

GUIDE NO. AERB/RF-RS/SG-2



GOVERNMENT OF INDIA

GUIDE NO. AERB/RF-RS/SG-2

AERB SAFETY GUIDE

RADIOISOTOPE HANDLING FACILITIES



ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY GUIDE NO. AERB/RF-RS/SG-2

RADIOISOTOPE HANDLING FACILITIES

**Atomic Energy Regulatory Board
Mumbai-400 094
India**

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Order for this 'Safety Guide' should be addressed to:

The Chief Administrative Officer
Atomic Energy Regulatory Board
Niyamak Bhavan
Anushaktinagar
Mumbai-400 094
India

FOREWORD

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

Safety codes and safety 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 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 AERB before they are published. The documents are revised as and when necessary in the light of experience and feedback from users as well as new developments in the field.

Type III radioactive facilities, such as facilities for commercial production of radioisotopes and radiopharmaceuticals for medical, industrial and research applications, handle radioisotopes/radioactive substances in all forms and in all stages starting from receipt of raw materials, production/processing, possession, interim storage, dispatch, transportation and finally management of the radioactive waste generated. This safety guide provides regulatory guidance with respect to radiological safety, waste management and transportation aspects relevant to siting, design, construction, operation and decommissioning of such facilities. For aspects not covered in this document, applicable national and international standards, codes and guides acceptable to AERB should be followed.

Consistent with the accepted practice 'shall' and 'should' are used in the safety guide to distinguish between a firm requirement and a desirable option, respectively. Annexures and bibliography are included to provide further information that might be helpful to the user. Approaches for implementation, different from those set out in the safety guide may be acceptable, if they provide comparable assurance against undue risk to the health and safety of the occupational workers and the general public and protection of the environment against ionizing radiations.

This safety guide has been prepared by a specialist in the subject drawn from BARC, Mumbai. It has been reviewed by the Safety Committee for BRIT Facilities, Standing Committee for Review and Revision of AERB's Radiation Safety Documents and Advisory Committee on Radiological Safety.

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



(S. S. Bajaj)
Chairman, AERB

DEFINITIONS

ALARA

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

Accident

Any unintended event, including operating errors, equipment failures or other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

Annual Limit on Intake (ALI)

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

Applicant

Any person who applies to the competent authority for obtaining consent to undertake any of the actions for which the consent is required.

Attenuation

The reduction in intensity of radiation passing through matter, due to processes like absorption and scattering.

Atomic Energy Regulatory Board (AERB)

A national authority designated by the Government of India having the legal authority for issuing regulatory consent for various activities related to nuclear and radiation and to perform safety and regulatory functions, including their enforcement for the protection of site personnel, the public and the environment, against undue radiation hazards.

Authorised Limits

Limits established or accepted by the regulatory body.

Bio-assay

The determination of the kind, quantity, location, and/or retention of radionuclides in the body by in-vitro analysis of material excreted or removed from the body.

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/the human body or other places, in excess of quantities, specified by the competent authority.

Containment/Confinement

Barrier, which surrounds the main parts of a nuclear facility, carrying radioactive materials and designed to prevent or to mitigate uncontrolled release of radioactivity into the environment during commissioning, operational states, design basis accidents or in decommissioning phase.

Consent

A written permission issued to the 'consentee' by the regulatory body to perform specified activities related to nuclear and radiation facilities. The types of consents are 'licence', 'authorisation', 'registration' and 'approval', and will apply according to the category of the facility, the particular activity and radiation source involved.

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

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

Cyclotron

A device in which charged particles (other than electrons) travel in a succession of semicircular orbits of increasing radii, under the influence of a constant magnetic field and are accelerated by traversing a number of times, in an electric field, produced by a high frequency generator.

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.

Decontamination

The removal or reduction of contamination by physical or chemical means.

Defence-in-Depth

Provision of having multiple levels of protection for ensuring safety of workers, the public or the environment.

Derived Air Concentration (DAC)

That activity concentration of the radionuclide in air (Bq/m^3) which, if breathed by reference man for a working year of 2000 h, under conditions of light physical activity (breathing rate of $1.2 \text{ m}^3/\text{h}$), would result in an inhalation of one ALI. Alternatively, it is the concentration, which for 2000 h of air immersion, would lead to irradiation of any organ or tissue to the appropriate annual dose limit.

Design

The process and results of developing the concept, detailed plans, supporting calculations and specifications for a nuclear or radiation facility.

Discharge (Radioactive)

Planned and controlled release of (gaseous or liquid) radioactive material into the environment.

Disposal (Radioactive Waste)

The emplacement of waste in a repository without the intention of retrieval or the approved direct discharge of waste into the environment with subsequent dispersion.

Dose

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

Dose Limit

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

Effluent

Any waste discharged into the environment from a facility, either in the form of liquid or gas.

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.

Emergency Plan

A set of procedures to be implemented in the event of an accident.

Exclusion

The deliberate exclusion of a particular category of exposure from the scope of an instrument of regulatory control.

Exemption

The deliberate omission of a practice, or specified sources within a practice, from regulatory control or from some aspects of regulatory control, by the regulatory body on the grounds that the exposures which the practice or sources cause or have the potential to cause are sufficiently low so as to be of no regulatory concern.

Existing Exposure Situation

Exposure situations that already exist when a decision on control has to be taken, typically, such situations as those caused by high natural background radiation.

Exposure

The act or condition of being subjected to radiation. Exposure may 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; 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.

Half Value Thickness (HVT)

Thickness of the shielding material required to bring down the radiation intensity by half of the initial value.

Intake

The process of taking radionuclide into the body by inhalation or ingestion, or through the skin, and the amount of given radionuclide taken in during a given period.

Medical Exposure

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

Member of the Public

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

Monitoring

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

Occupational Exposure

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

Operation

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

Optimisation of Protection

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

Packaging

The assembly of components which are necessary to enclose the radioactive contents completely. It may, in particular, consist of one or more receptacles, absorbent materials, spacing structures, radiation shielding, service equipment for filling, emptying, venting and pressure relief devices for cooling, absorbing mechanical shocks, providing handling and tie-down capability, thermal insulation; and service devices integral to the package. The packaging may be a box, a drum, or similar receptacle, or a freight container, tank or an intermediate bulk container.

Personal Protective Equipment (PPE)

Refers to protective gears such as lab-coat, safety shoes, shoe-cover, goggles, respirators, gloves, helmets, etc. which are used by radiation workers to protect themselves from hazard or injury.

Planned Exposure Situation

Exposure situations involving planned operations of radiation sources, including decommissioning, disposal radioactive waste rehabilitation of previously occupied land.

Potential Exposure

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

Public Exposure

Exposure incurred by members of the public from radiation sources, excluding any occupational or medical exposure and the normal local natural background radiation, but, including exposure from authorised sources and practices and from intervention situations.

Quality Assurance (QA)

Planned and systematic actions necessary to provide the confidence that an item or service will satisfy given requirements for the quality.

Radioactive Material

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

Radionuclide

An isotope of an element that possesses properties of spontaneous random disintegration (radioactivity) usually accompanied with emission of radiation.

Radioactive Waste

Any material, whatever its physical form, left over from practices or interventions for which no further use is foreseen: (a) that contains or is contaminated with radioactive substances and has an activity or activity concentration higher than the level for clearance from regulatory requirements, and (b) exposure to which is not excluded from regulatory control.

Radiopharmaceutical

Radioactive preparations of constant composition and adequate stability employed in medical diagnosis or therapy, making use of the nuclear decay characteristic of the constituent radionuclide. The design of these compounds is based solely upon physiological characteristics and functioning of the target organ. The radiolabeled preparation has known in vivo distribution pattern and its rate and mode of clearance is determined by both the biological and effective half-lives of the radionuclide.

Radiotoxicity

A radioactive substance emits radiation and the radiation is harmful to the body. The extent of the adverse effect viz. the radiotoxicity can be quantified by the magnitude of the effective dose coefficients.

Radionuclide Generator

A system containing a long lived parent radionuclide in equilibrium with its short-lived daughter radionuclide; and from which the daughter radionuclide is separated for use, particularly for medical applications.

Radiological Safety Officer (RSO)

Any person who is so designated by the employer and who, in the opinion of the Competent Authority, is qualified to discharge the functions outlined in the radiation protection rules.

Records

Documents which furnish objective evidence of the quality of items and activities affecting quality. It also includes logging of events and other measurements.

Reference Level

Action level, intervention level, investigation level or recording level established for any of the quantities determined in the practice of radiation protection.

Sealed Source

Radioactive source material that is either permanently sealed in a capsule or is closely bounded and in solid form. The capsule or material of a sealed source shall be strong enough to maintain leak tightness under conditions of wear and tear while in use for the intended application as well as under foreseeable mishaps.

Security Survey

A detailed evaluation pertaining to security of facilities involving nuclear material or radioactive substances, towards prevention, detection and providing response to theft, sabotage, unauthorised access, illegal transfer or other malicious acts.

Site

The area containing the facility defined by a boundary and under effective control of the facility management.

Site Evaluation Report (SER)

A document indicating the impact of a nuclear/radiation facility on the environment and the impact of the environment on the same so as to establish the suitability of the site for safe operation of the facility.

Siting

The process of selecting a suitable site for a facility including appropriate assessment and definition of the related design basis.

Shielding

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

Source

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

Surveillance

All planned activities, viz. monitoring, verifying, checking including in-service inspection, functional testing, calibration and performance testing, carried out in order to ensure compliance with specifications established in a facility.

Transport

International or domestic carriage of radioactive material by any means of transportation; beginning with the departure from the consignor's facility and ending with the arrival at the consignee's facility.

Tenth Value Thickness (TVT)

Thickness of the shielding material required to reduce the intensity of radiation to one-tenth of the initial value.

Radiation Worker

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

Zoning

Classification of radioactive areas within a radioactive facility, based on the nature of operations carried out in the area and the potential for the spread of radioactive contamination from the area.

SPECIAL DEFINITIONS

(Specific for the present ‘Safety Guide’)

Enclosures

Enclosures are containment to prevent the spread of radioactive contamination, protecting the operators from external radiation exposure and, if required, providing a controlled atmosphere for processing and/or taking care of the safety aspects.

Fume Hood

Fumehood is a partial enclosure in a radioactive laboratory used when contamination and external hazards are not significant. An opening of the front panel provides an access for the handling of the material. Laboratory air is exhausted through the opening to provide the required number of air changes.

Hot Cell

Hot cell is a shielded and ventilated enclosure which is kept under negative pressure (inside) and is equipped with remote handling tongs or master-slave manipulators to handle large amount of radioactive materials, emitting high intensity radiation.

Glove Box

A glove box is a leak-tight total enclosure with a negative pressure inside. The box has transparent walls/windows and fitted with flexible and good quality gloves for hand-entry and required handling.

Off-gas (Exhaust) Treatment Systems

Exhaust air from reaction vessels, precipitation tanks, enclosures in radioactive laboratories, containing radioactive aerosols, volatile chemicals, acid fumes, etc. is termed as off-gas. This needs to be treated to meet the regulatory requirement for discharge to the environment. The systems such as air filters, bubblers, condensers, scrubbers, etc. are used for treating the off-gas and are referred as off-gas treatment systems.

Radiochemical Purity

The fraction of the total radioactivity in the desired chemical form.

Radionuclide Purity

The fraction of the total radioactivity in the form of the stated radionuclide.

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1. INTRODUCTION

1.1 General

Facilities for handling of radioisotopes should be designed and operated with special care in view of the potential radiation hazards associated with the operations involving radioactivity. This guide elaborates various requirements with a view to ensuring the safety of the occupational workers and members of the public as well as the environment against such hazards, while setting up and operating such facilities. In India, control on handling radiation and radioisotopes is exercised as per the provisions of Atomic Energy Act, 1962 and the Atomic Energy (Radiation Protection) Rules, 2004, made thereunder. Atomic Energy Regulatory Board (AERB) lays down the safety standards and formulates appropriate rules and regulations towards ensuring safety associated with such activities.

1.2 Objective

The objective of this safety guide is to provide guidance for implementing radiation safety requirements in facilities handling radioisotopes in order to:

- (a) ensure that workers and members of the public are not exposed to radiation, in excess of limits, specified by the competent authority, under the Atomic Energy (Radiation Protection) Rules, 2004, and safety directives issued by the competent authority from time to time;
- (b) reduce such radiation exposures to levels as low as reasonably achievable (ALARA);
- (c) ensure safe handling, physical security of radioactive materials and management of radioactive wastes;
- (d) provide means for detecting/assessing of hazardous situations and initiating prompt remedial measures towards mitigating consequences; and
- (e) ensure accounting and recording of use of radioactive materials.

1.3 Scope

This document provides the regulatory guidance for a typical Type III radioactive facility, meant for handling of radioisotopes/radioactive substances in all forms, in all stages, starting from receipt of raw materials, production/processing, possession, interim storage, dispatch, transportation and management of the radioactive waste generated.

Such facilities are engaged in commercial scale production of radioisotopes and radiopharmaceuticals used for medical, industrial and research applications.

The safety guide is not applicable to radiation facilities or research facilities which are handling sealed radioactive sources for medical, industrial and research applications.

2. CONSENTING REQUIREMENTS FOR RADIOISOTOPE HANDLING FACILITY

2.1 General

Facilities for processing of reactor-irradiated targets and handling of radioisotopes are specially designed, constructed and operated to meet the objectives of occupational radiation protection, safety of the members of the public and the environment. Approval should be sought from the Competent Authority at the following stages:

- (a) Siting
- (b) Design and Construction
- (c) Commissioning and Operations
- (d) Decommissioning

2.2 Requirements for Siting

Any application for obtaining consent for setting up of a radioisotope handling facility should be submitted to AERB with comprehensive details of the proposed site. A site evaluation report (SER) should be prepared and submitted along with the application.

The SER will be reviewed by AERB before according clearance of the site for the setting up of the proposed facility. The land ownership document and necessary permissions for industrial use of the site from the local bodies should be submitted by the applicant alongwith the SER.

Some of the important aspects assessed by AERB with respect to the proposed site for the radioisotope handling facility are:

- (a) The location of the project - whether it is in an industrial area (and not in a residential premise, and not in premises shared with a public area)
- (b) Existing or proposed industrial and public facilities in the vicinity of the project and the evaluation of risk-factors from these to the proposed radioisotope facility and vice versa
- (c) Water table in the area and underground water movement to assess the potential hazard due to flooding of the facility
- (d) Flooding history of the site in last fifty years
- (e) Seismic history of the site for in last fifty years

- (f) Soil characteristics of the site (applicable only if there is the possibility of the formation of activation products, e.g. a cyclotron facility)

2.3 Requirements for Design and Construction

An application for obtaining approval of the design and construction of the facility should be accompanied by a preliminary safety analysis report (PSAR). The PSAR should give details of the site, design features of the facility and describe the operations proposed to be carried out in the new facility. The PSAR should identify the potential hazards to the proposed facility, describe and analyze the adequacy of the measures to be taken in order to eliminate, control or mitigate the identified hazards. The report should analyze and evaluate potential accidental situations and their associated risks. It should set forth the radiological protection design aspects of the facility and the envisaged radiation protection programme for the protection of occupational workers, public and the environment.

PSAR should have typically the following sections:

- (a) Summary
- (b) Site - description and assessment
- (c) Design criteria for the facility
- (d) Description of operations
- (e) Safety analysis
- (f) Quality assurance programme
- (g) Health, safety & environment management programme
- (h) Waste management programme
- (i) Environmental monitoring programme
- (j) Radiological emergency preparedness
- (k) Security plan for the facility
- (l) Decommissioning

Details to be furnished in each of the above sections are as follows:

- (a) Summary

This section should contain a brief summary of the objective, operations and potential benefits of the facility.

(b) Site Description and Assessment

This section should provide information on:

- (i) The location of the facility with a sitemap
- (ii) Demographical details
- (iii) Details about the water sources in the vicinity
- (iv) Seismicity of the site, if the proposed facility is to handle large quantities of radioactivity
- (v) Data on frequency, intensity, and cause for flooding in the past 50 years.
- (vi) Site drainage facilities and analyses.

(c) Design Criteria for the facility

This section should include the following:

- (i) Purpose of the facility
- (ii) Raw materials and products
- (iii) Site plan
- (iv) Building plan and structural details
- (v) Layouts of rooms, elevation drawings
- (vi) Instrumentation to ensure safety in the related processes
- (vii) Description of service and utility systems
- (viii) Criteria for the design of the ventilation and off-gas systems
- (ix) Radioactive waste handling systems
- (x) Other safety related systems viz. industrial, fire and chemical safety.

(d) Description of Operations

This section should focus on potential hazards that could result from processes/operations such as:

- (i) Description of operation of facility and process/operations to be conducted in the facility
- (ii) Typical and maximum quantities and forms of radioactive materials, utilised, or stored in the facility

- (iii) Summary of chemical and mechanical processes and control/support systems
 - (iv) Availability of written procedures for the receipt, storage, handling, and transfer of radioactive materials
 - (v) Availability of checklist for assessing integrity of the processing equipment
 - (vi) Methods for maintaining safe control during normal and abnormal situations or conditions
 - (vii) Operational reliability and maintenance
 - (viii) Provisions to ensure continued safe-operations or safe-shutdown under accident or abnormal conditions.
- (e) Safety Analysis
- This section should contain an analysis of credible accidents of a serious nature that could result from failure of operational safety systems and/or from natural phenomena. Accidents should be assessed for the radiological impact on the workers, general public and environment.
- (f) Quality Assurance Programme
- This section should include details such as:
- (i) Specifications and procurement documents
 - (ii) Inspection, surveillance, and testing
 - (iii) Radiometry of hot-cells and other shielded facilities
 - (iv) Quality assurance (QA) records
 - (v) QA audits
- (g) Health, Safety and Environment Management Programme
- This section should include details of:
- (i) Health and safety organization
 - (ii) Radiation protection programme
 - (iii) Industrial hygiene and safety
 - (iv) Fire protection and control
 - (v) Environmental safety programme

(h) Waste Management Programme

This section should include a description of the waste management program.

- (i) Waste management criteria
- (ii) Characteristics, concentration and volumes of radioactive wastes
- (iii) Radioactive gaseous waste treatment, if any
- (iv) Liquid waste management
- (v) Solid waste management

(i) Environmental Monitoring Program

This section should describe various components of environmental monitoring programme to measure radiation/radioactivity levels:

- (i) Perimeter monitoring
- (ii) Liquid and gaseous effluent monitoring schemes
- (iii) Environmental soil monitoring
- (iv) Environmental water monitoring

(j) Radiological Emergency Preparedness and Response Plan

This section should discuss the provisions made for handling radiological emergencies. Topics discussed should include:

- (i) Potential emergency scenarios
- (ii) Emergency-response plans and resources
- (iii) Radiation emergency exercise

(k) Security Plan for the facility

This section should have a description of the physical security plans for the facility. Security of the radiation sources and radioactive materials is to prevent unauthorised access, damage to, loss of, theft or unauthorised transfer of radioactive sources. Depending upon the vulnerability of the sources, specific security plan should be in place implemented. The security plan should include:

- (i) Appropriate designing of the facility in order to minimise the feasibility of malicious actions and to maximise the security considerations

- (ii) Prevention of unauthorised access
 - (iii) Surveillance and alarm system
 - (iv) Accounting and periodic inventory
 - (v) Minimisation of consequences of any malevolent use of source
 - (vi) Reporting to AERB.
- (l) Decommissioning

This section should provide the decommissioning plan for the facility under the circumstances such as the useful life of the facility being over, or the licensee and the AERB decide to decommission the facility. The plan should ensure that there are no radiological hazards present in the site after decommissioning. Some of the requirements are:

- (i) Radiological characterisation and activity assessment before decommissioning
- (ii) Availability of technical expertise for decommissioning
- (iii) Details with respect to the provision and availability of appropriate gadgets/equipment
- (iv) Resources-technical and financial
- (v) Radiological survey
- (vi) Waste management plan
- (vii) Reporting to the regulatory body
- (viii) Record keeping

2.4 Requirements for Operation

While seeking license for operation of the facility, the following documents should be submitted:

- (a) Final Safety Analysis Report (FSAR)
The FSAR should reflect the facility as built and include the results obtained during pre-commissioning tests
- (b) Standard operating procedures (SOP)
- (c) Technical specifications

- (d) Radiation protection manual
- (e) Emergency operating procedures (EOP)
- (f) Radiation emergency preparedness and response plans
- (g) Qualified/certified manpower including Radiological Safety Officer (RSO)
- (h) A report on the pre-operational testing and operating startup plans which should demonstrate that the facility, equipment and processes meet safety and design intent as described in the PSAR. Test results should be presented to verify the integrity of the facility, equipment, and process and to substantiate the safety analysis. Results obtained from carrying out the plans should be reported as an appendix to the completed application.

3. DESIGN AND OPERATIONAL CONSIDERATIONS

3.1 General

The facilities to handle significant quantities of radioisotopes should be designed so as to ensure that the radioactivity is totally contained and the operations are conducted safely. The design considerations should ensure radiological safety of the occupational workers, members of the public and the environment.

3.2 Type III Laboratories

The design safety features of a radioactive facility will depend both on the inventory and radiotoxicity of the radionuclides handled. Radioisotope facilities are classified into three categories, Type I, Type II and Type III, depending on the quantity of different radioisotopes that can be handled in such facilities. Type III facilities where radioisotopes are handled in commercial scale should have higher design safety features as compared to other types of facilities. Annexure-A gives the design safety features of a Type III facility.

The radioisotopes are classified into four Groups, 1 to 4, in the order of very high, high, moderate and low-radiotoxicity hazard, based on the relative radiotoxicity per unit activity of the radionuclide. The classification is based on the most restrictive (inhalation/ingestion) ALI (Annual Limit on Intake) values (ICRP-61, 1991) and specific activity of the radionuclides. Radionuclides which are highly toxic and with very low ALI-inhalation values are in hazard Group 1, whereas radionuclides with low toxicity, low specific activity materials such as natural uranium ore and thorium minerals are placed in Group 4.

Some of the radionuclides of interest are classified as follows:

Very high hazard (Group 1)	: ^{210}Pb , ^{210}Po , ^{226}Ra , ^{90}Sr ,
High hazard (Group 2)	: ^{125}I , ^{131}I , ^{99}Mo , ^{32}P , ^{212}Pb , ^{192}Ir , ^{60}Co , ^{89}Sr , ^{90}Y
Moderate hazard (Group 3)	: ^{82}Br , ^{14}C , ^{51}Cr , ^{18}F , ^3H , ^{24}Na , ^{32}S , ^{153}Sm , $^{99\text{m}}\text{Tc}$ ^{103}Pd
Low hazard (Group 4)	: ^{99}Tc , nat U, nat Th

Typical quantities of radionuclides that should be handled in the Type III laboratory for various groups of radionuclides are given in Annexure-B.

Depending upon the nature of operations and the associated hazard potential, modifying factors should be applied to arrive at the maximum amount of activity that can be handled in the laboratories. These modifying factors are also given in the Annexure-B. Most of the radionuclides of interest in medical and industrial applications belong to medium toxicity (Group 2 and Group 3).

3.3 Zoning of Areas

The working areas in a radioisotope facility are segregated, based on the potential for external exposure and for spread of radioactive contamination. The areas are classified as “white”, “green”, “amber” and “red” areas or zones.

TABLE 1 : TYPICAL CLASSIFICATION OF LABORATORY AREAS

Zone	Access Control	Typical Examples and Requirements
White	Unrestricted. General background level is prevailing	Office rooms, where there is no radioactive source and no radioactive contamination.
Green	Access generally permitted only to radiation workers. Change of clothing not necessary. Radiation level: < 1μSv/h; Airborne activity: <0.1 DAC; and Area contamination: <0.1 DWL. (Derived working level)	Health physicists’ room, control room, counting room, packing room etc. Being adjacent to radioactive areas, potential for radioactive contamination exists. Very low-active electroplated sources or sealed test sources (up to a few MBq) stored in appropriately shielded containers, are only allowed to be handled here.
Amber	Controlled areas, Access limited to radiation workers, entry with proper protective clothing through (shoe cover, lab coat/overall, cap if required for the process) the barrier. Airborne activity: <1 DAC; Area contamination: < 1 DWL	Laboratory areas where radioisotopes are handled. Radiation and contamination monitoring required. Certain level of surface contamination only is allowed. A ventilation system (once-through) having supply and exhaust through HEPA filters should be in place. The air activity should be continuously monitored and it should be below derived air concentration (DAC) levels. TLD dosimeter should be worn at all times. Other dosimeters such as pocket dosimeter should be issued for special operations or jobs involving high radioactivity.
Red	Access to this area is not envisaged during normal operation of the facility. Access is only through special work permit (SWP), with special protective clothing and respiratory protection, as specified by RSO.	Areas inside enclosures such as fume hoods, glove boxes, shielded boxes and hot cells where open radioactive sources/materials are handled. External radiation dose levels, air activity levels and surface contamination levels can be expected to be high in the red zones.

3.3.1 *Zoning Requirements*

- (a) The various zones should be clearly demarcated and identifiable. TLD badges should be stored and issued in white zone, before the barrier.
- (b) A physical barrier and shoe-covers should be provided at the barrier of green to amber zones. Fresh and used shoe covers should be kept separately.
- (c) Additional localized barrier should be erected as and when necessary to control spread of contamination, particularly during maintenance work.
- (d) A change room and decontamination room should be provided at the entry point to amber zones. Appropriate display boards should be provided to indicate the requirements for the change of clothing or use of shoe covers.
- (e) Hand, foot and clothe monitoring equipment should be made available at exit point of the facility.
- (f) Shower facility as well as decontaminating agents should be provided for decontamination of the personnel, if necessary.

3.4 **Enclosures**

Enclosures are the most effective means for restricting spread of radioactivity into work and general areas. For operations involving open sources/ radioactive materials, suitable enclosures should be provided in the laboratories by way of dry boxes, fume hoods, glove boxes, shielded boxes or hot cells/mini hot cells (Annexure-C). These enclosures are physical barriers that together with ventilation and operating systems prevent leakage/release of radioactive materials into the workplace and to the environment. The operations in shielded cells and mini-hot cells/hot cells should be conducted using appropriate remote handling equipment such as tongs or mini-manipulators/master-slave manipulators or special gadgets of appropriate size for remote and safe handling of the radioactive materials.

3.5 **Shielding**

Radiation sources should be stored, processed and packed in designated areas with adequate shielding to meet the requirements of the regulatory body. Factors considered in the design should include the build-up in the shielding material, allowances for voids and streaming, structural integrity of the shield-wall etc. Shielding requirements should meet the regulatory limit of $< 1 \mu\text{Sv/h}$ in fully occupied areas.

3.6 Ventilation

Ventilation system should provide a supportive role to the physical containment systems by ensuring an adequate and directional air supply to maintain the required air changes in various work areas and air-flow rate across the fume hood openings.

The design of an appropriate ventilation system requires preliminary safety analyses, taking into account:

- (a) Radiological hazards arising from the radioactive materials and nature of operations, levels of activity, classification of areas, acceptable levels of contamination, etc.
- (b) Effects on ventilation from possible natural and man-made events
- (c) Authorized discharge limits.

The ventilation design should be such that the air concentration in full occupancy areas should not exceed 1/10th of DAC values.

The ventilation system, normally once-through type, should be so designed as to direct the air-flow from white zones to green zones, green to amber zone and finally exhausted out through red zone via a chimney which is taller than buildings nearby to ensure efficient dispersion of the releases. In white zones, re-circulatory ventilation system should also be installed.

Sufficient inter-zone pressure differential is maintained to prevent back-flow of air from higher radioactive zones to lower radioactive zones. The total exhaust is generally designed to be about 10% higher than the supply air to maintain the inter-zone pressure differential. Stand-by blower/fan should be provided to ensure continued safe operations or for safe shut-down during malfunctioning of the equipment. Table 2 gives the typical pressure gradients maintained across different zones in a radioisotope laboratory. Table 3 gives the typical number of air changes maintained in different zones of radioisotope laboratory.

TABLE 2 : PRESSURE DIFFERENTIAL IN INTER-ZONE AREAS

Inter-zone	Pressure Differential in mm of Water Column (W.C.)
White to Green	2 (19 Pascal)
Green to Amber	5 to 10 (49 to 98 Pascal)
Amber to Red	15 to 45 (147 to 441 Pascal)

TABLE 3 : NUMBER OF AIR CHANGES IN DIFFERENT ZONES

Type of Zone	Number of Air Changes/h
White	4
Green	6 to 8
Amber	8 to 15
Red	20 to 25

Separate exhaust ventilation system should be designed for general lab ventilation and for off-gases from the enclosures (fume hoods, glove box, and shielded boxes), for filtration of any airborne radioactive particles. The exhaust system should provide the necessary negative pressure inside enclosures with respect to operating area. Over-pressurisation of enclosures should be prevented by providing pressure-relief valves. Exhaust air from glove boxes and shielded boxes, after filtration through HEPA or charcoal filters (for radioiodine) join the duct carrying general lab ventilation, and gets filtered again through HEPA filters before being released to the environment. Releases to the environment should be within the limits prescribed by the regulatory body.

The design of equipment for air cleaning systems such as absorber columns, scrubbers, etc. will be different depending upon type, concentration and chemical nature of airborne radioactive contaminants generated in the enclosures. Design provisions should be kept to clean-up the exhaust air during anticipated operational occurrences and also consequent to accidental situations.

The air cleaning equipment may be activated charcoal absorber, water/alkaline scrubber, condenser, high efficiency particulate air filters, etc. The exhaust air cleaning system should be designed such to facilitate maintenance and replacement of components resulting in least exposures to the personnel and also to control the spread of contamination is possible. Collection of discharge gases from hot cells into containers and allowing it to decay prior to discharge is followed in the case of short-lived isotopes produced in cyclotron facilities.

The materials used for construction of the ventilation systems, including air cleaning systems/filters should be corrosion resistant (for nitric acid, NO_x fumes, etc.) and should adequately be fire resistant, and the system should be able to confine small fires or explosions. Heat/fire detection devices and alarm systems should be provided to alert the control room personnel in such situations. The system should be able to withstand earthquakes or floods of

stipulated levels, specific for the facility/site. Different enclosures for handling radioisotopes, such as fume hoods, glove boxes and hot cells are given in Annexure-C.

3.7 Emergency Power Supply

The facility should be provided with emergency power supply with diesel generators of adequate capacity, in order to cater to the power needs of critical equipment, in case of failure of the mains supply. All the exhaust systems from radioactive enclosures, safety-related radiation monitoring system and fire detection system should be provided with emergency power supply.

3.8 Automation/Mechanisation

Design provisions should be available to handle the sources, including chemical processing of radioactive materials, so as to prevent individual exposures of workers from exceeding the stipulated limits.

Depending on the type of process/operations, suitably and specially designed remote handling systems should be fitted into the shielded boxes and hot cells. Reliable and well-tested equipment should be installed inside the shielded enclosures such that their maintenance requirements will be low. For critical equipment, there should be stand-by arrangements for operational convenience and have minimal intervention of maintenance personnel so as to prevent radiation exposure. Automation should be resorted to wherever repetitive operations involving radioactive materials are envisaged.

3.9 Security of Radiation Sources

Radiation sources should be kept secure so as to prevent theft or damage. Loss of control of radiation sources and malevolent events can lead to potential exposure situations. The basic principles applicable to the security of radiation sources in order to prevent theft or damage are given in the Code of Conduct on the Safety and Security of Radiation Sources (IAEA, 2004) and AERB Safety Guide titled 'Security of Radioactive Sources in Radiation Facilities', (AERB/RF-RS/SG-1).

3.10 Access Control

Access to the facilities should be controlled by the appropriate requirements such as:

- (a) Access to only authorised persons to the facility and to the radioactive areas
- (b) Appropriate interlocks for the access
- (c) Physical barriers at the entry to the radioactive areas

- (d) Proper administrative controls such as mandatory use of biometric verification, intrusion alarms, permits, etc.

3.11 Manpower Qualification and Training

Handling of radioactivity should be carried out only by adequately qualified and appropriately trained personnel. The facility should designate one of its staff members with qualifications as stipulated by AERB as Radiological Safety Officer (RSO), and the same personnel should be approved as RSO by the Competent Authority. The radiation workers should be made familiar with the radiological safety aspects of the facility including the use of personnel monitoring and protection devices. Periodic refresher courses should be planned for personnel handling radioactivity. Depending upon the process requirement and type of the facility, adequate number of trained man power should be available for the operation of the facility.

3.12 Transport of Radioisotopes

The radioactive material, depending upon the type, radiations emitted and the quantity, should be appropriately shielded, packed and labeled to meet the regulatory requirements for storage and transportation, in terms of proper authorisation, documentation, radiation leakage rates from the package, and security of the source. The surface of the package should be free of any radioactive contamination.

The areas used for the preparation of packages, interim storage of the packages and for dispatch, should be identified accordingly with caution boards. Adequate shielding should be provided for the storage area. The area should have an area gamma monitor, should be under regular surveillance by the RSO. In-house movement of the radioactive sources/samples should be recorded and the source movement should be always accompanied with the radioactive material transit tags giving the source details.

Transfer of sources from one authorised user to the other authorised user should be carried out only after completing all the necessary regulatory requirements, including the required authorisation to receive the source. The potential recipient of radioisotope should be made aware of the regulatory requirements and should be responsible for the safety and accountability of the source.

In cases of transfer of sources to any other agency, the sources should be properly shielded, packed, monitored and tagged. The source package should be accompanied with appropriate documentation and necessary clearance from the regulatory body for transportation. Prior acceptance from the agency which receives the package should be obtained before the dispatch of the package.

Safety of the package during transport should be ensured as per the transport regulations. Transport of all radioactive packages should be as per the AERB Safety Code on 'Transportation of Radioactive Materials', AERB/NRF-TS/SC-1 (Rev-1) under preparation.

3.13 Industrial, Fire and Chemical Safety

The design of the radioisotope laboratory should take into account requirements of industrial safety as per the national standards in order to ensure the health and welfare of the occupational workers. All chemicals and hazardous materials should be stored and used as per the standard guidelines. Fire safety should be ensured in the facility-design in particular with respect to the ventilation system. The safety aspects considered should include fire prevention, detection and mitigation systems.

4. RADIOLOGICAL SAFETY CRITERIA

4.1 General

During the handling of radioisotopes in a facility, exposure to radiation can occur to the occupational workers as well as to the members of the public. An appropriate radiation protection and safety programme should be established for control of both occupational exposure as well as public exposure.

4.2 Safety Provisions and Practices

The basic principles of protection and safety to be considered in the design of radioisotope facilities are:

- (a) All sources of radiation should be contained and shielded.
- (b) The radiation level in normal, full-occupancy areas shall not exceed $1\mu\text{Sv/h}$.
- (c) The ventilation design should be such that the air concentration in full occupancy areas should not exceed $1/10^{\text{th}}$ derived air concentration (DAC) values.
- (d) Systems and components should be designed, constructed, operated and maintained so as to prevent accidents as far as possible.
- (e) Provisions should be made for reducing, as far as practicable, the contribution of human error resulting in accidents and other events that could give rise to radiation exposures.
- (f) Provision for radiation monitoring should be available where conditions for normal and potential exposure exist.
- (g) The layout of the controlled areas should be such that there is a single entry and exit point at the controlled areas with proper barriers and interlocks.
- (h) Operational safety and radiation protection should be ensured by good engineering and sound management, quality assurance, trained and qualified personnel and comprehensive safety assessments.

4.3 Radiation Exposure Control

The normal exposures of individuals shall be restricted below the limits prescribed by AERB (AERB Directive No. 01/2011 provided as Annexure D). Further, all efforts should be made by the facility to keep the exposures as low as reasonably achievable (ALARA).

4.4 Radiological Safety Officer (RSO)

A person having appropriate training, qualifications and experience as prescribed by AERB should be designated as RSO by the employer with the written approval of the Competent Authority. The Responsibilities of the RSO are specified in Rule 22 of Atomic Energy (Radiation Protection) Rules, 2004.

4.5 Monitoring - Individual and Workplace

Operational radiation protection monitoring practice is an important aspect of safety and is needed to ensure and demonstrate an appropriate level of protection to the radiation workers, the members of the public and the environment. The general objective is the assessment of individual exposures, both internal and external, and to assess radiological status of the work areas.

4.5.1 Individual Monitoring

The doses due to exposure from external sources should be assessed by systematic individual monitoring of the workers using TLD. The RSO should ensure that all radiation workers use the prescribed personal dosimetry device while working in the radiation area.

In situations where the dose rates vary considerably or during maintenance operations, an additional electronic direct reading dosimeter (pocket dosimeter) should be used. In other situations of handling radiation sources where the radiation levels are expected to be higher, wrist TLD badges should also be used to evaluate the dose to the extremities. Proper arrangement should be made for issuing, storing, timely returning of the dosimeters and measurement of the accrued doses.

Low level contamination monitors using GM counters should be installed at the zone barriers for monitoring of hand, foot or clothing of the personnel. Contamination, if detected, should be removed in consultation with the RSO.

Those radiation workers who have potential for internal contamination as assessed by the RSO should be sent for assessment of internal exposure.

4.5.2 Workplace Monitoring

Work place monitoring should be carried out:

- (a) Routinely, during normal operations
- (b) Whenever, there is a change in the nature and type of operations
- (c) Comprehensive monitoring during incidents/accidental situations.

4.5.3 Area Monitoring

Wall mounted area gamma monitors should be installed at carefully chosen

locations of the facility to record the radiation levels in the working areas. In addition, periodic surveys of the facility with hand held radiation survey meters of an appropriate type should be carried out by the RSO.

Air Monitoring : The amber areas of the facility should be checked for any contamination of the working environment by installation of continuous air monitors. In addition, whenever some special work is carried out or failure of the ventilation system occurs, spot air samples should be collected and analysed for checking the air activity levels.

Surface Contamination Monitoring : Presence of surface contamination may cause intake of the contaminant, either through inhalation or ingestion route. All the surfaces in the amber area should be routinely monitored by wipe tests to check the possible presence of loose contamination. The presence and identification of the radionuclide(s) in the wipe samples can be determined using appropriate radiation measuring instruments. A direct reading surface contamination monitor to measure the levels of surface contamination should also be employed. The contamination levels are then compared with the Derived Working Levels (DWL) for further action.

4.5.4 *Decontamination*

The contamination may involve personnel, clothing, equipment or working surfaces. The radioactive contamination may be fixed, loose or partly fixed. When the levels of contamination exceed the DWL values stipulated by the AERB, decontamination should be carried out in order to bring down the levels to the acceptable values. The decontamination room should be equipped with all the decontaminating agents and should have eye wash equipment and a shower facility.

4.6 **Health Physics Instruments (Portable and Installed)**

The isotope laboratory should be equipped with adequate number of appropriate health physics instruments, as an essential part of radiation protection programme. The instruments required for carrying out radiation protection surveys include the following:

- (a) Radiation survey instruments (GM survey-meter)
- (b) Pancake-type GM survey meter is recommended for monitoring low energy radionuclides such as ³⁵S.
- (c) Radiation monitoring and alarm systems: area gamma monitors, continuous air monitors, and neutron monitors (in medical cyclotron facilities)
- (d) Hand, foot and clothing monitor

- (e) Health physics counting room instruments such as beta and gamma activity measurement systems.
- (f) Stack monitoring system wherever applicable.

The instruments used for monitoring should be tested periodically using a test source before taking a measurement. The periodic calibration of radiation protection instruments should be carried out in an accredited calibration facility as specified by the regulatory body.

4.7 Maintenance of Records

Every facility should adopt an appropriate procedure for preparation, reporting and maintenance of the following records:

- (a) Radiation monitoring data in the work place
- (b) Individual dose records for radiation workers
- (c) Record of calibration of radiation protection instruments
- (d) Record of the monitoring of liquid, gaseous and solid waste monitoring
- (e) Records of transfer of liquid and solid waste and disposal of gaseous waste
- (f) Records of significant events
- (g) Actions taken in cases of non-compliance with regulations
- (h) Carrying out periodic exercises to evaluate emergency preparedness
- (i) Training and refresher programmes related to safety.

The suggested retention period for records of work-place monitoring, calibration of survey-related instrument is five years. The exposure records for each worker should be preserved during the worker's life and afterwards, at least, until the worker attains or would have attained the age of 75 years, and for not less than 30 years after the termination of the work involving occupational exposure.

4.8 Environmental Safety

Routine operations in most facilities generate low level gaseous and liquid effluents which should be managed safely. Appropriate sampling and monitoring programme should be established to fulfill the requirements of demonstrating compliance with the discharge levels authorized by AERB. All environmental releases from facilities are governed by the limits authorised by AERB as per the Atomic Energy (Safe Disposal of Radioactive Wastes)

Rules, 1987 and/or as stipulated in approved technical specifications for the facility.

4.8.1 *Monitoring of the Environmental Releases*

Off-gases, chemicals or some residual radioactivity (e.g. radioiodine) from various equipment and the ventilation exhaust from the facility should be routed after HEPA filtration to a chimney of appropriate height to ensure adequate dilution and dispersion. The environmental releases should be monitored for the radioactivity content to ensure that the discharges are within the limits prescribed by AERB.

5. EMERGENCY PREPAREDNESS

5.1 General

Emergency situations requiring urgent attention may arise during the operation of a facility. This may be either a consequence of an accident or a result of a malicious act. In such situations, protective actions are undertaken whenever, such actions are justified. Optimisation of the actions is required to be done in order to produce the maximum benefit.

5.2 Events

Event is an occurrence of an unplanned activity or deviation from the normal activity. It may either be a single or a sequence of occurrences which may lead to an incident/accident. Such occurrences should be reported to AERB without any delay.

5.3 Types of Emergency

Emergency situations can arise in a facility due to which the radioactivity in significant quantities can get released from the containment to working areas and the adjoining areas. Such situations are termed as Plant Emergency. The activity is locally contained without any releases outside the plant boundary. Immediate steps should be taken to bring the situation under control.

Typical examples of minor incidents that can occur in Radioisotope processing and handling facilities are:

- (a) Spillage of radioactive solutions/liquids
- (b) Severe personnel contaminations
- (c) Injuries while transferring radioactive solutions/liquids
- (d) Misplacement or loss of sources.

Any uncontrolled radiological situations in the facility, such as incidents of serious nature may cause radiation exposures to the plant personnel and the radioactivity can get released out of the site boundary into the environment which may result in public exposures.

Some of the more serious radiological emergency situations that can arise in radiation source/material handling are:

- (a) Deliberate dispersion of radioactive materials in public areas with malevolent intentions
- (b) Widespread contamination due to loss of sources

- (c) Release of radioactivity due to rupture of exhaust filters
- (d) Major spillage of radioactive liquids
- (e) Temporary loss of shielding for sources
- (f) Rupture of sealed sources
- (g) Fire in radioactive areas.

In addition to the above mentioned possible accidental scenarios in facilities (plant emergencies), accidents may also happen due to many reasons during transportation of sources, including loss/unauthorised removal of sources due to terrorism, etc. resulting emergency situations.

5.4 Emergency Preparedness Plans

Every radiation facility should have an emergency plan for responding in case of an emergency situation and to mitigate the consequences. Essential features of the plan depend on the radiological evaluation of the facility during normal and anticipated or foreseeable abnormal situations. A written emergency plan should be prepared in advance and it should define the role and responsibilities of various agencies and personnel in the management of the emergency.

The emergency preparedness plans should address inter alia the following:

- (a) A quick and reliable monitoring methodology for detection of an emergency situation
- (b) Availability of personnel and material for quick response (emergency response teams)
- (c) A good and reliable communication system
- (d) Prompt initiation of the countermeasures.

A list of officers/agencies (fire, security, RSO, etc.) to be contacted during emergency situations should be prominently displayed in strategic locations in the facility and also should be circulated among the workers.

The emergency exercises should be conducted at periodic intervals as specified by the regulatory authority so that all workers and the management are familiar with the actions to be taken in the event of an emergency. Any deviations observed during the exercise should be recorded and corrected.

6. QUALITY ASSURANCE

6.1 General

A Quality Assurance (QA) program should be established as part of the radiation protection program by the licensee/Officer-in-charge of the facility. The program should be commensurate with the magnitude and the likelihood of potential exposures from the radioactive sources/materials. Quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of radiation protection measures in the facility should be in force.

For the radioisotope handling laboratories, particularly the isotopes used for medical applications, QA should be part of Total Quality Management (TQM) Program of the organization, which helps in instilling an attitude for team work and each individual understands his role and responsibilities in the organisation. The QA program should cover all safety related structures, systems and components.

6.2 QA Program for the Facility

A general quality assurance program should be in place in radioisotope production or dispensing facility, starting with:

- (a) The design of the facility and handling equipment (shielding, ventilation, radiation monitoring etc.)
- (b) Wherever applicable, technical specification document should be prepared and approved by the appropriate authority for compliance during operations of the facility.
- (c) Specifications for raw materials
- (d) Specifications for materials of construction
- (e) Establishing radiation protection and surveillance programs
- (f) Setting standards for commissioning - technical specifications
- (g) Checking for shielding adequacy and integrity
- (h) Trained and adequate man power
- (i) Commissioning to ensure compliance with the design intent
- (j) Standard operating procedures (SOP)
- (k) Acceptance criteria for products

- (l) Documentation at each stage
- (m) Incident/event reporting and investigation
- (n) Review, approval, issue, distribution and revision as appropriate
- (o) Communication/dissemination of information
- (p) Maintenance of records to meet regulatory requirements.

6.3 QA for Radiation Protection Instruments

The radiation protection instruments are very important part of the Radiation Protection Program for any facility. The monitoring and activity measurement instruments/systems should be procured from qualified vendors to meet the established criteria and perform as expected to meet the requirements of accuracy and precision.

Calibration of the instruments should be done at specified time period, against standard sources of appropriate strength (in terms of energy) of radionuclide. The calibration facility used should be accredited by the regulatory body.

6.4 QA for Packaging/Packages

QA of various components of packaging should meet the requirement specified for the given type, physical/chemical form, quantity and mode of transportation of the radioactive material. Packaging is the assembly of various components required to enclose and contain the radioactive material contents. These include:

- (a) Adequate shielding
- (b) Absorbent materials to absorb and contain the radioactive liquid within the package
- (c) Shock absorbing material around the shielded container
- (d) Handling provisions, if required.

Packages should meet the labelling requirements as specified for the radioactive material for safe transportation of different types of radioactive materials.

6.5 Radiopharmaceuticals

Radiopharmaceuticals should be protected from microbiological contamination by their environment. The quality assurance program should be as per the requirement of Indian Pharmacopoeia 2014. The facility should meet appropriate aseptic production conditions such as measuring the number of particles in air, microbiological contamination, integrity of HEPA filters,

determination of fungal contamination and pyrogenic concentration in the product, etc.

Radionuclide purity and radiochemical concentration should be determined using well-established quality control techniques using calibrated counting systems and spectrometry systems such as alpha or gamma spectrometry, with the required accuracy.

Quality assurance of the devices and equipment used in the radioisotope handling facilities should be well-tested and of standard design and approved quality.

7. DECOMMISSIONING OF FACILITIES

7.1 General

Design of any facility should consider and provide guidelines for the decommissioning of the facility. Following the completion of useful life of the facility, there may be requirement for decommissioning. AERB approved plan for decommissioning should be available at the time of commissioning of the facility. Plan should address the resources for the decommissioning.

7.2 Safety Assessment

The safety assessment during the decommissioning of radioisotope handling facility should address the following areas:

- (a) Procedures for management hot-spots due to scale formation or deposition of radioactive materials at some joints/bends/locations due to settling down/plate-out of activity
- (b) Requirement of remote handling mechanisms for heavily contaminated items
- (c) Waste disposal strategies for large quantities of radioactive wastes of different kind and characteristics, generated during decommissioning
- (d) Non-radiological hazards of the decommissioning should also be identified and action plan should be made available.

7.3 Decommissioning Operation

Decommissioning activities should be controlled through the use of documented procedures. These procedures should be reviewed and approved by appropriate agency responsible for ensuring safety. The execution of decommissioning activities should start only after approval by the Competent Authority.

At the end of the decommissioning activities, the facility or the authorized agency should demonstrate the stated end-state conditions to the regulatory body, and the final decommissioning report should be submitted to the regulatory body for review. The guidance for decommissioning aspects of medical, industrial and research facilities is provided in the AERB Safety Guide titled 'Management of Spent Radioactive Sources and Radioactive Waste arising from the Use of Radionuclides in Medicine, Industry and Research, including Decommissioning of Such Facilities', (AERB/RF/SG/RW-6).

8. RADIOACTIVE WASTE MANAGEMENT

8.1 General

Radioactive waste is generated during the production of radioactive sources and products and other radiological operations. Such radioactive waste may be in form of liquid, solid or gas. Appropriate strategy should be in place to manage these wastes in order to ensure that the radiation exposures to workers and members of the public are kept within the regulatory limits.

8.2 Radioactive Waste Handling Procedures

Radioactive wastes generated in the facilities during operation and maintenance of facilities handling radioactive sources/materials, should be managed as per the requirement of the Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987 and AERB Safety Guide titled 'Management of Spent Radioactive Sources and Radioactive Waste arising from the Use of Radionuclides in Medicine, Industry and Research, including Decommissioning of Such Facilities', (AERB/RF/SG/RW-6). This should be ensured by adhering to the stipulated authorised levels for disposal of the wastes or safe transfer of solid/liquid wastes to authorised waste management facilities. The radioactive waste generated should be classified as per the classification basis provided by AERB Safety Guide titled 'Classification of Radioactive Wastes' (AERB/NRF/SG/RW-1).

Solid wastes containing short-lived radioisotopes should be stored for about 10 half-lives and then should be disposed, after monitoring, as institutional waste.

Low-level liquid wastes containing short-lived radionuclides should be stored in hold-up tanks for sufficient time to allow the radionuclides to decay ensuring that the radionuclides are in chemical forms which are soluble and dispersible in water. The waste should be diluted sufficiently to an activity concentration level which is approved by AERB for disposal in municipal sewer. Organic waste, such as liquid scintillation cocktail should be disposed as chemical waste after ensuring the activity concentration is below the limits prescribed by AERB.

The disposal of decayed sources containing GBq/TBq levels of activity needs special consideration due to the long half-life and high intensity radiations emitted by the sources. Examples are decayed/disused sources of ^{60}Co , ^{137}Cs and ^{192}Ir . Such sources should be transferred to the authorised waste management agency identified by the regulatory body for disposal or sent to the original manufacturer.

8.3 Regulation for Radioactive Wastes

The annual limit for disposal of radioactive waste for a given facility is specified by the AERB in the authorisation issued for disposal of radioactive wastes. The solid and liquid wastes may be transferred also to authorised waste management facility after obtaining prior approval from AERB. The facility should maintain record of the inventory of wastes generated, transferred and disposed. The radiological protection and surveillance program should include monitoring of the waste storage and disposal sites.

ANNEXURE-A

DESIGN FEATURES OF TYPE III RADIOISOTOPE FACILITY

A typical Type III facility will have several rooms/laboratories with clear segregation of areas based on use, scale and type of operation with the radioisotopes. Some of the features of such a facility are as follows:

- (a) Polyvinyl floor and epoxy wall surfaces for ease of decontamination
- (b) Special table and kitchen cabinets with SS tops
- (c) Proper ventilation
- (d) Storage safe - concrete/steel/lead
- (e) Stainless steel sink (elbow/foot operated tap)
- (f) Change room and showers
- (g) Fume-hood with absolute filter exhaust
- (h) Air and area monitor
- (i) Foot, hand and clothing monitor
- (j) Decontamination room
- (k) Shoe barrier
- (l) Shielded enclosures like hot cells, glove boxes, fume hoods, etc.
- (m) Master-slave manipulator
- (n) Emergency power supply
- (o) Planned radioactive waste disposal methods
- (p) Foot operated dustbins
- (q) Fire safety measures

ANNEXURE-B

MAXIMUM INVENTORY OF ACTIVITY AND MODIFYING FACTORS

INVENTORY OF ACTIVITY

Group of Radionuclide*	Type III Facility
1	> 185 MBq
2	> 1.85 GBq
3 & 4	> 18.5 GBq

* Group classification according to radiotoxicity

MODIFYING FACTORS ACCORDING TO TYPE OF OPERATIONS

Procedure/Type of Operation	Modifying Factor
Simple storage	x 100
Very simple wet operations such as preparation of aliquots of stock solutions, dispensing etc.	x 10
Normal chemical operations such as analysis, simple chemical preparations etc.	x 1
Complex wet operations with risk of spills	x 0.1
Simple dry operations such as manipulation of powders	x 0.1
Dry and dusty operations such as grinding	x 0.01

ANNEXURE-C

DIFFERENT TYPES OF HANDLING FACILITIES - ENCLOSURES

C1. Dry Boxes

Dry boxes are simple enclosures to handle low levels of activity. The boxes are connected to area exhaust system and are partly open from one side. The dry box isolates the radioactive material from the operator's environment and an opening of about 12 inches allows accessibility to the material inside for handling. It is an all welded construction fabricated out of stainless steel sheets. The linear face velocity of air across the opening is about 100 - 150 linear feet per minute (30-45 m/min).

The laboratory ventilation air is exhausted through dry boxes and fume hoods. kBq amounts of beta/gamma activity is handled in dry form and few MBq levels in solution form in the boxes. Stored amount of activity in dry box should not exceed 10 times the amount of activity permitted to be handled.

C2. Fume Hood

A fume hood is an enclosed chamber, with a transparent (glass/toughened glass) vertically rising panel in the front for carrying out of operations. Fume hoods are located in low level amber areas used for handling low levels of activity. The actual quantity that can be handled depends on the type of radionuclide, type of operations (wet/dry), its radiotoxicity and its physical and chemical forms. The materials for construction of fume hoods can be M.S., S.S., PVC or fiber glass. Ducts exhausting air from the hoods should be constructed of non-combustible materials. Occasionally (e.g. during dispensing of high active solutions), lead shielding may be required in the front of the fume hood to shield the workers from radiation exposure. The organic solvents used in the chemical operations pose potential fire hazard. Storage of such solvents should be avoided.

Normally, kBq/MBq amounts of radioactivity are handled in fume hoods. Inside surface of the fume hood should have smooth finish (epoxy-painted or SS lined) to provide resistance to corrosion and for ease of decontamination. Services such as water, gas, vacuum and electricity are provided with the controls located outside the fume hood.

Containment of material inside the fume hood is achieved by directional air movement through the front panel opening. The fume hood opening provides passage for the amber zone ventilation air providing the required number of air changes in the area. Ventilation of the fume hood is of once-through type.

The minimum face velocity maintained through the front opening (of about 25 cm) of the fume hood is 0.5 m/s (100 linear feet per min).

The exhaust air from the fume hood is passed through appropriate filters (example: charcoal filter to retain radioiodine; HEPA filter for particulates), taken out through the ducting to the general lab ventilation system and released into the atmosphere through a chimney whose height is about 2 to 5 m above the roof of the nearest building. The discharge is directed vertically upwards. In situations where there is a likelihood of radioactivity build-up on the filters, it is advised to install the filters in a shielded enclosure.

The exhaust fans for the hoods should have a back-up power source, to exhaust contaminated exhaust air continuously (or until the operations in the hood are completed) even during power failure situations.

C3. Glove Box

In a glove box, open radioactive sources can be handled in isolation from the user's environment. It is a leak-tight total enclosure, with transparent walls/windows and open ports fitted with flexible good quality gloves (gauntlets) for hand entry. Portholes and transfer ports with air-locks are provided for material transfer. Services such as electricity, vacuum, compressed air, effluent drainage, etc. are provided inside the box.

Operational radiation protection considerations involve periodic monitoring of integrity of the gloves, healthiness of glove port O-rings, and negative pressure inside the glove box and dose rates in the vicinity of the gloves box.

Ventilation system for the gloves should be once-through type air supply which is generally through leakages from the area surrounding the glove box. The normal leakage rate of a leak-tight glove box is 0.5% of the box volume per hour. The exhaust from the box is designed so as to provide about 25 mm (water column) negative pressure inside the glove box using pressure regulating valves.

In an enclosure, at the inside top of the box, absolute filter (HEPA) is provided for the exhaust air to pass through. Pressure drop across the glove box HEPA filter should be monitored. Service lines for water, vacuum/compressed air are provided as per the process requirement. The HEPA filters are replaced when the measured pressure differential across the filter reaches 100 mm of W.C. or the dose rate on the filter surface exceeds 2 mSv/h.

Maintenance of adequate negative pressure and periodic checking of the gloves for pin-hole leaks during operations prevent contaminated air within the box from leaking into the work environment.

C4. Shielded Box

A shielded box (also called shielded tong box) is a shielded air-tight enclosure fitted with provisions for remote handling, which allows the performance of operations without subjecting the operators to radiation exposure beyond the acceptable dose limits. Depending upon the energy of the gamma emissions, shielded boxes are used to handle beta gamma emitters of MBq levels to TBq levels. Remote handling tongs are used in these boxes. The walls are constructed with lead bricks with S.S. lining. Ventilation in shielded boxes is similar to that of glove boxes. Sufficient numbers of air changes are provided for promoting good visibility and to dilute sufficiently the airborne activity levels inside the box. The exhaust from the shielded box passes through double filtration for removal of all the particulate and gaseous radioactive materials, before it is discharged into the environment. Sufficient negative pressure is maintained all the time.

Liquid wastes (short-lived, high-level) generated in the operations are stored in shielded enclosures inside the box, and low level wastes are transferred to delay tanks.

C5. Hot Cell

Hot cells, in general are used for producing/fabricating sealed radiation sources. The hot cell is a thick-walled enclosure with remote handling facilities for handling large quantity (several hundred TBq level) of gamma emitters such ^{60}Co . Hot cells are usually equipped with master slave manipulators and thick viewing windows made of high-density lead glass. Almost all physical, chemical and metallurgical operations can be carried out by remote handling, inside the hot cell.

The design of a hot cell should be carried out after hazard assessment has been done, taking into account the amount and type of activity to be handled and the nature of the operation to be carried out in the cell. The concrete shielding should be adequate to ensure $1 \mu\text{Sv/h}$ dose rate in the working side. Penetrations on the walls for the service lines and cables and joints/corners should be designed so as to prevent/minimise the streaming, leakage and scattered radiation contribution to the dose rate outside the cell. The adequacy of the cell-shielding should be ensured by radiometry using radiation source of appropriate strength.

Depending upon the nature of operation to be carried out in the cells, ventilation system is designed to provide sufficient ventilation (20 - 30 air changes per hour). The exhaust from the cell should be double-filtered using absolute filters (HEPA) at the exhaust end, and before it is released into the environment. Penetrations of the service lines on the walls should be designed so as to prevent any streaming or leakage of radiation to the working areas

outside the cell. Negative pressure, of the order of 25–50 mm water column should be maintained in the cell with respect to the adjoining operating areas.

The internal walls of the cells should be SS-lined or painted for smooth finishing and easy decontamination. Various services required in hot cells involving the use of water, steam, chemicals, viewing window and even welding units are provided inside the hot cells. Adequately shielded doors made of steel/lead should be provided for access to the cells for decontamination and maintenance.

Adequate lighting, mirrors, periscopes, cameras should be provided inside the cell in order to ensure effective performance of the work inside the cell.

ANNEXURE-D

AERB SAFETY DIRECTIVE 01/2011



25 Years of
Safety Regulation
1983 - 2008

परमाणु
ऊर्जा
नियामक
परिषद



भारत सरकार

GOVERNMENT OF INDIA

Atomic
Energy
Regulatory
Board



अध्यक्ष
CHAIRMAN

No. CH/AERB/ITSD/125/2011/1501

April 27, 2011

AERB Directive No. 01/2011

In exercise of rule 15 of the Atomic Energy (Radiation Protection) Rules, 2004, the Chairman, Atomic Energy Regulatory Board, being the Competent Authority under the said rules, hereby issues an order prescribing the dose limits for exposures from ionising radiations for workers and the members of the public, which shall be adhered to.

Dose Limits

General

- i. The limits on effective dose apply to the sum of effective doses from external as well as internal sources. The limits exclude the exposures due to natural background radiation and medical exposures.
- ii. Calendar year shall be used for all prescribed dose limits.

1.0 Occupational Dose Limits

1.1 Occupational Workers

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

- a. an effective dose of 20 mSv/yr 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;

Page 1 of 2



ISO 9001:2008
Organisation

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- d. an equivalent dose to the extremities (hands and feet) of 500 mSv in a year and
- e. an equivalent dose to the skin of 500 mSv in a year;
- 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.

1.2 Apprentices and Trainees

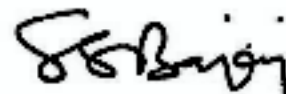
The occupational exposure of apprentices and trainees between 16 and 18 years of age shall be so controlled that the following limits are not exceeded:

- 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.

2.0 Dose Limits for Members of the 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.



(S. S. Bajaj)
Chairman

Atomic Energy Regulatory Board

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**LIST OF REGULATORY SAFETY DOCUMENTS ON
RADIATION SOURCES**

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AERB/SC/G	Regulation of Nuclear and Radiation Facilities
AERB/SS/3 (Rev.1)	Testing and Classification of Sealed Radioactive Sources
AERB//RF-RS/SG-1	Security of Radioactive Sources in Radiation Facilities
AERB/RF-RS/SG-2	Radioisotope Handling Facilities
AERB/RF/SG/G-3	Consenting Process for Radiation Facilities
AERB/SG/G-4	Regulatory Inspection and Enforcement in Nuclear and Radiation Facilities
AERB/RF/SM/G-3	Regulatory Inspection and Enforcement on Radiation Facilities

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