule 16 of Atomic Energy (Radiation Protection) Rules, 2004. This safety code is effective from the date of its issue and supersedes all the practice specific safety codes issued earlier for radiation facilities.

The special terms which are specific to this safety code are included under section on 'Special Terms and Interpretations'

This safety code has been drafted by an in-house working group. The draft was further reviewed by a Task Group with specialists drawn from technical support organisations and institutions, and other consultants. The Comments obtained from all the major stake holders have been suitably incorporated. The safety code has been vetted by the AERB Advisory Committee on Nuclear and Radiation Safety (ACNRS). AERB wishes to thank all individuals and organizations who have contributed to the preparation, review and finalization of the safety code.

(Dinesh Kumar Shukla)
Chairman, AERB

SPECIAL TERMS AND INTERPRETATIONS

Carers and Comforters

Carers and comforters are people, other than employees, who knowingly and willingly may incur an exposure to ionising radiation in support and comfort of a patient.

Graded approach

An application of radiation safety requirements that commensurate with the characteristics of the radiation installation, practice or the source and with the magnitude and likelihood of the exposures.

Operator

Operator is an individual who is certified in compliance with the eligibility criteria as specified by the AERB and is required to operate the facility/equipment as per written instructions and established standard operating procedures.

Potential Hazard

Exposure that is not expected to be delivered with certainty but that may result from an accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

Public (also Member of the Public)

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

Radiation work

Work involving exposure to ionizing radiation.

Safety Interlock

A safety interlock is an engineered device for precluding likely exposure of an individual to ionising radiation, either by preventing entry to the controlled area or by automatically terminating the cause of the exposure.

Contents

1 INTRODUCTION

1.1 General

Radioactivity is a natural phenomenon and natural sources of radiation are part of the environment. In recent times, man-made radiation sources have emerged as significant contributors to societal benefits. Radiation and radioactive substances have many beneficial applications, ranging from power generation to uses in medicine, industry, research and agriculture. The radiation risks to the workers and the public and release of radioactivity to the environment that may arise from these applications have to be assessed and, if necessary, controlled. Activities such as, production and use of radiation sources (hereinafter referred to as sources), the operation of radiation facilities, storage and transport of radioactive material, and the management of radioactive waste must therefore be subjected to safety requirements stipulated in this Safety Code.

1.2 Objective

This Code establishes requirements for the protection of the worker, the public and the environment from risk associated with applications in medicine, industry, research and agriculture and for the safety of radiation sources connected therewith. This Code is directed principally to the person responsible for carrying out activities and practices that may result in radiation exposures, and sets out the measures that shall be in place for radiation protection.

1.3 Scope

This Code gives requirements for ensuring radiological safety in radiation facilities to protect the workers, the public and the environment from ionising radiation.

Requirements for non-ionising radiation is outside the scope of this Code. This Code does not cover security measures in general, however, it covers physical security measures having a bearing on radiation safety.

This Code applies for protection against ionising radiation only, which includes gamma rays, X-rays, neutrons and charged particles such as electron, proton, alpha, beta particles and heavier ions, and safety of sources applicable to radiation facilities.

This Code covers all radiation sources involving radiation exposure that is amenable to control, except those that are exempted as notified by AERB.

Exposures from radiation sources, prescribed under exclusion, deemed to be not amenable to control are excluded from the scope of this Code. Requirements for safe transport of radioactive material shall be in accordance with the current national/ international regulations.

The licensing requirements and responsibilities of personnel such as licensee, RSO, worker, supplier and manufacturer are given in AERB Safety Code on 'Regulation of Nuclear and Radiation Facilities', AERB/NRF/SC/G (Rev.1), 20XX.

Note: ***All requirements of the code may not necessarily apply to every radiation facility. Guidance on applicable requirements for different facilities/practices is elaborated in the respective guides. Terms such as 'adequate', 'appropriate' and 'periodically' are elaborated in practice specific guides.***

2 RADIATION PROTECTION AND SAFETY

2.1 General

In this chapter, the principles of radiation protection, justification, optimization and dose limits are outlined. The licensee responsible for the radiation facility or activity that gives rise to radiation risks shall have prime responsibility for protection and safety and shall ensure that principles of radiation protection and safety are applied in all situations.

2.2 Justification

The employer shall ensure that no practice or activity involving exposure to radiation shall be planned unless it produces sufficient benefit to the exposed individuals or to society in comparison to harm or damage it causes. Practices which are specified in Atomic Energy (Radiation Protection) Rules, 2004 are deemed to be justified. Any other practices including human imaging involving ionizing radiation for non-medical purposes are subject to appropriate justification acceptable to AERB.

Only justified practices that produce a net benefit are permitted to be adopted.

2.3 Optimisation

The optimisation principle offers a means to take a graded approach in management of the radiation risks and focuses on balancing risks and benefits.

The principle of optimisation of protection requires that the likelihood and magnitude of exposures and the number of people exposed, be kept as low as reasonably achievable (ALARA), with economic and societal factors taken into account. The level of protection shall be appropriate under prevailing circumstances providing adequate margin of benefit over harm.

For activities that may give rise to environmental concern, it is important that the assessment consider both human health and the environment, so that the appropriate decision can be taken on the basis of a holistic understanding of radiation risks.

Licensee shall ensure that dose constraints are used in the optimization of protection and safety for sources within practice so that the exposures to the workers and the members of public are kept as low as reasonably achievable.

2.4 Dose Limits

Licensee shall ensure that the exposure of the workers or members of the public, neither the effective dose nor the equivalent dose to tissues or organs exceeds the dose limits specified by the Competent Authority under Atomic Energy (Radiation Protection) Rules, 2004.

Dose limits do not apply to medical exposure and emergency exposure situation.

2.5 Management for Safety

In order to achieve overall safety during handling of radiation sources, an effective management system shall be in place so that the safety requirements, which include health, human performance, quality, protection of the environment, promotion of safety culture, assessment of safety performance and lessons learned from experience, are fulfilled.

Safety measures and security measures have in common the aim of protecting human life and the environment. Safety measures and security measures shall be designed and implemented in an integrated manner, so that security measures do not compromise safety and safety measures do not compromise security.

The requirements of this Code are intended to be applied in accordance with a graded approach, where the radiation protection arrangements during normal operation and protective measures to be implemented during accident conditions shall be commensurate with the radiation risks associated with the situation.

3 DESIGN OF RADIATION SOURCES, EQUIPMENT AND INSTALLATION

3.1 General

The built-in design safety requirements for radiation sources, equipment and installation play a major role in ensuring radiation safety while handling the radiation sources. While designing, adequate provision shall be made to prevent any undue exposure to personnel and occurrence of incidents or emergency situations.

3.2 Sealed Source

The design of sealed source shall be as per the applicable national/ international standards.

3.2.1 Encapsulation

Sealed source encapsulation shall meet the specifications prescribed as per the national/international standards and/or the requirements provided under safety standards of AERB 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. The materials used for encapsulation shall be chosen as per the national/international standards and/or requirements as prescribed under safety standards of AERB so that the material remains unaffected by ionising radiation, adverse environmental conditions and the conditions in which it is expected to be used.

3.2.2 Contamination and Leak Test

Each sealed source shall be tested for contamination and leak tightness and if found contaminated and /leaky in excess of specified limits, it shall not be supplied.

3.2.3 Source Identification

Wherever physically possible, the encapsulation of sealed sources and sealed container shall have appropriate identification of radionuclide, source strength, serial number and manufacturer's name or logo.

3.3 Source Housing

3.3.1 Source Housing Integrity

The design of source housing shall meet the national/international standards and/or the requirements as prescribed under safety standards of AERB with appropriate marking and labelling. The source housing shall be so designed as to retain the integrity of the source and the shielding under normal operating conditions and wherever applicable all foreseeable accident conditions including adverse environmental conditions

3.3.2 Security of Radioactive Source in the Housing

The source housing shall have appropriate locking mechanism and the source shall be secured within the housing in such a way that its removal, if required, shall only be possible using special tools.

3.3.3 Radiation Warning Sign and Radiation Symbol

The radiation warning sign and radiation symbol shall be conspicuously and prominently displayed on externally visible surfaces of radiation equipment, and containers for storage of radioactive materials and packages for radioactive materials as prescribed by AERB. The radiation warning sign or radiation symbol shall not be used for any purpose other than those as prescribed by the Rules.

3.4 Design of Radiation Equipment

3.4.1 Design Objective

The design philosophy of the radiation equipment shall be based on the principle of defence-in-depth. Accordingly, there shall be multiple levels of safety systems in the radiation equipment to prevent any undue exposure to workers and public.

The design of the radiation equipment shall meet the requirements of relevant national/international standards. For radiation equipment emitting radiation, with significant hazard potential, provision shall be made to prevent unauthorised use.

3.4.2 Fail-Safe Mechanism

The radiation equipment, with significant potential hazard, shall be so designed that in the event of a break-down or malfunction of the actuating force, or in the event of unsafe conditions, the source shall attain safe situation and shall continue to remain so till the normal operating condition is restored.

3.4.3 Safety Interlocks

Wherever radiation equipment, with significant potential for hazard, is controlled by suitable means of control system, it shall be so designed that unacceptable risk to occupational workers and members of public can be prevented by suitable safety interlock systems. The safety interlocks shall be redundant and diverse.

3.4.4 Emergency Control Mechanism

Wherever source, with significant potential hazard, is controlled by electrically operated or other control system, to prevent/control any emergency condition, readily identifiable and accessible means shall be provided to attain safe situation.

3.4.5 Conventional Safety

The design and safety features of radiation equipment shall comply with the applicable national/international requirements for mechanical, electrical, fire, environmental and other safety specifications, as applicable, to prevent danger and/or personal injury.

3.5 Shielded Enclosure

3.5.1 Structural Shielding

The radiation installation, requiring shielded enclosure, shall provide adequate structural shielding for walls and doors, ceiling and floor so that the radiation levels outside the shielding do not exceed the prescribed dose limits or any other regulatory constraints for the occupational workers and members of the public. The radiation installation shall meet requirements for siting of the facility.

Construction and shielding of the facility or premises including open top installations shall be such that the dose constraints acceptable to AERB are applied for occupationally exposed persons and members of the public. Optimisation of the shielding shall be considered so that external radiation exposures are kept as low as reasonably achievable.

In the case of open top installation, the scattered radiation (sky-shine) shall also be considered. The shielding requirements shall take into account the scenarios including potential exposures and maximum workload.

Adequate safety margins in the design, construction and operations of the facility shall be taken into account to prevent accidents, mitigate the consequences of accidents and restrict potential exposures.

3.5.2 Control Room

Wherever the source is operated from a control room, it shall be appropriately located and provisions made available to comply with safety requirements and dose limits as specified by Competent Authority.

3.5.3 Conduit/Opening

The conduit/opening for cables provided in the wall between the control room and exposure room, in the case of shielded enclosure, shall be so designed as to prevent direct streaming of radiation.

3.5.4 Door Interlock

For radiation equipment, controlled by electrically operated control system, requiring shielded enclosure, the door between the control room and the exposure room shall be provided with an electrical interlock so as to prevent operation of the equipment when the door is not properly closed.

3.5.5 Audio-Visual Indicator

Wherever radiation equipment/source, with significant potential hazard is handled, provision at appropriate location shall be made for appropriate audio and/or visual indicators during operation.

3.5.6 Radiation Zone Monitor

Wherever the radioactive source, with significant radiation risk, is handled in an enclosure, an appropriate radiation area zone monitor shall be provided at a location near the entrance to alert entry to the radiation area inadvertently and prevent excessive exposure. Wherever, the discrete radioactive sources are handled in an enclosure, an appropriate zone radiation monitor shall be provided outside the entrance of controlled area to alert movement and prevent loss of the sources.

3.5.7 Radiation Warning Sign and Radiation Symbol at Entry point

Radiation warning sign and radiation symbol as prescribed by AERB shall be posted conspicuously and prominently at the entrance of the controlled area. A legend in English, Hindi and local language indicating the radiation hazard and restricted entry shall be posted near the radiation symbol.

3.5.8 Ventilation systems

In case of handling of unsealed radioactive source in an enclosure, appropriate ventilation system shall be provided.

In case there is production of ozone, noxious gas or dust particulates during operation of radiation installation, provision shall be made for appropriate air changes to keep them under prescribed limit at the time of entering into the installation.

4 OPERATIONAL SAFETY

4.1 General

The operational safety plays a major role in ensuring radiation safety in addition to engineering controls. In order to ensure effective operational safety, necessary infrastructure, adequate manpower and their knowledge in radiation safety, appropriate operating procedure and its compliance are important.

4.2 Manpower Requirement

Employer[1] shall ensure availability of adequate number of workers by taking into account radiation equipment, workload and operating shifts as prescribed by AERB.

No person under the age of 18 years shall be employed as a radiation worker. While employing the workers, the employer shall ensure that the workers have appropriate training and instructions in radiation safety, in addition to the qualification and training required for performing their intended tasks as prescribed by the relevant authority. Every worker, initially on employment, and classified worker, thereafter at-least once in three years as long as the individual is employed, shall be subjected to general medical examination and health surveillance as specified by AERB.

The employer shall designate a Radiological Safety Officer (RSO) for the facility with the approval of AERB. Employees, who are likely to receive an effective dose in excess of three -tenths of the average annual dose limits prescribed by the Competent Authority shall be designated as classified workers by the employer. Such employees shall be informed that they have been so designated.

4.3 Trainees

No person under the age of 16 years shall be taken as trainee or employed as an apprentice for radiation work. Person undergoing training shall be allowed to use radiation sources under direct supervision of qualified personnel and the dose received by trainee shall not exceed the dose limits prescribed for trainees by Competent Authority.

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[1] Typically employer is the licence holder

4.4 Monitoring, Protection and Safety Tools/Accessories

Licensee shall establish and maintain organisational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for monitoring of the workplace as part of radiation protection programme.

4.4.1 Personnel Monitoring

Radiation workers handling radiation sources shall be subjected to appropriate personnel monitoring, which means determination or estimation of the dose received by an individual from external and/or internal radiation, implementing the dose constraints and investigation level, and appropriate records shall be maintained.

4.4.2 Personnel Protective Equipment

Radiation workers, while handling radiation sources, shall be provided with appropriate personnel protective equipment for adequate protection.

4.4.3 Radiation Monitoring Instrument

Appropriate radiation monitoring instrument, such as radiation survey meters, and contamination monitors shall be made available. The monitoring instrument shall be maintained in good working condition having valid calibration from an appropriate agency/laboratory.

4.4.4 Measuring Instrument

Appropriate instrument(s) for measuring radioactivity and radiation doses for diagnostic and therapeutic purposes shall be made available. The measuring instrument shall be maintained in good working condition having valid calibration by an appropriate agency/laboratory.

4.4.5 Handling Tools

All the tools used for handling the radiation sources shall be provided such that adequate protection can be achieved without hampering convenience and speed of operation.

4.4.6 Mobile Shield/L-Bench

Wherever the source, with significant potential hazard, is to be handled or to be prepared with close proximity without any shielding, provision of mobile shield or L-Bench with

provision of lead equivalent glass viewing window of appropriate thickness and other necessary arrangements shall be made available so as to provide adequate protection to the operator.

4.5 Operation of Radiation Equipment

Prior to operation of radiation equipment, it shall be ensured that necessary arrangements are in place to offer adequate protection to the workers, the public and the environment around the radiation installation. The operator shall be familiar with all the safety features of the radiation equipment to ensure that the dose received is as low as reasonably achievable.

4.6 Source Location and Storage

4.6.1 Premise/Location for Source Handling

Radiation source shall be used only in the approved premise/location for the intended purpose and the same shall not be taken out of the approved premise/location for any purpose without the prior approval of AERB.

4.6.2 Transfer of Radioactive Source

The radiation source shall not be lent, gifted, transferred, sold, supplied or disposed of without the prior approval of AERB

4.6.3 Safe and Secured Storage

The radioactive sources shall be stored in safe and secure manner at the designated area. Inventory of radioactive source(s) shall be maintained and verified periodically.

4.6.4 Emergency Storage Container

Wherever the radioactive source is remotely driven out of source housing and possibility of failure in retrieval exists, emergency storage container with adequate shielding shall be available at the place of operation.

4.6.5 Source Movement within the Facility

A logbook shall be maintained with appropriate information regarding operational movement of the sources from, and to, the safe storage.

4.6.6 Security of Radioactive Material

The physical security of the radioactive material under possession of the employer shall be ensured at all times.

4.6.7 Source Handling in Other's Premise/Facility

In case radiation equipment/source is to be handled in client's premise/facility, prior approval shall be obtained by the licensee from AERB. The licensee shall have an appropriate written agreement with the client clearly specifying the associated roles and responsibilities, including safety and security of the equipment/source in client's premise/facility, of each party.

4.7 Safety Checks, Quality Assurance and Maintenance

It shall be ensured that adequate maintenance, testing and servicing are carried out as necessary so that sources remain capable of fulfilling their design requirements for protection and safety, throughout their useful life.

It shall be ensured that, maintenance, inspection and testing appropriate to the preservation of the provisions for protection and safety can be carried out without scope of undue exposure.

4.7.1 Safety Checks

For each safety system such as fail-safe mechanisms, interlocks, timers, couplings, pneumatic systems and drive cable mechanism, emergency stop buttons, radiation monitoring systems and any other safety systems, the frequency of periodic checks shall be established, keeping in view the nature and probability of failure. The periodic checks shall be carried out and records thereof shall be maintained. In the event of detecting a defect in the radiation equipment, it shall not be used till it is repaired.

4.7.2 Quality Assurance Tests

The quality assurance (QA) of the radiation equipment/source including their systems and components and their related equipment shall be established, keeping in view the nature and probability of failure. The QA tests shall be carried out periodically and records thereof shall be maintained. In the event of detecting any defect in the equipment, it shall not be used till it is repaired. In the case of radioactive source(s), if it/they, is/are found to be defective and the leakage/contamination level is in excess of the limit

prescribed by AERB, it/they shall be returned to the source supplier/manufacturer with prior approval of AERB.

4.7.3 Servicing and Maintenance

Licensee shall ensure that servicing and maintenance of radiation equipment is carried out throughout the useful life. It shall be carried out by persons having appropriate training and instructions for radiation safety as prescribed by AERB, in addition to the appropriate qualifications required for performing the intended task. It shall be ensured that the spares and accessories used during the servicing and maintenance meets the technical specifications of original spares and accessories.

Servicing and maintenance of radiation equipment having low hazard potential (all consumer products, X-ray equipment of less than 450kVp except those used in radiation therapy) may be carried out by persons other than supplier/manufacturer, provided the service agency is registered with AERB. Service agency shall have trained manpower, proper radiation monitoring instrument, personnel monitoring and arrangement for genuine spares and accessories. Only successfully completed radiation safety trained person is permitted to carry out servicing and maintenance of radiation equipment.

4.8 Management of Disused Source/Decommissioning of Equipment

4.8.1 Management of Disused Sealed Radioactive Source

Whenever the sealed source is no longer in use, an arrangement shall be made without delay to send it back to the supplier/manufacturer of the source for its safe management with prior approval of AERB. The safe custody of the disused source shall be ensured till it is sent back to the supplier/manufacturer.

4.8.2 Disposal of Unsealed Source (Radioactive Waste)

Unsealed radioactive material or radioactive waste shall be disposed of, with prior approval of AERB, in accordance with the regulatory provisions and the records thereof shall be maintained.

4.8.3 Decommissioning of Radiation Equipment/Facility

When the radiation equipment is no longer to be used, after sending back the radioactive source to supplier/manufacturer of the source, contaminated parts or activation products,

the employer shall ensure decommissioning of the radiation equipment/facility including safety management of contaminated parts or activation products, as per the prescribed procedure with prior approval of AERB. The licensee shall comply with such directive as may be issued by the Competent Authority to ensure adequate protection of the persons in and around the decommissioned installation. Decommissioning shall consider possibility of reuse of equipment and facility as the case maybe.

4.8.4 Prior to acquiring radiation source, appropriate provisions shall be made and maintained for sending back the radioactive source to supplier/manufacturer of the source for safe management and decommissioning of radiation equipment when they are no longer in use.

4.9 Safe Transport of Radioactive Material

The requirements for safe transport of radioactive material shall be in accordance with the prevailing national/international regulations.

5 MEDICAL EXPOSURE

5.1 General

Medical exposure means exposure incurred by (i) patients as part of their own medical diagnosis or treatment; (ii) persons, other than occupationally exposed, while knowingly and willingly helping in the support and for comfort of patients; and (iii) volunteers in biomedical research. The requirements stated herein are applicable for all the institutions/personnel involved in carrying out medical exposures.

5.2 Optimisation of Medical Exposures

It shall be ensured that the relevant aspects of optimisation process are considered for all types of medical exposures. Due consideration shall be given to optimise medical exposures of pediatric patients, pregnant woman in view of embryo or fetus and breastfeeding woman, as applicable.

5.2.1 Quality Assurance

The licensee carrying out diagnostic or therapeutic procedure using radiation generating equipment, sealed or unsealed sources, shall ensure that performance of the equipment is verified by appropriate quality assurance tests with appropriate periodicity for optimising the medical exposure.

5.2.2 Exposure of Humans for Research Purposes

It shall be ensured that exposure of humans for bio-medical research is carried out only on healthy volunteers with their prior consent in writing having informed about radiation risk and after due review by ethical review committee constituted by the employer.

5.3 Records of Medical Exposure

5.3.1 Maintenance of Records

It shall be ensured that the records of radiation dose received by the patient undergoing therapeutic procedures, activity administered to the patient for diagnostic and therapeutic purposes and other relevant parameters, as applicable, are maintained for each patient as specified by competent authority.

5.4 Isolation of Patient

In case of hospitalised patient(s) administered with radioactivity or implanted with radioactive sources, it shall be ensured that the patient is kept isolated in order to prevent spread of contamination and minimize exposure to staff, other patients and the members of public.

5.5 Discharge of Patients administered/implanted with Radioactivity

5.5.1 Monitoring of Patient prior to Discharge

The patient administered/implanted with radioactivity shall be monitored prior to discharge from medical facility in order to prevent loss of source in case of temporary implant, and to minimise dose to members of public in case of patient administered or permanently implanted with radioactive source.

5.5.2 Discharge of Patients

The patient administered/implanted with radioactivity shall be discharged only after ensuring that the dose rate(s) from the patient or implant site does not exceed the limits prescribed by AERB.

5.5.3 Instructions during Discharge of Patients

The patient shall be provided with written and oral instructions concerning contact with other persons and relevant precautionary measures for radiation protection purposes, so as to ensure radiation protection for carers and comforters, members of the public and for family members before discharge of patient from medical facility.

5.6 Carers and Comforters

It shall be ensured that care and comfort for patient undergoing diagnostic or therapeutic procedures using radiation is provided by a person who is willingly and voluntarily helping.

It shall be ensured that no individual incurs a medical exposure as a carer or comforter unless the person has received, relevant information on radiation protection prior to providing care and comfort to an individual undergoing diagnostic or therapeutic procedures. Carers and comforters shall be provided with adequate radiation protection measures as applicable.

5.7 Control of Exposure to Persons other than Patient

It shall be ensured that no person is present in the imaging, administration or treatment area during a radiation exposure or the administration of a radioactive substance to a patient unless the attendance of that person is absolutely necessary.

5.8 Unintended/Accidental Medical Exposures

5.8.1 Prevention of Unintended/Accidental Medical Exposures

It shall be ensured that all practicable measures are taken to minimise the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment including human error.

5.8.2 Reporting of Accidental Medical Exposures

Any unintended or accidental medical exposure shall be promptly investigated by the licensee and corrective actions as applicable shall be taken. A written report on such exposures shall be promptly submitted to AERB.

5.9 Death of Patient with Radioactive Source In-Situ

In the event of death of patient administered/implanted with radioactivity, radiation safety precautions shall be followed, during handing over the body to claimants and during disposal, in accordance with the procedures laid down by AERB.

6 HANDLING INCIDENTS/EMERGENCY SITUATION

6.1 General

Incidents may occur during handling of radiation sources. The requirements pertaining to radiological emergencies is provided in AERB Safety Code on 'Management of Nuclear and Radiological Emergencies', AERB/NRF/SC/NRE, 2022.

6.2 Emergency Preparedness for Response

The Licensee, in consultation with Radiological Safety Officer (RSO), shall prepare suitable emergency preparedness and response (EPR) plan and procedures commensurate with hazard to mitigate foreseeable emergency conditions and maintain emergency preparedness.

The EPR plan and procedures, as applicable, shall be submitted to AERB prior to the commissioning of the installations.

Any modification in the EPR plan and procedure shall require prior approval or review by AERB.

The Licensee shall demonstrate the capability for response to incidents/accidents as per the EPR plans.

6.3 Response to Incidents/Emergencies

The EPR plan shall indicate personnel to be contacted, tools, instruments and equipment to be utilised and safety instructions to be followed. The EPR plan shall be updated/modified as and when required. The updated/modified EPR plan requires review/approval of AERB. The emergency plan shall be displayed at conspicuous location. Further, the equipment required for handling of incidents/accidents shall be well-maintained and placed at conspicuous locations.

The Licensee, on the advice of RSO and supplier or manufacturer, as applicable, of radiation sources/equipment, shall ensure response to incidents in such a manner that the exposures are kept minimum. The incident/accidents and the remedial actions taken shall be informed to AERB within 24 hours.

In the event of an accident involving source or release of radioactive material, the employer shall, (i) make every effort to mitigate the consequences, (ii) reimburse the

expense incurred by the experts, if assigned by the Competent Authority, to give advice or provide assistance in mitigating consequences of the accident and (iii) comply with the directions issued by AERB, which may be issued to ensure safety including the immediate closing/shutting down of the radiation installation.

7 PUBLIC SAFETY

7.1 General

Some of the radiation installations are located at places frequently visited by general public. Adequate protection of the public is ensured by in-built safety systems of the equipment, shielding of the enclosures, shielding of radiation sources and proper operational, administrative procedures and monitoring of radioactive waste discharges (if any).

7.2 Measures for Public Safety

The Licensee, in consultation with RSO, shall establish, implement and maintain procedures for protection and safety of the public. The following measures shall be ensured:-

7.2.1 Containment is established for the design and operation of a radioactive source that could prevent undue exposure/the spread of contamination in areas which are accessible to members of the public.

7.2.2 The radioactivity discharged in to the environment shall not cause radiation exposures to members of the public beyond the levels prescribed by AERB.

7.2.3 Appropriate radiation monitoring programme shall be implemented to ensure that public exposure due to sources is within the limits prescribed by AERB.

7.3 Protection of Fetus and Breastfed Infants

The fetus of a female radiation worker is considered as member of the public. Thus, the procedures shall be incorporated in such a manner as to ensure that the dose to the fetus shall not exceed the prescribed limits for member of the public.

A female worker shall, on becoming aware that she is pregnant, notify the employer, licensee and RSO in order that her working conditions may be modified, if necessary. It shall be ensured that the dose to the fetus because of the modification of working conditions shall be as per the prescribed limits.

For the breast feeding female radiation worker wherein unsealed radionuclides are handled, the working conditions shall ensure that the internal exposures shall not result

in exposures to the breast-fed infants beyond the dose limits prescribed for members of the public.

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Dates of Meetings: December 17, 2021, January 12, 2023 and January 7, 2025

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