GUIDE NO. AERB/RF/SG/MCF

GOVERNMENT OF INDIA

AERB SAFETY GUIDE

MEDICAL CYCLOTRON FACILITIES

ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY GUIDE: AERB/RF/SG/MCF

MEDICAL CYCLOTRON FACILITIES

Atomic Energy Regulatory Board

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India

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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 (REGDOCs) establish the requirements and guidance for all stages during the lifetime of nuclear and radiation facilities and transport of radioactive materials. These requirements and guidance 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 (REGDOCs) 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 (REGDOCs)

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 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 REGDOCs. .

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

The Medical Cyclotron Facilities (MCF) are required to obtain licence from AERB under Atomic Energy (Radiation Protection) Rules, 2004. They are required to obtain regulatory consents at various stages starting from the approval of the design and construction, commissioning and operation of the facility, to the decommissioning of the equipment/facility and safe disposal of the radioactive waste. This safety guide provides guidance on the pre-requisites for obtaining licence of MCF and the safety requirements to be complied with for safe handling of the radiation sources produced in the MCF and safe operation of Medical Cyclotron (MC). It provides an approach through which the regulatory requirements can be complied with by the MCF. The guide provides guidance for complying with the requirements specified in AERB Safety Code for Radiation Facilities (AERB/RF/SC, 2025). This Safety Guide is effective from the date of its issue and supersedes earlier Safety Guide on 'Medical Cyclotron Facilities' (No. AERB/RF/RS/SG-3, October 2016).

Consistent with the accepted practice, 'should' and 'may' are used in the Guide to distinguish between a recommendation and a desirable option respectively. Appendix is an integral part of the document, whereas annexure and bibliography are included to provide further information on the subject that might be helpful to the user(s).

The initial draft was prepared by an In-House Working Group (IHWG) of AERB, which was then reviewed by the Task Force (TF) with specialists drawn from technical support organizations and institutions, and other consultants. The Comments obtained from domain experts and relevant stakeholders have been suitably incorporated. The Safety Guide has been reviewed and concurred 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 Guide. The list of experts, who have participated in this task, along with their affiliations, is included for information.

D. Shukla.

(Dinesh Kumar Shukla)
Chairman, AERB

SPECIAL TERMS S AND INTERPRETATION[1]

(Specific for this Guide)

Airlock

An enclosed space with two or more doors, which is interposed between two or more rooms e.g. for the purpose of controlling the airflow between rooms of differing classes of cleanliness and contamination, which needs to be entered into. An airlock is designed for and used by either people or goods (PAL = Personnel airlock and MAL = Material airlock).

Clean room

A room or area with defined and controlled environmental particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation and retention of contaminants in it , and in which other relevant parameters (e.g. temperature, humidity and pressure) are maintained as necessary.

Dosimeter

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

Havar Foil

A foil made of Havar (alloy) having high tensile strength at very high temperatures, used for separation of high pressure target from the vacuum system of a medical cyclotron.

HEPA Filter

High Efficiency Particulate Air filters (HEPA) are a specialized type of air filters which in general have a capacity to remove 99.97% particles of 0.3 μm size from the incumbent air flowing through it.

Hot-cell

A shielded and ventilated enclosure which is kept under negative pressure to contain radioactive material and is generally equipped with remote handling tongs or Master Slave Manipulators for safe handling of large amount of radioactivity.

Laminar air flow (LAF)

[1] Special definition may have different interpretation from definition in AERB Glossary on the same term.

A rectified airflow, usually through a HEPA filter, over the entire cross-sectional area of a clean zone with a steady velocity and approximately parallel streamlines (modern standards no longer refer to laminar flow, but have adopted the term unidirectional airflow).

Machine operator

A person who is certified in compliance with the eligibility criteria as specified by the AERB and is required to operate the machine and/or facility as per written instructions and established standard operating procedures.

Manufacturer

A person engaged in the commercial manufacture of Medical Cyclotrons that are designed in conformance with the applicable safety standards. A manufacturer can also be a supplier.

Medical Cyclotron (MC)

Medical Cyclotron is a compact cyclotron used for production of medically important and useful radioisotopes by bombardment of accelerated charged particles onto a suitable target.

Medical Cyclotron Facility (MCF)

A radiation facility that consists of Medical Cyclotron in a shielded vault and associated operational systems and infrastructure. This typically includes, inter alia, control room, radiochemistry and radiopharmaceutical production areas (hot-cells), transfer line, radiopharmaceutical/radioactivity dispensing and packing and dispatch area, Quality Control (QC) lab, radioactive waste storage area, personnel radiation surveillance area (such as decontamination area) and other areas e.g. ventilation area, cold-chemistry lab areas etc.

Protection and Safety

The protection of people against exposure to ionizing radiation or exposure due to radioactive material and the safety of sources, including the means for achieving this, and the means for preventing accidents and for mitigating the consequences of accidents if they do occur.

Safety is primarily concerned with maintaining control over sources, whereas (radiation) protection is primarily concerned with controlling exposure to radiation and its effects.

The two are closely connected and radiation protection is very much simpler if the source in question is under control, so safety necessarily contributes towards protection.

Self-shielded Cyclotron

A type of MC having in-built shielding around the cyclotron tank and target to minimize the neutron and gamma dose rates around the cyclotron.

Supplier

A person engaged in the supply of MC which are designed in conformance with the applicable safety standards and having responsibilities prescribed by the AERB.

Target

The target in the medical cyclotron is the material on which accelerated charged particles are incident and interact with its nuclei to produce radioisotope.

Unidirectional air flow

See Laminar air flow

Unshielded (Bunker Type) Cyclotron

A medical cyclotron without an in-built shielding around the cyclotron tank and target but housed within a shielded vault (bunker) to minimize the neutron and gamma dose rates around the cyclotron bunker.

Zone Monitor

A fixed area monitor to detect photons with pre-set alarms installed at the control room, product entry/exit area, etc (typically with the minimum measurable dose rate of 1µSv/h with a minimum increment of 0.1µSv/h).

Note: Words and expressions used in this document and not defined, but defined in the Act, the Rules, and AERB Glossary shall have the meanings as assigned in the Act, Rules, and AERB Glossary.

Reader may also refer AERB Safety Code on 'Radiation Sources, Equipment and Installations' AERB/SC/RF and AERB Safety Glossary, No. AERB/GLO, Rev.1 for Definitions of specific terms used in this Guide.

Contents

1. INTRODUCTION

1.1 General

Medical Cyclotron is a device which is used for the production of radioisotopes used in various medical applications.

In Medical Cyclotron (MC), a beam of negative hydrogen ions (H^-) or deuteron (D^-) ions is accelerated under the influence of alternate electric and magnetic fields. The alternating polarities (due to alternate electric field) of the Dees and the bending effect of the magnetic field move the ion beam from Dee to Dee in a spiral path and accelerates the beam. After multiple accelerations and attaining the desired energy, the ion beam reaches the extraction edge where the extracted beam is intercepted with a thin carbon foil/stripper foil where loosely bound electrons are removed by the foil to produce positive ions. Ultimately the beam of accelerated positively charged particles, bombard on a suitable target to produce the desired radioisotopes used in PET (Positron Emission Tomography) or SPECT (Single Photon Emission Computed Tomography) scanning or any other nuclear medicine applications. In this process, prompt gamma and neutrons are emitted because of nuclear reactions. The components and shielding walls may also get activated due to interaction with produced neutrons in the process and become a source of radiation. This needs to be taken into account during maintenance. Further these radioactive components need to be disposed of safely at the time of decommissioning or as and when required during lifetime of operation of the machine.

The cyclotron produced radioisotopes are incorporated or tagged to chemicals in a radiochemistry module placed inside the hot-cell to synthesize appropriate radiopharmaceuticals.

Medical Cyclotrons (MC) may be classified as self-shielded and unshielded cyclotron. The self-shielded cyclotrons come with an in-built shielding around all its components including the Dees, target body, accelerating chamber, target holders etc. The self-shielded cyclotrons generally require more floor space as compared to unshielded cyclotrons. On the other hand, unshielded cyclotrons render ease of access to, or for adoption of new targetry options. Such cyclotrons are housed within a shielded vault to keep the dose rates acceptably low outside

the cyclotron vault. For enforcing personnel safety, the vault needs to be provided with access controls.

A Medical Cyclotron Facility (MCF) consists of a MC in a shielded vault and associated operational systems and infrastructure e.g. control room, radiochemistry and radiopharmaceutical production areas (hot-cells), radiopharmaceutical/radioactivity dispensing and packing and dispatch area, Quality Control (QC) lab, radioactive waste storage area, ventilation area, cold-chemistry lab areas and personnel radiation surveillance area (such as decontamination area).

1.2 Objective

This safety guide provides guidance on complying with the relevant regulatory requirements prescribed in the AERB Safety Code on 'Radiation Sources, Equipment and Installations' AERB/SC/RF, 2025, pertaining to MCF by specifying relevant procedures and elaborating radiation safety requirements for design, commissioning, operation and decommissioning.

1.3 Scope

This Safety Guide addresses radiological safety requirements for regulated entities such as manufactures / suppliers of MC and users of an MCF for production and, where applicable, supply of radioisotopes for use in nuclear medicine. It addresses MC of two types, namely self-shielded and unshielded (bunker type), along with the safety requirements of the radiochemistry and radio pharmacy laboratories associated with the MCF. In addition to this, the safety guide uses the broad types of MCF (drawn from IAEA classification and cited in Table 3.1 of this Guide) and covers regulatory requirements for Type I to Type III MCF, while only broad guidelines are given for Type IV MCF. The use of Cyclotron solely for research purpose is excluded from the scope of this Guide. However, there may be MC which are combined with research purposes and in such case additional reviews of safety need to be considered on a case by case basis. Also, Radiopharmaceutical specific safety aspects are not addressed in this guide.

2. RADIATION PROTECTION AND SAFETY

2.1 General

Radiation Hazard from a MCF is due to presence of both an accelerator and handling of unsealed radioisotopes produced in the facility.

The licensee of an MCF is responsible for the establishment and implementation of a radiation protection programme during normal operation, maintenance and decommissioning, and in emergency situations to ensure protection and safety and for compliance with the regulatory requirements. The licensee has the overall responsibility for overseeing radiation safety and verifying that work is carried out in accordance with regulatory requirements. The licensee should ensure that procedures are developed for the protection of workers, the public and the environment, and for ensuring that exposures are kept as low as reasonably achievable and that the prescribed dose limits are not exceeded. All policies and procedures relating to radiation safety should be documented, and made available to all the staff and for verification during regulatory inspection. The radiation protection and safety principles apply to the design, manufacture, construction, operation, maintenance and decommissioning of the MC equipment and the MCF as a whole.

This chapter outlines the radiation protection principles of justification, optimization, dose limitation and safety.

2.2 Justification

The employer should ensure that no practice or activity involving exposure to radiation is performed unless it produces more benefit than any harm it may cause. The operation of a medical cyclotron (MC) brings substantial benefits owing to the production of medical radioisotopes and radiopharmaceuticals which are essential for the practice/procedures of nuclear medicine. If the licensee desires to use the ionizing radiation produced in the facility for any purpose other than its intended purpose, he/she is required to provide proper justification demonstrating that the benefit accrued is more than the harm or damage it may cause.

2.3 Optimisation

The licensee should ensure that procedures are in place for the protection of personnel working in the MCF, the auxiliary staff, the public and the environment. The licensee should ensure that radiation protection measures commensurate with the hazard associated with the MCF are developed and implemented. The management structure of the facility, policies, responsibilities, procedures and arrangements should be in place, to optimize radiation protection, to prevent/reduce exposures, and to mitigate the consequences of any incidents associated with the operation of the MCF. The optimization process should consider minimizing the number of individuals exposed and the magnitude and the likelihood of exposure. There should be provision to store radioactive waste in a controlled manner and provision for its safe management. The radiation protection measures should be commensurate with the needs of the facility, keeping the exposure to the public to a minimum and in no case exceeding the prescribed dose limits (Appendix-1).

2.4 Dose Limits

The Dose Limits for Radiation workers, trainees & apprentices and members of public have been prescribed by AERB in its safety directive (refer Appendix-I). The licensee should ensure that the exposure to workers including service engineers and members of the public arising from the MCF is so restricted that neither the effective dose nor the equivalent dose to tissues or organs exceeds the dose limits prescribed by AERB. It is to be ensured that external dose is assessed using personnel monitoring badges on a regular basis (quarterly) while internal dose should be assessed by the RSO in certain situations where worker might have inhaled/ ingested radioactive material.

2.5 Management for Safety

In order to achieve overall safety during the handling of the sources and operation of the MCF, an effective management system should be in place so that the safety requirements, which include health, human performance, quality management, protection of the environment, security, promotion of safety culture, assessment of safety performance and lesson learned from experience including any unusual occurrences, are fulfilled.

Safety and security measures should complement each other recognizing synergies between them. The Licensee should develop a Radiation Protection Programme (RPP) in consultation

with the RSO and adhere to the same. The important elements of a radiation protection programme include equipment designed to ensure safe operation, radiation installation designed to optimize protection of workers and public, quality assurance program, availability of qualified and trained personnel, means for detection, mitigation and reporting of unusual incidents/accidental exposures, promoting safety culture, safe work practices including use of personal protective accessories, and a provision for periodic review of effectiveness of the RPP. All the relevant aspects of RPP are addressed in detail in respective chapters of this Safety Guide.

3. DESIGN OF RADIATION SOURCES, EQUIPMENT AND INSTALLATION

3.1 General

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

3.1.1 Site Safety

Suitable site for installing an MCF should be assessed in accordance with engineerability of the system, structure and components for the seismic condition, proximity to a capable fault, soil characteristics, flooding potential, groundwater level, geo-hydrology, bearable load, approach road and on the basis of occupancy. Further, presence of any ammunition dumps, and storage of inflammable and toxic substances having potential impact in the proposed facility should be considered in the design. Basement is a suitable site for location (after ensuring appropriate provision to prevent flooding due to any reason like torrential rains or bursting of any water supply lines) as the earth provides natural and effective shielding. The medical cyclotron installations solely operated for the purpose of commercial radioisotope production and distribution should be housed in an industrial area.

3.1.2 Design Safety

The design safety of the MCF should be such that the radiation exposures received by the workers and the members of the public do not exceed the dose limits prescribed by AERB. This should be achieved by providing adequate/appropriate shielding around the MC unit, hot-cell, radiochemistry and dispensing modules. Proper ventilation in the MCF, should be provided with air movement from low to high radioactive zones (area) and its final release to atmosphere (Figure 3.1). Air circulation in the facility should be such that the conditions inside the facility are comfortable to work.

A medical cyclotron facility comprises several areas. Such as:

(i) shielded vault with cyclotron, control room and associated systems

(ii) the Radiochemistry and Radio-pharmacy production (including Hot-cell), Quality Control (QC) lab, dispensing, packaging and dispatch areas

(iii) Radioactive waste storage area and personnel radiation surveillance area (such as decontamination area)

(iv) Other facilities such as ventilation room and cold chemistry lab (no radioactivity is handled) etc.

In a MCF, the cyclotron vault is the area having high exposure rates when the machine being operated. After termination of irradiation and transfer of produced radioactive material to the hot-cells, the dose rate inside the cyclotron vault reduces considerably, while that inside the hot-cells in the radiochemistry and radiopharmacy lab increases significantly. After synthesis, the finished radiopharmaceutical product is moved into the dispensing hot-cell. Dispensed radioactive material is packed and dispatched to the user. A few samples of the finished radiopharmaceutical product, usually with limited radioactivity, are sent to the QC lab for quality control tests.

MCFs are characterised based on their design features, intended use and radiation hazard potential. A broad classification is made as follows. This classification helps in formulating regulatory requirements, specific to the Type of MCF.

Table 3.1: Classification of Medical Cyclotron Facilities

Type of MCF	**Medical Cyclotron**	**Particle energy, beam current**	**Commonly produced radionuclides and allied pharmaceutical products**	**Usage: In-house and/or Distribution**
I	Self-shielded	Proton beam only up to 20 MeV Current ~150 μA	[^{18}F]FDG	In-house[#]

II	Self-shielded or Unshielded	Proton/Deuteron beam up to 20 MeV Current ~300 μA	[^{18}F]FDG and other ^{18}F-RPs $^{13}NH_3$, ^{11}C-RPs, ^{68}Ga-RPs (via liquid target) ^{15}O-H_2O ^{18}F-RPs	In-house# and/or for distribution
III	Unshielded with external beamline	Proton/Deuteron beam up to 20 MeV Current ~ 300μA	All those listed in Type-II above plus others, e.g. ^{124}I/^{123}I –RPs, ^{64}Cu-RPs, ^{89}Zr-RPs	In-house# and/or for distribution
IV	Unshielded with one or more external beamlines	Proton/Deuteron beam 20 – 30 MeV Current up to 500μA	All those listed in Type-II above plus other SPECT and PET RPs	In-house# and/or for distribution.

Based on the IAEA Technical Report Series 471: Cyclotron Produced Radionuclides: Guidelines for Setting up a Facility (modified and updated to include new radioisotopes and cater to Indian context)

 # In-house refers to supply of radioactive material to a co-located Nuclear Medicine facility where the transport of the container is not through a public area and hence extensive packaging of the radioactive material is not envisaged.

Values are mentioned considering parameters of currently operated Medical Cyclotrons in the country. Thus, information cited in the Table is indicative only and not necessarily binding.

Relevant sections of this guide deals with the overall design of the MCF and the specific design aspects of the Cyclotron vault, Radiochemistry and Radio pharmacy rooms (including hot-cell, radiochemistry, dispensing modules and QC lab). Several factors decide the design and layout of a MCF, of these, the type of the facility is the most important. Typical layouts for Types I to III MCF are given in Annexure-1.

3.2 Sealed Source

Sealed sources may be used in an MCF (e.g. ^{137}Cs, ^{68}Ge sources for functionality check of radiation monitors). Typically, the activity of such sources varies from a few kBq to MBq. The safety of these sources is the responsibility of the licensee and an inventory of these sources should be maintained by the licensee.

3.3 Source Housing

Not applicable for this Guide

3.4 Design of Radiation Equipment

Potential exposure situations should be prevented by design features through interlocks and other features which should include the following:

(i) Redundancy: The principal components of the safety systems should be duplicated;

(ii) Independence: Faults in the cyclotron or radioactive material handling areas should not impair any of the safety system; and

(iii) Fail-safe: Failure of any component /device in a safety system should always result in safe conditions.

The principle of defence in depth includes multiple levels of protection to minimize the need for human intervention. MCF should only be operated if all the levels of defence are in place and functioning. The design requirements of an MCF are described below:

3.4.1 Design of Radiation Equipment (MC)

The following features should be considered in the design of MC

(i) Physical or mechanical means of disabling the main control system for beam production

(ii) Built-in monitoring of machine parameters

(iii) Built-in remote machine diagnosis

3.4.1.1 Control System

The systems and sub-system to control the operation should be fully automated, so that isotope production requires minimal operator's intervention. The details of control logic and interlocks for safe running of the system and sequential logic for cyclotron routine operation such as system start-up and shutdown in automatic/manual modes should be

provided to AERB as a part of design document (PSAR/FSAR). Some examples of the control systems include the following;

(i) Thermo-switch for overheat protection and flow switch for water cooling system provided to various systems such as magnets, various high voltage power supplies, target-and beam window and other critical components.

(ii) Monitoring and control of vacuum in the vacuum chamber which includes vacuum system controller to perform pressure monitoring, vacuum pump sequencing and system operation.

(iii) Control and monitoring the efficiency of beam extraction (single or dual) system.

(iv) Beam diagnostics: continuously monitoring of the extraction foil carousel, collimators and targets to allow fully automated start-up, tuning and operation.

3.4.1.2 The licensee should ensure that the MC has necessary approval from AERB prior to its procurement. Manufacturer/supplier of an MC should ensure that design approval of the equipment has been obtained from AERB prior to its supply.

3.4.1.3 The manufacturer/supplier of an MC should ensure that the thickness of the self-shield in case of a self-shielded MC should provide adequate shielding as per the relevant national/international standard against the radioactivity build-up, prompt radiation emitted during irradiation and radiation generated during activation of inner components during the maximum life time of the machine.

3.4.1.4 Radiological Safety Consideration for Layout:

The Type of MCF as detailed in Chapter 1 of this Guide has an important bearing on the layout requirements. Annexure-1 gives typical layouts for different types of MCF which facilitate in the understanding of layout requirements as detailed further.

(i) An MCF should be planned in such a manner so as to ensure that movement of radioactive material within the facility is minimized and contained. This is achieved by ensuring that the room for carrying out each step in the processing is in close proximity to the preceding step. A typical radiation field gradient in an MCF is given in Figure 3.1.

(ii) Adequate space should be available for ease of handling of radioactive material.

(iii) Shielded containers and pass boxes in the walls of adjoining rooms may be provided to minimize or eliminate the chance of the spread of contamination.

(iv) The facility should be so designed as to provide for restricted access to the areas where radioactive materials are either produced or handled.

(v) There should be suitable provisions for safe storage of radioactive wastes.

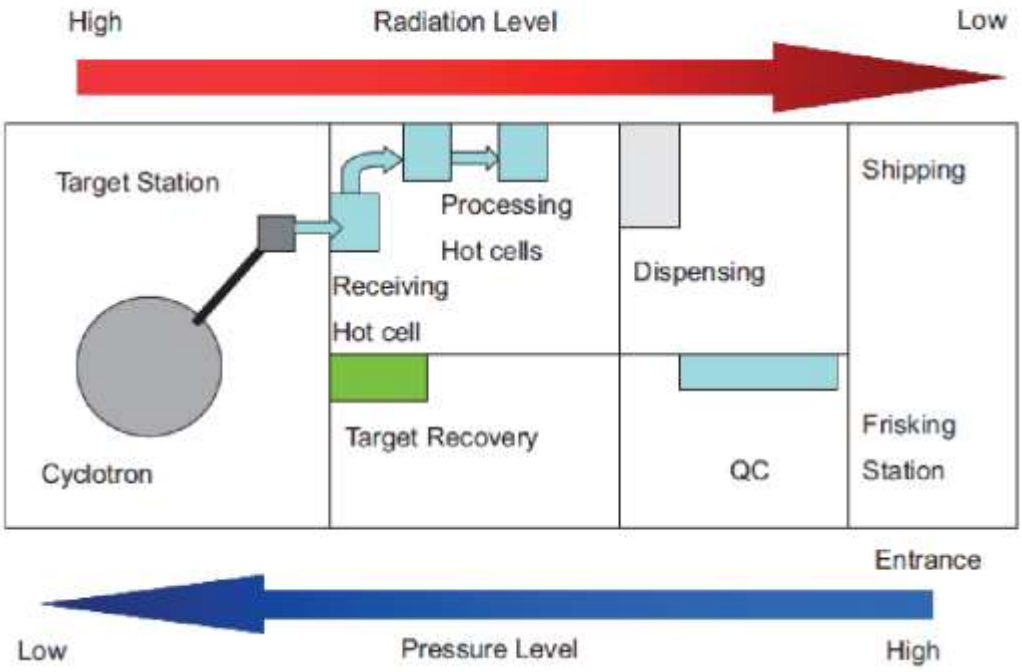

Figure 3.1: Typical Radiation Field gradient and Pressure Gradient in a MCF (Adopted from: IAEA TRS 471)

3.4.1.4.1 Layout considerations for different types of MCFs:

While the general considerations are applicable for all types of MCFs, there are specific requirements depending on the type of MCF, as given below.

(i) In the Type-I MCF, since only fluoride oxyglucose ([^{18}F] FDG) is made, the layout is relatively simple. The cyclotron in such a facility should be self-shielded and housed in a vault adequately shielded against gamma and neutron radiations. Type-I MCF is meant to supply FDG only to a co-located Nuclear Medicine facility and hence transport of radioactive material through public domain is not envisaged.

(ii) A Type II facility has a larger scope than a Type I MCF to accommodate adequate number of synthesis modules in the hot-cell for preparing different radiopharmaceuticals. The floor plan should also accommodate dispatch and shipping of the finished products. A Type II facility can also be an un-shielded cyclotron. The space requirement would be more than that for a Type I facility. An unshielded cyclotron should be housed in a designated concrete vault with adequate shielding.

(iii) A Type III MCF, is built around a cyclotron that is somewhat similar to that in a Type II MCF, except that it has, in addition, beam line(s) for irradiating solid target(s) to produce other radioisotopes such as ^{64}Cu, ^{89}Zr, $^{123/124}$I. Since the scope of activities in this facility includes production of relatively longer lived SPECT and PET isotopes, there are additional radiation safety requirements. There should be a provision for a small cave type vault, (of much smaller size than the one housing the cyclotron) where the beam line from the cyclotron extends into. Since these facilities will also be producing ^{18}F routinely for FDG, for the irradiation of two targets to produce two different isotopes and the processing of solid targets, more space should be provided. A bunker type vault is required for the cyclotron as it will not be self-shielded, to facilitate an external beam line. The handling of solid targets requires a specialized transport system from the target cave to the hot-cell.

(iv) A Type IV facility can produce and supply several SPECT and PET radiopharmaceuticals on a large scale with multiple beam lines ending in shielded caves where the targets, (solid, liquid and gas) will be irradiated. In Type II and III cyclotrons the liquid and gas targets are mounted on the cyclotron itself. Access to the cyclotron to maintain the target will be possible in these types, where the cyclotrons will be ‘OFF’ for some time in a day. All the targets in Type IV are

mounted at the end of beam lines, since it is expected that most of the time, the cyclotron will be 'ON' and access to the cyclotron to maintain the target will not be possible. The floor plan for a Type IV cyclotron facility would be highly individualized depending on the purpose and goals.

3.4.1.4.2 Floor design in the Cyclotron Vault:

(i) The floor of the cyclotron vault should have sufficient load bearing capacity, as recommended by the manufacturer. The concrete used for the floor should be of required density and adequate thickness to provide adequate attenuation and absorption of neutrons so that the elements in the soil and groundwater below are not activated.

(ii) The floor of the cyclotron vault should have adequate space to accommodate vacuum pumps, waste gas compression systems, L-bench for target maintenance, storage pits or lead shielded bins for long-lived radioactive waste, (e.g., Havar foils) etc., as appropriate to the type of cyclotron. However, in case of unshielded cyclotrons where activation of metal components is likely, a separate well-ventilated area with appropriate negative pressure should be available to locate and use the above systems.

(iii) During maintenance, it is often necessary to remove water from the water lines. The floor of the vault, therefore, must have drains for water. These drains are normally connected to the sanitary sewer system. They should be connected to a hold up system, for the water to be checked for radioactivity, before it is released into the sanitary sewer.

(iv) Like the walls in the vault, the floor should also have appropriate finish to prevent it being a source of dust and fines. It should be non-absorbent, hard, washable and non-slippery.

3.4.1.5 Hot-cell design:

Hot-cells are the most effective way to contain and shield the open radioactive sources, which are to be chemically converted to the final radiopharmaceutical products, e.g. FDG. Adequate numbers of fully automated synthesis modules are preferred for safety. The size, layout and the number of hot-cells for synthesis and dispensing in the radiochemistry area will depend on the type of the facility.

Hot-cells should fulfil the following requirements:

(i) The frame should be sturdy enough to bear the load. The thickness of the shielding should be adequate for the type, energy and intensity of radiation to keep exposures outside of the shielded hot-cells within the regulatory limits.

(ii) The interior surface of the hot-cells should be made of high quality stainless steel, preferably 316 grade, with smooth impervious joints.

(iii) Electrical and data communication cables should pass through shielded ports with bends to prevent radiation streaming.

(iv) The hot-cell used for chemical synthesis and dispensing of the finished product(s), ^{18}F-FDG in most cases, should be maintained at negative pressure to contain the spread of radioactivity.

(v) On closing the door, there should be an air-tight seal with the body of the hot-cell and leak-tightness should be tested periodically as specified by the manufacturer.

(vi) Lead equivalent glass window with adequate thickness should be provided and overlapping of lead glass, where applicable, should be such as to avoid radiation streaming.

(vii) There should be at least 20 air changes per hour during operation. Inlet air should pass through HEPA filters to prevent introduction of dirt and exhaust air should pass through HEPA + Charcoal filters to prevent exhaust of any contaminated particles/gas respectively.

(viii) Hot-cells should be fitted with air pressure gauges to monitor the negative pressure inside the hot-cell and sound an alarm if it exceeds a pre-set value.

(ix) Hot-cells for synthesis of radiopharmaceuticals should be connected to radioactive waste gas compression systems, which maintain the required negative pressure in the hot-cells, ensures required number of air changes from a HEPA-filtered inlet and compress the exhaust (which will contain some air-borne activity during synthesis) from the hot-cell into a small volume and store it for delay and decay. In the absence of waste gas compression system, an alternate arrangement for containing the air borne activity and delayed release should be used with proper justification.

(x) The door of the hot-cell should be interlocked with radiation monitors such that the door would not open unless the dose rate inside the hot-cell is less than a pre-set value with provision for bypassing the interlock in case of operational exigencies with approval from and necessary supervision by the RSO.

(xi) The door of the hot-cell should also be interlocked in such a way that the radioactive material produced in vault can't be transferred into a hot-cell until the hot-cell door is properly closed.

3.4.1.6 Target Systems: Solid, Liquid and Gas

The target system(s) supplied by manufacturer with the MC should only be used for production of radioisotopes. The target system should be maintained periodically as recommended by the manufacturer. The design of target system should not be changed or modified. If the change is absolutely necessary, it should be done only with prior approval from AERB. The target to be replaced should meet the technical specifications.

In an event when the target system gets damaged or become un-usable, it should be stored appropriately as radioactive waste.

3.4.1.7 Provision for Utilities:

(i) The utilities required for cyclotron operations viz. (i) electric power supply unit, (ii) RF power supply unit, (iii) chilled water unit, (iv) supplies of compressed air and the gas cylinders should be housed at appropriate locations taking into account the industrial safety requirements.

(ii) Appropriate openings for the ventilation ducts for air inlet and air exhaust for maintaining the negative pressure and required number of air changes should be provided.

(iii) Lighting in the vault should be designed so as to facilitate critical inspection and maintenance.

(iv) The peripheral equipment for unshielded cyclotrons, should be installed in a separate area outside the vault, to avoid potential damage to sensitive electronic equipment due to radiation.

(v) The work surfaces of L-bench should be inert, non-absorbent, easy to clean and should not generate dust.

(vi) Hydrogen and/or Deuterium gases which are highly inflammable should be housed in well ventilated location and meeting the applicable requirements for the safe siting/storage of such gases.

3.4.1.8 Radiochemistry and Radio-pharmacy (R&R) Lab

The radiochemistry lab has to be planned for both radiation safety as well as product safety as directly injectable radiopharmaceuticals are processed here. The radiopharmaceutical lab should also fulfil the local statutory requirement applicable from time to time.

The following general requirements should be complied with:

(i) The R&R-area should be, as far as possible, located adjoining the cyclotron vault/target caves to ensure minimum length of tubing required to transport the radioactive material from the cyclotron target to the hot-cells.

(ii) The R&R lab space should be physically separated from personal desk space, meeting space and eating areas.

(iii) The area available should be sufficient for arranging the required number of hot-cells, laminar/unidirectional air flow hoods, space for installation of QC equipment and carrying out QC, packing and dispatch of the radiopharmaceutical, maintaining production and QC records and interim storage of radioactive waste till complete decay or till transferred to another designated area.

(iv) The facility should be designed to ensure the orderly handling of materials and equipment to prevent mix-up and contamination of equipment and product. This can be most readily achieved by employing the clean room concept.

(v) If experimental production of radiopharmaceuticals is planned to be a regular feature, then, the R&R-area may be partitioned to provide for a separate area dedicated for R&D purpose.

(vi) In an MCF, the hot chemistry lab for solid targets has to be situated adjacent/proximal to the target caves so that the transport of the solid target after irradiation is facilitated.

(vii) Access to the R&R area should be through a changing room and personnel air lock. There should be quick access to a decontamination area, preferably through the emergency exit, equipped with shower to be used in case of personal contamination due to incidents such as accidental spillage of radioactive material. Hand and foot monitor should be available at the exit point from the R&R-area. There should be a provision for a properly designed eye-wash, in case of suspected contamination.

(viii) Flooring in R&R-area should be able to bear the weight of the hot-cells. The flooring should also be waterproof, hard and impervious to any radioactive spills. It should be chosen such that it can be used with minimum number of joints and should be made of such a material that facilitates ease of decontamination.

(ix) Table tops and other work surfaces should be finished with hard, impervious, heat resistant, stain resistant, chemically resistant material (e.g. stainless steel, industrial grade PVC) which can easily be decontaminated and easily replaced, preferably in large sheets with a minimum of joints.

3.4.1.9 In-house Transfer of Radioactive Material

(i) After irradiation, radioactive gases, liquids and solids produced in the target will normally be transferred out of the cyclotron vault into the hot-cell via the transfer line through tubing. The lines are generally routed through underground trenches to the bottom of the hot-cell. If transfer involves long routing other than mentioned above, it should be shielded so that dose rates would allow normal occupancy during transfer. The composition of the tubing used to transport the radioactive material

should be such that the tubing would not suffer any deterioration due to the intense radiation from the radionuclide and the chemical form of the radionuclide being transported. Supply line should be tested/checked and replaced periodically to avoid any mishap.

(ii) If pneumatic chute system is used for transport of radioactive material from hot-cell, its design and layout should be through the shortest possible route and through least occupancy areas so as to ensure that exposure received by workers and public during the transfer of radioactive material is minimized. Also, in case of any accidental jamming or obstruction of the lead capsule containing radioactive material during transfer, safe removal or retrieval of the capsule should be possible.

(iii) The production room should be connected to the preparatory room through a material air-lock, from where raw materials, kits, vials, shielding containers and consumables are transported into the clean room. It should also be connected to the packing room through a material airlock, through which the shielding containers are taken out of the clean room for packaging.

3.4.2 Fail Safe Mechanism

The typical design feature of Safety Interlocks should be such that

(i) The safety interlocks for hazardous operations in an MCF (including accelerator operations and radioactive material handling) should be fail safe that is, designed so that a defect or component failure in the interlock system prevents operation of the accelerator.

(ii) The interlock trip system should ensure that the cyclotron will resume operation only after manually resetting the controls at interlocks position and finally at the main control console.

3.4.3 Safety Interlocks

The interlock protection should be provided such that the machine cannot be operated while it is in an unshielded configuration. There should be two sets of independent interlocks. Access to the accelerator or target should be allowed only if three independent devices have

been turned off which are required to be operating in order to accelerate the beam. For example, high voltage to the RF, the ion source arc, and a beam stop being closed.

The safety interlock and warning system should ensure that no person is in the vault at any time when the cyclotron is in operation. The 'last person out' feature should be incorporated in the safety interlock or administrative controls [see 4.5.2 (v)(c)]

The facility should be equipped with area monitors, various interlocks and audio-visual alarm system. Suitable interlocks should be available to ensure that the cyclotron cannot be operated when radiation shields for self-shielded cyclotron are not in place.

The area should be equipped with devices that will automatically activate visible and audible alarms to alert personnel in the vault area for operation of the cyclotron. The system should allow sufficient time for an individual in the area to operate a clearly identified control device (e.g. SCRAM) which should be present in the area, and which can prevent the initiation of irradiation.

3.4.4 Emergency Control Mechanism

Emergency scram switches or buttons to turn off the cyclotron in emergency situations should be available and must be placed inside and outside the cyclotron vault facility including the control room. All these scram switches should be clearly and conspicuously marked.

The functionality of scram buttons or other emergency power cut-off switches which are located in high radiation areas should be such that it is not possible to restart the accelerator from the control console without manually resetting the cut-off switch.

3.4.5 Conventional Safety

The facility should ensure conventional safety as per the applicable state/central government regulations during design in order to avoid any accident or unsafe situations arising out of equipment failure or operational errors. While obtaining the necessary clearances from various statutory authorities, the safety implication due to radiation generating nature of the facility should be taken care of. This is owing to the possibility of any industrial accident that may have a bearing on radiation safety such as causing spillage of radioactive material or discharges into the environment.

The design of cyclotron should ensure to meet conventional safety requirements as required by relevant authorities. All equipment inside the cyclotron vault including wiring, electrical equipment, lighting, etc. should be selected so as to minimise failure due to prolonged exposure to radiation. The applicable regulatory requirements for conventional safety should be complied with.

3.4.6 Fire Safety

Fire safety is one of the most primary concerns for a medical cyclotron facility as a fire incident may lead to dispersal of radioactivity and contamination of the surroundings. To avoid this, suitable fire safety measures should be available well before the commissioning of the facility.

3.5 Shielded Enclosure

3.5.1 Structural Shielding

The MC should have adequate shielding against both gamma and neutron radiations generated during the operation. At the time of commissioning, the adequacy of shielding against gamma should be duly evaluated employing an appropriate gamma survey meter. Radiation streaming through crevices or discontinuities in the shielding barriers may be checked using gamma monitors. The efficacy of neutron shielding similarly should be evaluated employing suitable neutron monitors during commissioning. Provision should exist to maintain negative pressure in the vault. The ventilation exhaust from the vault should be connected to outer duct directly/ separately.

3.5.1.1 Structural Requirements

The shielding around the cyclotron vault will depend on the type of cyclotron, the energy, types of particles, beam current and the targets to be irradiated. The purpose of the shielding is to reduce the neutron and gamma dose rates not exceeding the applicable dose limit (1mSv for public and 20 mSv for occupational exposure in a year). Adequate structural shielding should be provided for the walls, ceiling and where appropriate, the floor of the vault so that exposure rates outside the cyclotron vault do not result in the dose limits being exceeded. The vault, in case of Type II, Type III and Type-IV MCs, generally requires thicker structural RCC shield and need wider floor space than that of a self-shielded MC.

The vault, in case of a self-shielded MC should provide adequate shield against the build-up radioactivity and prompt radiation emitted during irradiation as well as radiation generated during activation of inner components. Further, due attention should be paid to the following specifications:

(i) The structures, systems and components should be built as per the relevant IS Standard for Earthquake Resistant Structure in force.

(ii) Standard concrete (2.5 g/cc) or equivalent should be used for the cyclotron vault with required thickness to provide adequate shielding.

(iii) The use of boron in the concrete to absorb neutrons should be as boron carbide. The concrete used should be of low alkali grade to minimize activation through neutron capture reactions of vault walls over the lifetime of the facility.

(iv) Cobalt content in the concrete should be kept as low as possible. Hence, the presence of iron or iron rich minerals with the likelihood of cobalt and nickel as additives to the concrete is to be avoided.

(v) Several other chemical elements, normally found in the cement, sand and aggregates used in concrete may become activated when irradiated by neutrons in the vault. The composites used in the concrete should be such as to minimize the activation of the concrete by the neutron flux generated during irradiation of target.

(vi) The concrete used in the vault walls for unshielded cyclotrons, should be built with about 20-30 cm strippable layer or as estimated by design, without affecting the concrete integrity, density etc. There would be build-up of induced activities in the structure of the vaults. At the time of decommissioning the facility, it is recommended that all structure need not to be treated as radioactive. The outer layer up to 30 cm should be stripped off, treated and measured for radioactivity. The management of such stripped material should be based on the activity content.

(vii) The concrete walls should have smooth finish so that they do not become a source of dust and fines on which radioactivity can attach itself and migrate out of the vault. Epoxy surface finish is the standard for clean areas and is suitable for cyclotron vaults. Other fixtures in the vault should be made of corrosion resistant materials, and the

exposed metal surfaces should be treated to prevent corrosion wherever possible. The vault passage should be of sufficient width to take material and equipment in and out of the vault.

(viii) For the vaults housing unshielded cyclotrons, a maze type structure or a plug door should be provided with sufficient shielding to attenuate the gamma and neutrons to acceptable exposure levels at the entrance door. To protect against neutrons that may stream through the maze, doors provided with neutron shielding (e.g. rigid steel shells filled with low mass number material such as polyethylene), as required, should be fitted on hinges at the entrance to the maze and also at the entrance to the vault.

(ix) The vault door may be made up of sufficiently thick High Density Polyvinyl Ethane (HDPE) sandwiched between layers of lead of adequate thickness.

(x) Inside the vault, there should not be any water leakage, seepage and/or clogging from rain water or from any other source of water.

3.5.2 Control Room

A control room for operation of the MC should be located near the access to the room/vault housing the MC. The display units of all online monitors and status of ventilation and exhaust systems should be available at the control desk or visible from the control desk. Provisions should be made for storage of the radiation measuring and monitoring instruments inside or near to the control room. Access to cyclotron vault should be under visual surveillance (e.g. CCTV) from the control room for taking prompt action (circuit breaker, scram button etc.), when required.

3.5.3 Conduit/Opening (Access of Control cables and Utility lines to Vault)

There is need for providing openings/conduits to the vault from outside to accommodate power cables, control cables, HV ducts, water and gas supply lines. These are brought into the vault either through wall penetrations or via trenches. It should be ensured that for such openings/conduits following provisions are duly satisfied:

(i) Penetrations for power cables, cooling water lines, ventilation and air-conditioning, transfer of radioactive material, etc., into the vault should so be designed that exposure levels in the occupied areas are within the applicable regulatory limits.

(ii) Penetrations in the vault walls should preferably have S bends to prevent direct streaming of radiation. In addition, the gaps between the cables and tubing should be filled with high density polyethylene balls and a layer of lead wool or iron balls.

(iii) Floor trenches are required as conduit for chilled water supply, electric cables, communication cables and the passage of radioactive products from the target to the hot-cells in the radiochemistry lab. The trenches should be adequately covered to facilitate easy servicing, taking into account any possible seepage of radioactive material into the trench. Further, if the trenches are passing under the walls of the vault to the outside, then they should be covered with attenuating/absorbing material and angled in such a way as to prevent direct streaming of neutrons and gamma radiation. Trenches can accommodate larger cables than wall penetrations and are, therefore, preferred for heavy power cables, large water lines, and other utilities which require considerable space. Trenches should be separated based on their function. Power cables should be run in separate trenches from control and signal cables, and the water should be run in a separate trench for the electrical cables.

3.5.4 Door interlock

Suitable interlocks should be available to ensure that the cyclotron cannot be operated when vault doors are not closed properly.

(i) The entry of personnel into the MC vault area or target caves should be through access door(s) having adequate shielding and equipped with fail-safe interlock switches. These interlock switches should be such that any accidental or wilful opening of the access door would stop or trip the MC.

(ii) Suitable interlocks should be provided in the door of a self-shielded cyclotron and in the vault door of an unshielded cyclotron, to ensure that when radiation shields are not in place or vault doors (unshielded cyclotron) are not closed, the cyclotron cannot be operated.

(iii) Zone monitors located outside the vault door and target cave(s), should be interlocked in such a way that it will cause the cyclotron to trip, when in operation, if the dose rates outside the vault exceed 10 µSv/h.

(iv) Zone monitors inside the vault of an unshielded MC, and the target cave(s) should be

interlocked to the vault/cave door so that they cannot be opened unless the level falls to permissible levels for workers to enter the vault.

3.5.5 Audio-Visual Indicator

Indicators that warn of start-up conditions of the cyclotron like switching 'ON' of the magnet and the radiofrequency power and the beam, should be located at the entrance and inside the cyclotron vault / room. In case of Type III & IV cyclotrons, the target caves should also have safety indicators at the entrance and inside of the cave. The warning light and beacon should be interfaced with the cyclotron controls to provide visible and audible indication of the cyclotron beam "ON" condition.

3.5.6 Radiation Zone Monitor

Appropriate radiation gamma area zone monitor(s) should be installed at a location near the entrance to warn about the presence of radiation during the operation of the MC and to prevent unauthorized entry to the radiation area. Further, wherever radioactive sources are handled in an enclosure, an appropriate area zone monitor should be provided outside the entrance of the controlled area.

3.5.7 Radiation Warning Sign and Radiation Symbol at Entry point

Appropriate radiation symbol as per the directive issued by AERB (Appendix- 2) should be posted conspicuously and prominently at the entrance of the cyclotron vault and at the entrance of the controlled and supervised areas. A legend in Hindi, English and local language(s) indicating radiation hazard and restrictions on unauthorized entry should also be posted near the radiation symbol. The dimensions of the symbol and legends to be used in the warning sign should be as per the said directive. There should also be warning signage for high voltage, magnetic field and radio frequency.

3.5.8 Ventilation Requirements

The air flow pattern in a MCF is one of the most critical parameters to control airborne contamination. The air handling requirements for radiation protection and radiopharmaceutical manufacture are often at odds with one another. For example, to reduce the chance of the spread of contamination, the flow of air in a hood or hot-cell should be

away from the personnel and up the exhaust stack. In contrast, maintenance of pharmaceutical quality of the products requires air flow out of the hood, away from the product and towards the personnel. To prevent the spread of contamination, the air flow should always be designed so that the cyclotron vault is at the lowest pressure in the building, and the hot laboratories are at slightly higher pressure and the surrounding public areas are at the highest pressure. On the other hand, the area where vials are prepared and product is dispensed is typically a clean room with specified air particle quality and it needs to be at higher pressure than its surroundings. Furthermore, the area in immediate contact with the open product vials is the most critical and should be controlled for achieving the highest quality of air. An additional requirement for air flow is the number of air changes in unit time, particularly in the clean rooms and hot-cells. Therefore, the air flow patterns must be engineered to accommodate these opposing requirements.

In the design of an MCF, regardless of the type of facility, the following requirements should be complied with:

(i) The ventilation system should be provided in such a manner that the air-flow should be from a low-activity area to a potentially high activity area.

(ii) It should also prevent microbial contamination to the areas where radiopharmaceuticals are produced and dispensed. Both goals should be achieved by proper design.

(iii) The cyclotron vault should be at the lowest pressure in the building, and also the location from where the air from the premises should be exhausted.

(iv) Ventilation in a cyclotron vault should be once through with filtered, cooled and dehumidified air. The air flow should enter the vault near the entrance and exhaust from the opposite end ensuring required air changes.

(v) Exhaust air should be passed through a filter bank consisting of pre-filter, HEPA filters and Charcoal filters before releasing through a stack situated on top of the highest location in the building.

(vi) The radiochemistry area should be supplied with HEPA-filtered high pressure air vis-à-vis the QC-labs and the cyclotron vault.

(vii) The hot-cells inside the R&R area should be maintained at a lower pressure than the surroundings and should have a separate inlet air that is HEPA-filtered. The hot-cell exhaust should be filtered through activated charcoal filters before release through the stack mentioned above in (v).

(viii) The height of the stack and/or the estimated diffusion pathway(s) of the stack-exhaust from the MCF should be such that it will not result in public exposure beyond the limits prescribed by AERB.

(ix) Another critical aspect in designing an MCF is the number of air-changes in the premises. The air pressure gradient would be in the opposite direction to the dose rate gradient, as shown in Figure-3.1.

4. OPERATIONAL SAFETY

4.1 General

Operational safety plays a major role in ensuring radiation safety as it is not always possible to have engineering controls to address all safety issues. In order to deal with operational safety, appropriate manpower with adequate knowledge of radiation safety and appropriate operating and maintenance procedures, compliance with safety requirements and availability of the necessary infrastructure are important. A well-designed facility as per stipulated requirements ensures a high level of safety. In order to sustain the high level of safety, it is essential that operation and maintenance of the MCF are carried out as per well established procedures as recommended by manufacturer consistent with the regulatory requirements.

The facility should have an appropriate organizational set up with well-defined line of command and responsibilities. All administrative controls through policies and procedures indicating local and regulatory safety rules should be conspicuously displayed in the MCF in English, Hindi and the local language.

This section describes the requirements to be followed to ensure radiation safety during the operation and maintenance of MCF.

4.2 Manpower Requirement

Adequate number of qualified persons required for ensuring radiation safety should be employed in an MCF to ensure that facility is operated with the required number of radiation workers (certified operators) in every operational shift and an RSO. The number of staff members and their qualifications should be in compliance with the requirements prescribed by the relevant authority specific to each practice. However, in the absence of such prescribed requirements by relevant authority, the suggested provisions are given in Appendix-III. All the radiation workers and the designated RSO should fulfil their roles and responsibilities for safe work practice.

4.2.1 Radiological Safety Officer (RSO)

The employer of the MCF should designate Radiological Safety Officer(s) (RSO) with the approval of AERB. The qualification and radiation safety certification for RSO should be as given in Appendix-III

For each authorized MCF, at least one RSO should be available to ensure compliance with the requirements specified in the AERB Safety code on 'Radiation sources, equipment and installations' (AERB/ RF/SC/2022).Where more than one person has been designated as the RSO of a facility, the duties and responsibilities of each RSO should be well defined. Each RSO should have a valid certificate from AERB.

The RSO should provide safety coverage during the operation and maintenance of the MCF.

4.2.2 Manpower Requirements for Suppliers of MCF Equipment

Suppliers of an MC should employ/engage qualified and trained personnel as Service Engineers for performing QA checks and servicing and maintenance of the equipment. The minimum qualification and training of persons who may be authorized to perform should be as prescribed by AERB. The persons involved in these activities are considered as radiation workers and should comply with the duties and responsibilities of radiation workers as stipulated in the Safety Code for Radiation Facilities (AERB/RF/SC, 2022) and elaborated in this safety guide.

4.3 Trainees

Persons undergoing training or apprenticeship in an MCF are required to do so under the direct supervision of trained radiation professional. The dose limits for trainees above 18 years of age is the same as those for occupational radiation workers. In case of trainees/students/apprentice between 16-18 years of age it should be ensured that their radiation dose does not exceed 6 mSv in a year. Trainee/students/apprentice below 16 years of age should not be taken for training in radiation related work.

4.4 Monitoring, Protection and Safety Tools/ Accessories

4.4.1 Personnel Monitoring

All workers and trainees entering the controlled areas should be covered by personnel monitoring services. These personnel monitoring badges should be worn by radiation workers for external radiation dose measurements. In addition, the facility should also have

sufficient numbers of Direct Reading Dosimeters (DRDs)/ Digital Pocket Dosimeters with alarm for immediate information on personnel exposure. These should be issued to radiation workers and to the service/maintenance personnel whenever required, in addition to personnel monitoring badges while working in the radiation areas. Proper use of the dosimeters should be ensured by the RSO. The readings of the DRDs should be maintained in a logbook. Wherever appropriate, extremity dose measurement using wrist badges should also be undertaken.

The institution should ensure that the workers use the TLD properly. TLD badges should be returned at the beginning of every monitoring period to the TLD service providing agency.

Dose records should be maintained by the radiation facility. The licensee (employer) should furnish dose records to each worker in his employment annually and as and when requested by the worker.

To ensure that the Dosimeters (TLDs/ DRDs) provide an accurate assessment of the dose to the radiation workers, the following guidelines should be followed:

(i) TLDs should be worn by workers at all times when carrying out any work with radiation.

(ii) Dosimeters should be worn in accordance with recommendations from the PM Service provider and RSO.

(iii) For TLDs, the TLD card should be correctly positioned in the badge holder.

(iv) The dosimeter should be worn only by the person to whom it is issued.

(v) Dosimeters can be sensitive, and care should be taken to avoid damaging its measuring element (e.g., dosimeters can be damaged by water, high temperature, high pressure and physical impact).

(vi) TLDs should not be exposed to radiation when not being worn by workers (the dosimeter should be stored in an area away from radiation sources).

(vii) TLDs should be promptly processed by the dosimetry service in case there is suspected exposures in excess of investigation levels (i.e. currently radiation dose in excess of 15 mSv in one monitoring period i.e three months).

(viii) The AERB and PM service provider should be informed if the MCF suspects that the dosimeter has been damaged or has been exposed to radiation while not being worn.

(ix) Detailed instructions for proper use of TLD are given in AERB website (https://aerb.gov.in/english/aerb-advertisement).

4.4.1.1 Investigation of reported Excessive Exposure cases

In order to ensure that radiation dose to the workers does not exceed the dose limit, an investigation level of 15mSv in a given monitoring period is recommended. The monitoring period for an MCF is quarterly. If the dose recorded by the personnel monitoring badge of a worker exceeds the dose constraint value mentioned above, the licensee should submit an investigation report to AERB together with a statement from the worker reported to be excessively exposed. In case the reported dose is greater than 100 mSv, biological dosimetry such as chromosomal aberration (CA) test of the individual should be conducted, if so directed by AERB to ascertain/determine the genuineness of the dose.

4.4.2 Personnel Protective Equipment

Radiation workers while entering the R&R area should use appropriate PPE such as coveralls, gloves and goggles, to prevent any personal contamination while handling radioactive sources. Similarly, the maintenance personnel of the MCF/ hot-cell should also use appropriate personnel protective clothing to prevent personal contamination.

4.4.3 Radiation Monitoring Instrument

Appropriate contamination monitors, gamma radiation survey meters and gamma zone monitors should be available at relevant locations in an MCF (e.g. inside the vault, outside vault door, control room etc). The survey meters should be capable of measuring dose rates over the range of 0.1 µSv/h to 1 Sv/h. Further, suitable zone monitors with audio signals should be available in the facility. The workers should check themselves for contamination before leaving the premises and contamination monitors should be available at the decontamination room and at the exit of the R & R area.

4.4.3.1 Calibration of Instruments

Only instruments having a valid calibration certificate should be used for the dosimetry and monitoring purposes and the records of calibration should be maintained. The radiation and contamination monitoring instruments should be calibrated by accredited calibration laboratories once in two years unless otherwise specified and immediately after repair. A certificate of calibration should be obtained from the calibration facility.

4.4.3.2 Periodic Checks of Measuring Instruments

All instruments such as area monitors and contamination monitors should be checked with a calibrated ^{137}Cs reference/check source of known activity. The checks should be carried out by selecting a particular fixed measuring geometry. The instrument reading observed in this geometry should be noted and be kept for future reference at the time of performance check of the instrument. Performance check can be made at any time by placing the check source in the same fixed geometry and comparing the reading/result with the reference reading. If the check reading varies considerably from the expected reading, the instrument should be sent for servicing and re-calibration. These checks should be carried out soon after purchase and after every calibration or repair of the instruments. Radiation safety devices should be routinely checked by check sources, at least once in a month.

4.4.4 Measuring Instrument

Measuring instruments such as dose calibrator and those used in QC should be maintained in good working condition with valid calibration.

4.4.5 Handling Tools

All the tools used for handling the radiation sources should be available in the MCF so that adequate protection can be achieved without hampering convenience and speed of operation. Appropriate protective equipment, such as shielded L-bench, shielded threaded blocks, lead pots, long handled tools and forceps, should be used for handling the sources. In no case, the sources should be handled directly with hands. Every individual source should be identifiable by suitable means.

Equipment and tools used for work with radioactive materials should not be used for other purposes and should be surveyed for potential contamination prior to removal from the lab.

4.4.6 Mobile Shield/L-Bench

The L-bench (an L-shaped block of lead of appropriate dimensions and shielding fitted with lead glass of appropriate lead equivalent thickness) should so be so designed as to provide adequate protection for the person using it, under normal working conditions. Mobile shield of adequate thickness may also be used as a protective barrier.

4.5 Operation of Radiation Equipment/Sources

Prior to operation of the MC, the licensee should ensure that necessary safety provisions are in place to offer adequate protection to the worker and public around the radiation installation and also to the environment. The machine operator should be familiar with all the safety features of the radiation equipment to ensure that the dose received by workers and public is within the prescribed limits.

The personnel involved in handling the radiation sources should be duly trained in the equipment-specific operational safety, radiation safety in general and management of radiation emergencies. Further, the personnel should follow the radiation safety procedures, carry out routine maintenance of the MC as may be specified by the manufacturer of the MC and be periodically retrained and updated on aspects related to radiation safety. These measures would be necessary to ensure that the exposures received by them are well within the regulatory limits. The licensee should obtain, from the manufacturer/supplier of MCF and associated processing systems, necessary information and support to evolve and institute standard operating procedures for the MC and all the radiochemical works. This should include the various features and requirements for ensuring radiation safety in all the practices at the MCF. The latter should be available with the RSO among other stakeholders and the RSO should ensure appropriate dissemination and its familiarisation among the personnel engaged in radiation work at the MCF.

4.5.1 Work Area Zoning

Access to the work areas should be regulated by categorising the areas into different zones. Access control gates should be put at inter-zone boundaries where entry of persons authorised is suitably regulated e.g., biometric or magnetic card. Every work area in an MCF should be categorized into one of the following zones:

(i) Zone- 1: Normal Area of Full Occupancy

These areas should be accessible all the time and irrespective of whether accelerator beam is in OFF, STANDBY or ON mode. These include places such as- corridors and passages, plant process equipment rooms, cold chemistry and storage areas. The radiation shielding should be designed so as to ensure that the radiation dose rate in such areas at any time does not exceed 0.5 μSvh^{-1} for full occupancy and 1 μSvh^{-1} for partial occupancy.

(ii) Zone-2: Controlled/Restricted Entry Area

These areas are accessible during beam ON mode with appropriate administrative controls in place. Appropriate area monitoring and personnel radiation monitoring should be provided for workers visiting these areas during beam ON mode. In these places, the dose rate during beam 'ON' may exceed 1 μSvh^{-1} but should not exceed 10 μSvh^{-1} so that personnel can work for no more than eight hours per day in such places. If dose rate in any location in zone-2 exceeds 10 μSvh^{-1} then facility should investigate the cause and based on the investigation should take appropriate action i.e. either to restrict the access to particular location or reduce the dose rate. No maintenance work during beam 'ON' mode should be undertaken without a radiological work permit.

(iii) Zone-3: Inaccessible Areas

Areas, having high dose rate i.e. exceeding 100 μSvh^{-1} during beam ON mode should be designed and engineered with safety interlocks and access/ administrative controls to exclude access and/or breach of safety during beam STANDBY/ON mode.

No maintenance work during beam 'OFF' mode should be undertaken without a radiological work permit.

Only authorised persons should be allowed to enter zone-2 and zone-3 areas and when so allowed they should wear appropriate personnel radiation monitoring devices.

4.5.2 Operational requirements of Medical Cyclotron

The following requirements should be duly fulfilled before the operation of the MCF:

(i) The machine operator of an MC should be trained and experienced in its operation.

(ii) Before operating the MC, the machine operator should ensure that all the interlocks and circuit breakers are in place and functional. The machine operator should undertake search and secure operation to ensure that no person is present inside the vault/bunker before closing the door. No person should be allowed inside MCF without the knowledge of the RSO of the facility.

(iii) The MC should be operated only after obtaining a licence for operation from AERB and the licensee should adhere to the conditions stipulated therein.

(iv) There should be a well-established program pertaining to training and qualifying the machine operator. The cyclotron should be operated only by such qualified and trained machine operators.

(v) The cyclotron should be operated as per the Standard Operating Procedure issued by the manufacturer which may include among others

a) The established operational sequence to ensure safe operation.
b) Monitoring and control of critical operational parameters at specified frequency.
c) A “Search and Secure” procedure to be conducted before closing the vault door and prior to starting cyclotron operation to prevent the trapping of any person in the hazardous area.
d) Procedure for prevention of possible incidents/emergency situations and follow-up actions.

(vi) All personnel should undergo an appropriate radiation safety orientation programme including emergency response plans. A Radiation Protection Programme (RPP) should be prepared by the licensee in consultation with the RSO and the radiation safety requirements specified in the approved RPP should be duly implemented.

(vii) Dose rate measurements in and around the MCF before, during and after the routine operations should be conducted periodically by the RSO and record of such survey should be maintained.

(viii) Transfer of produced radioactive material to the intended hot-cell should be ensured by the machine operator while keeping the radio-pharmacist duly informed. The safe transfer of radioactive material from the cyclotron to the radiochemistry module should be undertaken through proper communication between the operator and radiochemist. It should only be transferred after ensuring that the shielding doors of the hot-cells, chemistry and dispensing modules are firmly closed and negative pressure inside the module is confirmed.

(ix) There may be rare instances which demand safety/ interlock systems to be bypassed. Such justifiable bypass can only be carried out with the approval of the licensee and under the direct supervision of the RSO. Bypass of interlocks should be permitted only under carefully controlled and monitored conditions. The interlock should be restored immediately after serving the justifiable purpose for which it was bypassed.

(x) Entry into the target cave should not be allowed if the dose rates inside are above permissible levels, e.g., after irradiation, until the radioactive target is safely transported into the hot-cell for processing or stored for cooling.

(xi) Incidents (including bypass of interlocks / safety systems) should also be recorded in the logbook during the daily runs and the same should be reported to AERB.

(xii) Periodic maintenance as may be specified by the OEM/supplier of MC, at regular interval, and repair work as necessary should be undertaken. Use of spare parts and accessories meeting original specifications is very important from radiation safety standpoint. Any replacement parts should also meet original safety specifications. Such work should be carried out by service engineers (trained by OEM) authorised by the supplier/manufacturer and recognized by AERB

(xiii) A MC should not be operated if it is malfunctioning or any safety interlock is defective or the hot-cell and/or the radiochemistry and dispensing module is/are defunct.

(xiv) Repair and maintenance work should be carried out under the supervision of the RSO of the MCF. There should be a provision for a shielded container in Cyclotron vault,

for interim storage of radioactive waste generated during processing of targets including Havar Foils & Target Foils.

(xv) Spillage of radioactive material should be attended to as per the guidelines mentioned in facility's emergency preparedness document. The waste generated in the decontamination process should be treated as radioactive waste and disposed of as per the guidelines given in section 4.8.1 of this Guide.

4.5.3 Operational safety requirements of Radio-pharmacy & Radio-chemistry lab (R&R lab)

The following requirements should be in place in the R & R lab:

(i) The preparation and dispensing of radiochemicals and radiopharmaceuticals should be carried out by trained and qualified workers, duly authorised by the licensee.

(ii) All radiation workers including radio-pharmacists and radio-chemists should undergo an appropriate radiation safety orientation programme including emergency response plans. It should be ensured that the hot-cells are operated in compliance with SOP meeting the radiation safety requirements. Hot-cells should not be used beyond their design capacity for handling of radioactive isotopes. All radioactive materials should be stored/handled only in specially designated areas equipped with the necessary safety infrastructure to carry out such operations.

(iii) Standard Operating Procedure should be available and followed for various activities in R&R area

(iv) An inventory of all radioactive materials should be maintained by the facility and all radioactive sources and their activity should be accounted for. Any disposal of radioactive waste generated from operation of the facility should be made in accordance with the norms set by AERB.

(v) Visual display of the pressure, or the pressure differential value, should be in place.

(vi) Adequately shielded containers should be used for transfer of radio-chemicals and radiopharmaceuticals from R & R lab to QC lab.

(vii) During QC testing, proper radiation safety measures should be ensured as mentioned below:

a) The transfer of syringe containing radioactive material should be undertaken in a shielded syringe carrier.

b) All persons, tools and gadgets involved in QC procedures should be monitored for any detectable contamination and appropriate measures should be implemented for decontamination, when required.

c) Samples collected for Quality Control should be handled in a safe manner in a fume hood / or behind an L-bench as the case may be and the sample should be disposed in a safe manner.

(viii) All personnel in the clean room or the Hot Lab during radioisotope processing operations must monitor their hands and feet before leaving the facility. If contamination is found, decontamination procedures must be followed.

(ix) Handling of waste should be as per procedures specified in the Radiation Protection Manual. There should be a provision for a shielded container, for interim storage of radioactive waste generated during processing of solid targets in R&R lab.

4.5.4 Radiation Surveillance

Monitoring of dose and dose rates and measurement of contamination levels are essential components of any radiation protection program. Such monitoring includes:

(i) Area monitoring, i.e. measurement of radiation dose rate at various points in areas, rooms or enclosures where radioactive materials are produced/handled.

(ii) Contamination monitoring, i.e. measurement of contamination levels in all areas, rooms or enclosures where unsealed radioactive materials are used or stored.

(iii) The licensee should submit a safety status report to AERB once in 6 months. The safety status report should briefly provide information about the functioning of the MCF including any maintenance and servicing carried out during the reporting period. The safety status report should include particulars about any incidents during the relevant period and the response actions implemented.

(iv) Personnel monitoring, i.e. measurement of the total dose received by individual radiation workers over a period of time. The total dose includes external dose and internal dose to the radiation worker. External dose is assessed using personnel monitoring badges. Internal dose needs to be assessed in certain situations where worker might have inhaled/ ingested radioactive material.

(v) Management and surveillance of radioactive waste is also required. .

(vi) In special situation (e.g. excessive exposure or an incident involving radioactivity), when an incident occurs and ingestion/incorporation of radioisotopes is suspected, internal burden should be determined in case of radioisotopes ingested or inhaled by the user accidentally.

4.5.4.1 Area Monitoring

The objective of area monitoring is achieved through -

(i) Installation of gamma radiation area monitoring devices with audio-visual alarm in areas that can have continuous occupancy and where dose rates are likely to change based on the operation of the facility.

(ii) The area monitors should have appropriate pre-set alarm conditions depending on their location in the facility.

(iii) Low and high range gamma radiation survey instruments, and contamination monitors should be available for measurement of ambient radiation fields.

(iv) A portable air sampler may also be made available at the facility to collect air samples for measurement of airborne activity.

(v) The gamma dose rate outside (around) the MCF should be measured periodically (at least once a week) and records maintained.

(vi) Neutron shielding evaluation of structure should be carried out at the time of renewal of licence and at the time of any maintenance/modification having impact on radiation shielding.

4.5.4.1 Contamination Monitoring

(i) Hand and foot monitor should be provided at the exit of the controlled area. Portable Contamination Monitor should also be provided to detect the presence of any radioactive contamination on the skin, body, personnel protective clothing, personal clothing, footwear etc inside the controlled area.

(ii) In case of spillage of any radioactive material, the presence of loose/transferrable contamination on any work surface should be evaluated either by direct survey or taking a smear/swipe sample for counting.

(iii) Periodic monitoring for possible contamination should be carried out in the cyclotron vault (depending on accessibility), radiochemistry and QC laboratories.

(iv) Provision of instruments and facilities for decontamination, for both equipment and personnel, should be made.

Contamination should be promptly addressed through proper decontamination procedures. Decontamination kit – comprising appropriate agents for decontamination, mops, containers for collection of waste arising from decontamination activity should be available in the MCF premises for use when required.

4.5.4.1 Recordkeeping

4.5.4.3.1 RSO of the MCF should maintain a log of the following data:

(i) Radiological Survey Data of the MCF including the results of area monitoring and contamination monitoring.

(ii) Personnel Dose Records including DRD's data.

(iii) Unusual Incidents and Occurrences Record.

(iv) Radioactive Waste Storage and Disposal Record.

(v) Preventive Maintenance Procedures of the MC and its components.

(vi) Details of Operation of the Cyclotron and R &R lab.

(vii) Release of radioactive gas through stack on daily basis.

4.5.4.3.2 The Licensee should keep a record of the following particulars with date:

(i) Total activity of Radioisotope Produced per Batch of Irradiation.

(ii) Total activity of Radiopharmaceutical Synthesized per Batch of Synthesis.

(iii) Total number of consignments dispatched with activity content.

(iv) Particulars relating to the consignees (name, address, reference of the authorization issued by AERB to receive the radioisotope being supplied).

(v) Details of waste generated and its management.

4.6 Source Location and Storage

4.6.1 Premises/Location for Source Handling

Radioactive source produced in the cyclotron should be handled only in the premises (radiochemistry lab and QC lab) approved by AERB. If there is a change in the location of the source handling facility, prior approval of AERB should be obtained.

4.6.2 Transfer/Supply of Radioactive Source

A licensee should transfer/supply radioactive source only to a person authorised by AERB. In respect of such supplies prior permission from AERB should be obtained by the licensee. The licensee should also receive consent and authorisation letter from the authorised person for procurement of radiopharmaceuticals before initiating or resuming supply. Details of such transfer including identity of radionuclide, total radioactive material transferred/supplied over a specified period and the persons to whom such supplies were made should be included in the periodic safety report to AERB.

4.6.3 Safe and Secured Storage

The following requirements should be fulfilled for safe and secure storage of radioactive sources:

(i) All radioactive material should be kept in adequately shielded containers that are marked with appropriate radiation warning signs and display a label indicating the name of the radioisotope, its activity, date and time of the assay of the activity.

(ii) The storage area also has to be identified with proper radiation warning sign if, (i) more than 100 exempt quantities of a radioactive substance are stored in the area, or (ii) if there is a reasonable probability that a person in the area will be exposed to an effective dose rate greater than 10μSv/h.

(iii) The storage location or facility must have sufficient shielding to reduce the dose rate not exceeding 10 μSv/h in areas accessible to radiation workers only, and to a level not exceeding 1 μSv/h in areas accessible to other persons.

(iv) It is strictly forbidden to store or to consume any kind of food or beverage in an area where radioactive material is used or stored.

(v) The storage facility must be fireproof.

(vi) Gaseous radioactive materials should be kept in a fume-hood having adequate ventilation.

4.6.4 Emergency Storage Container

Not applicable for this Guide

4.6.5 Source movement within the facility

Not applicable for this Guide

4.6.6 Security of Radioactive Material

The licensee should be responsible for providing adequate physical protection measures in respect of the radioactive sources in the possession of the MCF. The cyclotron vault and other associated facilities handling/containing radioactive materials should be kept under access control and in the custody of the licensee.

4.6.6.1 Security of Sources

The licensee of the MCF is responsible for the safety and security of the source(s) (check sources, damaged / replaced targets and foils with induced activity kept in shielded container / waste pit for physical decay) and other radioactive materials in possession with the facility. The employer should ensure that appropriate measures for security level D as mentioned in Security of Radioactive Sources in Radiation Facilities', Safety Guide No. AERB/RF-

RS/SG-1, (2011) are implemented for the sources in the MCF all the time. The security measures should include the following salient features:

(i) General administrative measures

(ii) Quarterly accounting

(iii) Routine measures to ensure safe use and protection as an asset.

A detailed Security plan should be prepared as per the format prescribed in the Safety Guide on 'Security of Radioactive Sources in Radiation Facilities', Safety Guide No. AERB/RF-RS/SG-1, (2011) and submitted to AERB along with the Preliminary Safety Assessment Report (PSAR) while applying for licence.

4.6.6.2 Security during Transport

The Consignor of the radioactive material is responsible for security during transport of the source(s) supplied by him. The Licensee (employer) should ensure that appropriate measures for security level 2 – basic security measures [Security of Radioactive Material during Transport', Safety Guide No. AERB/NRF-TS/SG-10, (2008)] are implemented for transport of the source(s) forwarded by the facility.

The responsibilities of the various agencies involved in ensuring the security of the source(s) should be clearly defined in the security plan prepared by the licensee and the concerned agencies and the concerned individuals should be duly informed thereof.

4.6.7 Source Handling in other's Premise/Facility

Not applicable for this Guide.

4.7 Safety Checks, Quality Assurance and Maintenance

It is the responsibility of the Employer to carry out health surveillance of all radiation workers in the MCF. It includes provision and maintenance of plants and systems of work in the workplace that are safe for the use, handling, storage and transport of hazardous material; and monitoring of the work environment. For this purpose, the employer should ensure that, in addition to radiation surveillance (covered in section 4.5.3), regular safety checks are carried out to ensure all safety features / systems are functioning. There should be a preventive maintenance programme established to prevent failure of any system /

components due to wear and tear. The appropriate Quality Management System should be in place for all operations of the cyclotron as well as handling of radiopharmaceuticals. The management of quality in the finished product and integration of the internal policies and procedures of the organization are achieved through a well-defined and executed quality management system (QMS).

4.7.1 Safety Check

For each safety system such as fail-safe mechanisms, interlocks, pneumatic systems, emergency stop buttons, radiation monitoring systems and others, the frequency of periodic checks should be established, keeping in view the nature and probability of failure. The safety checks should be carried out at least once in a month and records thereof should be maintained. In the event of detecting a malfunction in the MC, it should not be operated till it is rectified.

4.7.1.1Safety Checks for Cyclotron Operation

(i) Each day at the start-up of the cyclotron, an operational check should be made of interlocks, fixed monitors and warning devices.

(ii) All bunkers used for housing targets for extended beam lines in case of a Type IV facility should have Search and Secure facility interlocked with operation of the cyclotron.

(iii) Before the cyclotron vault is secured and irradiation begins, the target system and/or experimental arrangements should be inspected for conformity with approved safety practices, and the vault cleared of all personnel.

(iv) Entry into the cyclotron vault should not be permitted without the approval of the cyclotron operator.

(v) Vault areas, to be occupied for extended periods by personnel, should be monitored with portable survey instruments prior to entry.

(vi) At least two cyclotron lab staff members should be present when the cyclotron is operated or radioisotopes are processed/handled in the Hot Lab.

(vii) The interlock system requires that the cyclotron operator actually carries out the search operation inside the vault and manually resets the interlock system. This operation ensures that the operator has physically ensured clearance of personnel before

proceeding with beam generation. The interlock should be fail-safe so that the machine is immediately shut down, if any one of the interlock switches is interrupted.

4.7.1.2 Safety Precautions for Handling of Radioactive Materials

(i) Lab coats or other protective clothing should be worn when handling radioactive material, or working in an area designated as a controlled area where work with Radioactive Material (RAM) is carried out.

(ii) Disposable gloves should be worn when handling RAM.

(iii) Personnel should not eat, drink, smoke, store food, or mouth pipette in areas where RAM is used or stored.

(iv) Careful experimental planning, dry runs, shielding, observing careful distance, and monitoring should be required for minimizing exposure.

(v) RAM should be used, stored, and transported in appropriate containers.

(vi) The facility should be secured at all times against unauthorized entrance.

(vii) All Gloves and other Personal Protective clothing & Equipment should be stored Inside the MCF pending disposal.

4.7.2 Tests for Quality Assurance

Tests for Quality Assurance of radiopharmaceutical produced has to be carried out as per the National / International standard.

4.7.3 Servicing and Maintenance

In order to maintain reliability of performance of the cyclotron and associated sub-systems, periodic servicing and maintenance should be carried out throughout the lifetime of the equipment. The servicing of the equipment should be done under the supervision of RSO by person(s) who has been trained (by OEM), authorised by the supplier/manufacturer and recognized by AERB. The periodicity of servicing should be as prescribed by the manufacturer of the equipment. In medical cyclotron, use of spare parts and accessories meeting original specifications is very important from radiation safety standpoint. Any replacement parts should also meet original safety specifications. Licensee should arrange

that after servicing and maintenance, the equipment performance is verified as per the manufacturers' recommendations/licensee QA protocols prior to using the equipment.

The following requirements should be duly fulfilled for maintenance of MC:

(i) A programme of scheduled maintenance, followed by safety inspection, should be established, implemented and documented for the MC and its associated safety systems.

(ii) All planned or breakdown maintenance activities, should be carried out by trained personnel duly authorised by the Licensee.

(iii) The RSO should ensure that all maintenance activities are carried out in compliance with radiological safety requirements.

(iv) All personnel accessing the cyclotron vault area during maintenance should be provided with Direct Reading Dosimeters in addition to any other personnel monitors provided to them by the employer. The dose received by them during the maintenance work should be recorded.

(v) The licensee should be notified of any modifications that are proposed to be made in the system during maintenance. The licensee should evaluate any implication on operational safety before carrying out the said modification.

(vi) The licensee should seek prior permission from AERB for any design changes in the cyclotron and its associated safety systems.

(vii) Before re-starting the cyclotron, suitable changes, if warranted, in the standard operating procedure should be effected.

(viii) The safety interlocks must be tested at least once in a month to ensure that they are functioning as designed.

(ix) Warning devices, both audio and visual signals, should be inspected and tested at least once in a month to ensure that they are functioning properly as per the design intent.

(x) Routine checks of the safety systems should be carried out once in a month. Any malfunction or deviation from the intended response should be corrected before re-starting the MC.

(xi) Records relating to all maintenance work carried out on the MC as specified above should be maintained and made available to AERB, whenever required.

4.7.3.1 Maintenance of Target and Target System

General Requirement for Maintenance of the Targets

(i) The composition of induced activity in the target should be identified, evaluated and allowed to decay to levels sufficiently low to carry out maintenance work without exceeding the regulatory limits for individual exposure. The radioactive parts of the target should be handled with care and stored to allow for decay or disposed of properly.

(ii) Targets should be maintained after the specified number of hours of usage as prescribed by manufacturers.

(iii) Maintenance should be carried out behind a suitable shielding and lead-glass window. The work should be done in a suitably defined area with adequate control to ensure that there is no inadvertent spread of radioactive material.

(iv) Havar foils should be replaced periodically as a part of preventive maintenance.

(v) All the material used for cleaning the target, viz., solvents, solutions, absorbent paper, brushes etc., should be properly stored and disposed of as radioactive waste. Equipment such as the sonicator, which is used to clean the target and ion-source parts should be used exclusively for this purpose only.

(vi) In case of target foil rupture, the radioactive foil pieces should be carefully retrieved from the cyclotron tank, vacuum pump oil etc., and disposed of as per the procedure specified in this safety guide.

(vii) Records relating to all maintenance work carried out on the target as specified above should be maintained and made available to AERB, whenever required.

4.7.3.2 Maintenance requirements of Radio-chemistry and Radiopharmaceutical Lab

(i) A programme of scheduled maintenance followed by a safety inspection should be established, implemented and documented for the hot-cells and transfer lines and its associated safety systems.

(ii) All planned or breakdown maintenance activities, should be carried out by trained personnel duly authorised by the Licensee.

(iii) The RSO should ensure that all maintenance activities are carried out in compliance with the radiological safety requirements.

(iv) Safety interlocks must be tested at least once in a month to ensure that they are functioning as per the design intent.

(v) Records relating to all maintenance work carried out as specified above should be maintained and made available to AERB, whenever required.

4.8 Management of Disused Source/Decommissioning of Equipment

4.8.1 Management of Disused Sealed Radioactive Source

Check sources are used in an MCF and these are sealed sources. Hence, for safe management of disused sealed radioactive sources, the licensee should–

(i) return the radioactive source(s) to the authorized disposal agency for safe disposal in compliance with the transport regulation;

(ii) check the objects, which were in contact with the source(s) for contamination and in case of contamination, separate out the contaminated objects and send them back to the disposal agency for safe disposal in compliance with the transport regulation and

(iii) monitor the area where the sources were kept or used for any residual radioactive contamination and decontaminate the area, if it is found to be contaminated.

Sealed spent or disused sealed sources, if any present in the facility, should be securely stored. The disposal agency for the radioactive sources may be the foreign supplier (imported sources) or supplier in the country (for locally procured sources). It is the licensee's responsibility to return the disused sources for safe management of the radioactive sources

taking into consideration the regulatory requirements/permission for ensuring radiation safety.

4.8.2 Disposal/Discharge of unsealed source (Radioactive Waste)

The radioactive waste management policies and procedures at the MCF should be as per the Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987. The licensee should put in place appropriate procedures to ensure safe collection, segregation, storage, transfer/disposal of the radioactive waste generated during routine operations, maintenance and incidents or emergency situations. Onsite disposal of unsealed radioactive waste should be carried out only after obtaining necessary approval from AERB. The licensee should have in place a document of standard operating procedures for waste management of the MCF (SOP-WM); updated from time to time, as may be required), and along with the help of RSO ensure adherence to SOP-WM by all the personnel involved. Typical aspects to be addressed (not exhaustive) concerning the solid, liquid and gaseous waste are cited below.

4.8.2.1 Solid Waste

(i) Generation of solid waste:

Solid radioactive waste is generated during cyclotron maintenance and following production of radiopharmaceuticals. The common solid wastes generated during cyclotron maintenance are cyclotron targets, foils, components left over of solid radiopharmaceuticals produced, used cartridges, etc., which have induced radioactivity. Other solid radioactive waste that is generated is from components in the cyclotron tank due to wear and tear over time.

Solid radioactive waste is also generated during the cleaning of targets.

In routine radiochemistry operations, the solid wastes like cassettes, separation and purification cartridges, tubings, reagent vials, syringes, membrane filters, etc. are generated during radiochemical processing, synthesis and dispensing operations.

The radioactive wastes generated during Quality Control procedures are chromatography support strips, pipette tips, syringes, needles, tissue papers, rubber bungs, aluminium caps etc.

(ii) Management of solid waste

a) The generated waste prior to its disposal should be monitored for the presence of any detectable radioactivity.

b) All radiation safety precautions should be implemented during handling, removal, collection, transfer and storage of radioactive waste. The contents inside the pit should be safely stored. A label with the legend, 'access to authorized personnel only' should be displayed on the closure/lid of the pit, in order to prevent inadvertent handling by other staff.

c) The entire procedure of radioactive waste handling, storage, removal and disposal should be carried out under the guidance and supervision of the facility's RSO.

d) The solid radioactive wastes should be segregated according to the half-life of radioactive source incorporated. Short- and long-lived radioactive waste should be stored appropriately.

e) Solid wastes generated during preventive maintenance should be collected in an impermeable polythene bag and transferred to the dedicated lead lined storage pit inside the cyclotron vault.

f) Solid radioactive waste generated during the wear and tear of normal use and radioactive Havar Foils, should be stored in a customized lead pot inside the lead-lined pit since these may require long term storage.

g) The solid radioactive waste generated during the target cleaning process should be monitored and stored in the lead-lined pit.

h) Waste related to cyclotron components having induced radioactivity, may be characterized using a Gamma Ray Spectrometry System to identify and understand the typical profile of the induced radionuclides per µAh

operation of the MC. This will be beneficial in management of waste generated in subsequent operations.

i) The waste generated during radiopharmaceutical synthesis and dispensing operations should be handled the next day, collected and stored for decay in a lead-lined storage bin and stored inside the radiochemistry lab.

j) The radioactive waste generated during Quality Control procedures should be stored in a lead-lined foot operated waste bin inside the QC lab.

k) Short-lived radioactive waste containing ^{18}F, ^{68}Ga, ^{11}C, and ^{13}N should be stored for decay until the activity of each radionuclide or mixtures thereof is so low that it may be deemed as exempt from regulatory requirements as stipulated by AERB and discarded as non-radioactive waste. However, provision for interim storage of longer-lived radionuclides like ^{64}Cu, ^{89}Zr and ^{124}I, if produced, should be made in addition to the short-lived radionuclides.

4.8.2.2 Liquid Waste

(i) Generation of liquid waste:

Liquid radioactive wastes are generated during target maintenance and during recovery of liquid target(s), radiochemical processing and/or synthesis of radiopharmaceuticals and liquid chromatography eluates during QC.

(ii) Management of liquid waste:

a) Liquid waste generated during target maintenance should be contained in leak proof containers and stored in lead storage pit till decay to acceptable limits.

b) Liquid waste collected during synthesis and QC should be stored for interim period for decay, monitored and disposed of in lab sinks.

c) Disposal of liquid waste should be such that the activity and concentration are well within the limits prescribed by AERB for disposal through sanitary sewerage.

4.8.2.3 Gaseous Waste

(i) Generation of gaseous waste:

Gaseous radioactivity can be generated during cyclotron operation by activation of gaseous targets, activation of air in the cyclotron vault and release of radioactivity, particularly ^{18}F, ^{11}C, ^{13}N, ^{15}O, etc. during synthesis operations in the radiochemistry hot-cell.

(ii) Management of gaseous waste:

a) Radioactive gases generated during radiochemistry synthesis operations should be passed through a Waste Gas Compression System, which will compress and store the radioactive waste air in leak proof cylinders for an appropriate period to allow for radioactive decay. The mechanism of operation of the waste gas air compressor system should be such that it permits release of contents only when the radioactivity levels are below the set threshold values, and released through the stack. The threshold values would be determined by the activity that is permitted to be released to the environment under the applicable rules for safe disposal of radioactive waste.

b) Air-changes provided by design in the cyclotron vault should be such that there is ~~a~~ proper venting of gaseous radioactive waste through the stack /chimney. The released activity should not exceed the limits specified by AERB for safe disposal of radioactive waste. The stack should be provided with a calibrated stack monitor to quantify the activity released through the stack. A record of such releases should be maintained and submitted to AERB in the periodic safety status report.

c) The facility should have provisions to promptly detect any releases of air-borne radioactive contamination during radioisotope production and radiopharmaceutical synthesis procedures. For this purpose, continuous on-line monitoring systems should be provided in the stack/chimneys / at the vault exhaust.

4.8.3 Decommissioning of Equipment/ Facility

4.8.3.1 Decommissioning of Medical Cyclotron

The term decommissioning refers to a set of actions to be implemented at the end of the useful life of a particular facility, or when a facility ceases to be utilised for its intended purpose. Such facility should be duly decommissioned before the site and building premises are made available for other uses. Decommissioning needs to be carried out in a systematic manner to ensure safety of the workers, public and the environment. The decommissioning process involves removal of radioactive materials and sources, decontamination and dismantling, subsequent management of waste, final radiation survey and release of the facility for unrestricted use.

The entire facility along with the cyclotron should be checked for radioactive contamination. The contaminated components should be segregated depending on their half-lives and properly disposed of as radioactive waste. For this purpose, the licensee should obtain permission from AERB for transfer/disposal of radioactive waste to authorised waste management agency.

Upon completion of the decommissioning operation, a comprehensive survey of the facility should be conducted by the RSO. It should be confirmed that the dose rate, fixed and non-fixed contamination level, if any, at the facility are within the limits stipulated by AERB.

It is advisable to make plans for decommissioning at the time of planning for the MCF, keeping in mind the fact that the decommissioning will be carried out at a much later point in time that, hence, ensuring continuity of accountability of licensees of the MCF, as well as the following major aspects:

(i) Provision should be made to take out the MC from the vault, and as far as possible without having to break/cut it into pieces.

(ii) Provision should be made to cover the estimated cost of decommissioning.

(iii) Provision should be made to safely store the radioactive waste that would be generated during decommissioning.

(iv) Clearance of solid wastes should be carried out in accordance with the regulatory requirements.

4.8.3.2 *General Provisions for Decommissioning*

(i) Financial Provisions:

The employer of MCF possessing radioactive sources and activated components should make adequate financial provisions for the decommissioning of equipment and transfer/export of the sources for safe management at the end of its useful life or in the unlikely event of the equipment becoming disused. This provision should be made at the time of procurement of the medical cyclotron, so that in case it is rendered disused in future, prompt action can be initiated for its safe management in the interest of safety.

This financial provision should be adequate to meet the cost of decommissioning and transport of disused sources. The quantum of fund should be reviewed periodically by the utility and supplier.

(ii) Regulatory Consent for Decommissioning

Consent for decommissioning should be obtained from AERB when the facility is no longer to be used and/or usable for the purpose for which it was licensed to operate. A plan of the decommissioning operation should be submitted by the licensee to AERB while applying for the necessary consent from AERB. The decommissioning operation should be carried out in complete conformity with the plan approved by AERB. If it is necessary to modify the plan, prior approval should be obtained by the licensee from AERB.

(iii) Decommissioning Report

A decommissioning report prepared by the RSO providing details of the radiation survey should be submitted by the licensee to AERB, on completion of decommissioning, detailing safe disposal of the source and radioactive components and particulars relating to personnel doses received during the decommissioning operation. Licensee upon receiving from AERB the final clearance of the

decommissioning operation, issued based on the report submitted by the RSO, may opt to release the decommissioned facility premises for use by others/the public. Records of the monitoring results must be maintained for three years. Records should be maintained by the individual requesting the decommissioning and the RSO.

More guidance on Decommissioning is given in Annexure – 2.

4.9 Transport of Radioactive Material (Labelling, Marking, Packaging & Distribution)

In the case of medical cyclotron facilities engaged in production and distribution of radiochemical and radiopharmaceutical products to other authorised facilities for clinical use, proper packaging and transportation programs should be established to ensure radiological safety. The radiochemicals/radiopharmaceuticals, being radioactive material, should be transported through public domain in a safe manner **according** to the regulatory requirements (AERB/NRF/SC/TR-1 Rev. 1). Licensee of the MCF has the role of the consignor and, therefore, is primarily responsible for the preparation of the package including labelling, marking, packing, distribution and ensuring safe transport. The package should be prepared in accordance with applicable national/ international regulations for safe transport of radioactive material. Type of package normally used for the transport of cyclotron-produced radioisotopes is a Type A package. Accordingly, all the applicable requirements of a Type A package should be duly complied with by the consignor. The package design should be as per the AERB Safety Code AERB/NRF-TS/SC-1 (Rev. 1) and the applicable regulatory requirements should be duly complied with. The radiation surveillance of the driver/staff, if employed at the facility, carrying radioactivity for transport and distribution should be the responsibility of the Consignor. In case, the transport and distribution of radioactive material is outsourced, the licensee (Medical Cyclotron Facility) should ensure radiation safety including surveillance by having suitable arrangements with the transport agency.

5. MEDICAL EXPOSURE

The chapter on ‘Medical Exposure’ is kept intentionally blank since the same is not applicable to ‘Medical Cyclotron Facilities’

Footnote: There may be instances where a radiopharmaceutical produced from MC is directly administered to a patient. Such instances may attract additional guidance for management of medical exposure.

6. HANDLING INCIDENTS/EMERGENCY SITUATION

6.1 General

Radiation equipment and radioactive materials used/operated in a MCF, if handled unsafely, could lead to potential exposure situations. Incidents in MCF occur mainly due to operator error or failure of safety systems, and some incidents have resulted in workers receiving avoidable radiation doses. Excessive exposures can also occur in certain cases due to inadvertent access to a restricted area or leakage of radioisotope in the working environment due to equipment failures.

The basic obligations, responsibilities and requirements for emergency preparedness and response are established in Atomic Energy (Radiation Protection) Rule-2004. Specific details pertaining to MCF are provided in this guide, along with a list of typical incidents and emergency situations (Annexure-3).

It is the responsibility of the Licensee to prepare emergency response plans designed to ensure the protection and safety of workers and members of public. The emergency response plan should be prepared in consultation with the RSO of the facility. A qualified expert may be consulted if required. Response to an emergency consists of initial actions to be taken immediately and follow-up actions to be taken subsequently. Some follow-up actions may be taken up by the manufacturer/supplier of the MC depending on the resources necessary to implement the actions. The emergency response plan should, based on postulated scenarios, provide actions for minimizing radiation exposure, regaining control of the situation to restore the facility to its normal conditions, and treating any persons who have been injured or overexposed. Disconnecting the electrical power to MC will reduce or eliminate further radiation hazards. In addition, potential hazards due to any activation products that may be present should be considered.

6.2 Emergency Preparedness for Response

Plans need to be prepared in advance for emergency preparedness as well as response. A copy of the plans should be submitted while applying for Design and Construction approval of the installation. Also, any modifications in the emergency plan should be informed to AERB. The plan should postulate emergency conditions and method of identification of those conditions as well as preparedness (infrastructure) and response (functional)

requirements. These requirements include necessary equipment, emergency response personnel within the institution, contact details of relevant persons and agencies, start and cessation of emergency situation, modes of communication, mitigatory and protective actions etc. Operational experience, lessons learned from emergencies at similar facilities and errors made in maintenance and in quality management programmes also serve as sources of information for developing emergency plans.

The facility should plan to deal with all types of accidents envisaged in the safety assessment and be prepared and equipped to manage emergency situations. When an accident occurs, workers and the public may be exposed to radiation or other industrial hazards.

The responsibility for each action must be delineated and the required information as to whom to contact etc. must be displayed in the control room of the facility. The procedures should also include contact details of the persons/agencies to be informed for directing remedial action for example the police, fire brigade, medical help and relevant authorities. The licensee is responsible for liaison with emergency authorities and other bodies. AERB should be kept informed of any emergency situations, unusual occurrences and occurrences which may have radiation safety implications.

The licensee should review the emergency plan at appropriate intervals, normally not exceeding 12 months. Emergency plans should also be reviewed following relevant operational changes and in conjunction with analysis of and lessons learned from accidents in similar facilities or with similar radiation sources.

A list of typical incidents and emergency situations is given in Annexure-3.

6.3 Response to Incidents/Emergencies

The licensee, on the advice of RSO, should ensure that incidents are handled in such a manner that the exposures to the personnel are minimized. All such incident and the remedial actions taken should be informed to AERB.

In the event of an accident involving MC, the licensee is required to:

(i) Make every effort to mitigate the consequences, (Please refer: Safety Guide on ‘Management of emergency arising from radiation sources, equipment and installations' AERB/RF/NRE-2 (DRAFT).

(ii) Comply with the directions of AERB which may be issued to ensure safety including the immediate shutting down of the radiation installation.

The response action should be as per the plan. However, depending upon the situation, the actions may vary. The protection action should be such that it does more good than harm.

6.3.1 Emergency Handling Tools

The following emergency handling tools (working and calibrated, if applicable) should be available with the institution for handling any radiological incident / emergency in an MCF

(i) Appropriate and functioning survey meters to measure dose rates;

(ii) Personal alarm and direct reading dosimeters (preferably digital electronic units);

(iii) Emergency light (Torches)

(iv) Communication equipment (e.g. mobile phones);

(v) Spare batteries for survey meters, personal electronic dosimeters and torches;

(vi) Suitable stationery supplies, including an incident logbook;

(vii) Equipment manuals;

(viii) First aid equipment;

(ix) A copy of the emergency procedures.

(x) Decontamination kit – comprising appropriate agents for decontamination, mops, containers for collection of waste arising from decontamination activity should be available in the MCF premises for use when required

Emergency equipment should be kept in a clearly labelled cabinet in a readily accessible place. A list of the emergency equipment should be affixed to the cabinet. Audits should be made periodically and immediately after use of the equipment to ensure that all items are present and functioning correctly, or that they are replaced as necessary. Emergency exercise (drills) should be conducted periodically. Deficiencies observed during exercise should be documented and promptly rectified. The emergency plan should be revised accordingly.

6.3.2 Reporting an Emergency

Licensee/employer should:

(i) report to AERB and CMG, DAE regarding the incident within 24 hours of its occurrence including date and time of occurrence and brief description of the incident, source, activity, action initiated, proposed measures, any support required, etc.

(ii) lodge a written complaint with the police in case of loss or theft of the radioactive sources and not traceable within 24 hours.

(iii) submit to AERB a brief report within 5 days including status of the source and action taken etc. followed by monthly (or more frequently as directed by AERB) update till termination of emergency. Further, a complete detailed report of the incident including the preventive measures taken to avoid recurrence of such incidents should be submitted to AERB within 30 days of termination of emergency.

7. PUBLIC SAFETY

7.1 General

AERB has specified dose limits for members of the public which are given in Appendix-I. To ensure public safety, the design and operation of the facility should be such that radiation exposure to the members of the public is kept to a minimum and well within the prescribed limits. To further strengthen public safety, warning symbols should be displayed to caution/alert/prevent public before coming closer to hazardous/restricted areas of the facility. These efforts should be supported by carrying out regular radiation surveillance around the facility.

7.2 Measures for Public Safety

The Radiation Protection Programme established by the licensee, in consultation with the RSO, should include the safety of the general public. Graded safety requirements should be established in the facility as per the level of radiation hazards expected to be encountered. Access to the facility by the general public should be restricted in controlled area/supervised area in accordance with zoning arrangement or classification of area. Access control system should be available to ensure entry of only authorised persons to high-hazard zones. In addition, regular radiation surveillance should be carried out to ensure that the dose rates in public access areas are acceptably low. The radiation exposure of the public from all sources including that due to operation of the facility in one week should not exceed 20 µSv taking cognisance of the annual dose limit of 1 mSv.

7.3 Protection of Foetus/Breast fed infants

The foetus of a radiation worker is considered as member of the public. A female worker, on becoming aware that she is pregnant, should notify the employer, licensee and RSO so that her working conditions may be modified suitably, to ensure that the dose to the foetus remains well within the dose limit prescribed for general public. The lactating radiation worker in the facility should be aware of chances of internal contamination. The RSO should ensure that lactating radiation worker is prevented from exposure due to internal contamination.

Appendix I Dose Limits for Exposures from Ionising Radiations for workers and the members of the public

AERB Directive No. 01/2011 [Under Rule 15 of the Atomic Energy (Radiation Protection) Rules 2004]

Ref. No.CH/AERB/ITSD/125/2011/1507 dated April 27, 2011

In exercise of rule 15 of the Atomic Energy (Radiation Protection) Rules, 2004, the Chairman, Atomic Energy Regulatory Board, being the Regulatory Body 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

- 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.
- Calendar year shall be used for all prescribed dose limits.
- Occupational Dose Limits
- Occupational Workers

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

- an effective dose of 20 mSv/yr averaged over five consecutive years (calculated on a sliding scale of five years);
- an effective dose of 30 mSv in any year;
- equivalent dose to the lens of the eye of 150 mSv in a year;
- an equivalent dose to the extremities (hands and feet) of 500 mSv in a year and
- an equivalent dose to the skin of 500 mSv in a year;
- 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.
- 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:

- an effective dose of 6 mSv in a year;
- an equivalent dose to the lens of the eye of 50 mSv in a year;
- an equivalent dose to the extremities (hands and feet) of 150 mSv in a year and
- an equivalent dose to the skin of 150 mSv in a year.
    - Dose Limits for Members of the Public
    - The estimated average doses to the relevant members of the public shall not exceed the following limits:
        - an effective dose of 1 mSv in a year;
        - an equivalent dose to the lens of the eye of 15 mSv in a year; and
        - an equivalent dose to the skin of 50 mSv in a year.

Appendix-II Specifications for Radiation Symbol and Warning Sign

AERB Directive No. 02/2011 [Under Rule 14(3) of the Atomic Energy (Radiation Protection) Rules 2004]

Ref. No. No.CH/AERB/ITSD/125/2011/1508 dated April 27, 2011

In exercise of rule 14(3) of the Atomic Energy (Radiation Protection) Rules, 2004, the Chairman, Atomic Energy Regulatory Board, being the Regulatory Body under the said rules, hereby issues an order prescribing the specifications for the radiation symbol and warning sign.

Specifications for radiation symbol/warning sign:

- The radiation symbol for radioactive sources other than medical diagnostic and industrial X-ray radiography equipment shall conform to the specifications given hereunder:
  - The relative dimensions of the trefoils and the central circle shall be as shown in Fig.1
  - The trefoils and the circle shall be of magenta colour.
  - The background of the above symbol shall be yellow.
  - The symbol should be accompanied by appropriate legend in English, Hindi and local language indicating radiation hazard and restricted entry, e.g. CAUTION – RADIOACTIVITY.
  - Small objects, containing radioactive material may, however, have on them only the aforesaid trefoil symbol engraved in a conspicuous colour when their dimensions do not permit compliance with the above.
- The radiation symbol for radiation generating equipment such as medical diagnostic X-ray equipment, industrial X-ray radiography equipment and accelerators shall have a warning sign as illustrated in Fig.2 and the warning sign shall conform to the specifications given hereunder:
- The triangle shall be equilateral.
- The ratio of the outer to the inner sides of the triangle shall be 1.5.
- The area between the outer and inner triangle shall be in yellow colour on white background.
- The printing on the area between the outer and inner triangle and figure inside the inner triangle shall be bold, proportional and red in colour.
- The area between the outer and inner triangle should be accompanied by appropriate legend in English, Hindi and local language indicating radiation hazard and restricted entry.

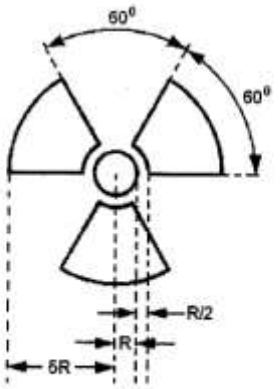

Fig. 1.
Radiation Symbol for Radioactive Sources

Fig. 2.
Radiation Symbol and Warning Sign for Radiation Generating Equipments

Appendix-III: Qualification of Radiation Professionals in Medical Cyclotron Facility

The qualifications of professionals are stipulated/ prescribed by the relevant authorities. Where such stipulations are not available, the qualifications suggested below may be considered.

Radiation Workers (Personnel in Medical Cyclotron Facility)

The efficient utilization of a Medical Cyclotron facility for production of radioisotopes and radiopharmaceuticals requires availability of a Radiological Safety Officer (RSO) and other trained personnel for operating the equipment and preparation of radiopharmaceuticals. These personnel are identified in this section as RSO, Medical Cyclotron Operator and Radio-Pharmacist. This section also provides the minimum desirable qualification, radiation safety certification and adequacy of personnel in Medical Cyclotron facility.

1 Radiological Safety Officer (RSO)

Eligibility Criteria and Safety Certification:

(i) Medical Physicist with RSO (Medical)

OR

(ii) Radiation Technologist (NM) with RSO (NM) certification;

and

Successful completion of specialized training and certification on 'Operational and Safety Aspects of Medical Cyclotron' in a well-equipped medical cyclotron facility (as applicable)

Adequacy of Personnel:

(i) Each medical cyclotron facility should have a Radiological Safety Officer (RSO).

2 Medical Cyclotron Operator

Minimum Qualification:

Qualification recognized by the relevant authority of India, such as

(i) Post Graduate Diploma/ Degree in Nuclear Medicine (Technology) or Basic degree in Science with Physics as one of the subjects or Diploma/Degree in Engineering (Electrical /Mechanical/Instrumentation/Bio-medical) passed from a recognized University/Institution

and

(ii) Training in Cyclotron Operation from Manufacturer/Supplier of the Medical Cyclotron

or

On Job Training in Cyclotron Operation from any Medical Cyclotron Facility under the supervision of a trained operator for a period stipulated by AERB

Radiation Safety Certification:

(i) Medical Cyclotron Operator should successfully complete Training in Basic Radiation Safety from AERB recognised agency for radiation safety certification.

Adequacy of Personnel:

(i) One Medical Cyclotron operator for each medical cyclotron facility.

(ii) Number of Medical Cyclotron operator should be enhanced proportionately with number of medical cyclotron equipment or workload including multi-shift operation.

3. Radio-Pharmacist:

Minimum Qualification:

Qualification recognized by the relevant authority of India, such as

(i) Post Graduate Diploma/ Degree in Nuclear Medicine (Technology) or Basic degree in Chemistry or B. Pharm or an equivalent from recognized University/Institution

and

(ii) Training in Operation of Radiopharmacy (Processing of Radioisotopes & Radiopharmaceuticals) from Manufacturer/Supplier of the Medical Cyclotron and or/of Processing Modules/Cells

Or

On Job Training in Operation of Radiopharmacy (Processing of Radioisotopes & Radiopharmaceuticals) from any Medical Cyclotron Facility under the supervision of a trained Radio-Pharmacist for a period stipulated by AERB

Radiation Safety Certification:

(i) Radio-pharmacist should successfully complete Training in Basic Radiation Safety from AERB recognised agency for radiation safety certification

Adequacy of Personnel:

(i) One radio-pharmacist for each medical cyclotron facility.

(ii) Number of radio-pharmacist should be enhanced proportionately with number of medical cyclotron equipment and/or processing facilities or workload including multi-shift operation.

4. Medical Cyclotron Service Engineer (for MC Manufacturer/Supplier Facility)

Minimum Qualification:

(i) Diploma in Engineering or an equivalent from a recognized University/Institution;

(Note: Qualification should be supported by certification from original equipment manufacturer (OEM) about successful completion of training on servicing/ maintenance and installation of MC equipment.)

Radiation Safety Certification:

(i) The service engineer should obtain Training in Basic Radiation Safety from AERB recognised agency for radiation safety certification.

(Note: The manufacturer/ supplier should ensure that radiation testing, QA, servicing & maintenance of MC equipment should be carried out only by trained and certified service engineer.)

Appendix IV: Responsibilities

I.1 General

There are various stakeholders involved in handling the radiation sources and equipment during the life cycle of the radiation facility. This includes personnel involved in the manufacture, supply, installation, commissioning, operation, maintenance, and decommissioning of the radiation equipment or radiation facility. Responsibilities are assigned to these personnel for radiation safety in the facility. All the personnel should understand and fulfil their responsibilities to ensure radiation safety effectively. The responsibilities of the employer, licensee, RSO, Cyclotron Operator, Radiochemist, Radiation Worker, and Suppliers of Medical Cyclotron are provided in this chapter.

I.2 Responsibilities of the Licensee (Employer)

The person responsible for any facility or activity that gives rise to radiation risks should have the prime responsibility for safety. The prime responsibility of ensuring radiation safety in handling Medical Cyclotron Facility should rest with the Licensee (Employer) who has obtained the licence and this responsibility cannot be delegated.

The Licensee should:

(a) ensure compliance with all the applicable provisions of Atomic Energy Act, 1962 and rules made thereunder, and stipulated requirements in regulatory documents/ conditions referred to or contained in the licences or Safety Directives/Orders from AERB or otherwise applicable;

(b) designate, with the written approval of AERB, a person having qualifications as specified in this guide, as RSO.

(c) ensure that relevant provisions of this guide are implemented by the RSO and other worker(s);

(d) ensure that no person under the age of 18 years is employed as a worker and no person under the age of 16 years is taken as trainee or employed as an apprentice for radiation work;

(e) provide facilities and equipment to the RSO(s) and other worker(s) to carry out their

functions effectively in conformity with the regulatory constraints;

(f) prior to employment of a worker, procure the dose records and health surveillance reports, from his/her former employer. Also upon termination of service of worker provide his/her dose records and health surveillance reports on request to his/her new employer;

(g) arrange for and maintain health surveillance of workers as specified under Rule 24 & 25 of Atomic Energy (Radiation Protection) Rules, 2004;

(h) arrange for personnel monitoring of radiation workers, proper implementation and also to maintain the individual dose records as prescribed by AERB;

(i) furnish to each worker dose records and health surveillance reports of the worker in his/her employment annually, as and when requested by the worker and at the termination of service;

(j) inform AERB if the licensee or the RSO leaves employment;

(k) ensure that written procedures and plans are established for controlling, monitoring and assessment of exposure for ensuring adequate protection of workers, members of the public and the environment, during normal operation and emergency situations;

(l) ensure that periodic safety status report of the facility in the prescribed format is submitted to AERB;

(m) ensure radiation monitoring is carried out in accordance with this safety guide;

(n) ensure radiation monitoring equipment is/are regularly inspected, maintained and periodically calibrated at least once in two years and all systems/components are regularly serviced and maintained in good working order as per the manual provided by the manufacturer/ designer and records are maintained. Records should also be maintained for replacement of components, if any;

(o) ensure periodic tests and inspections of safety systems and control mechanisms are carried out; the records are maintained and are available for inspection by AERB;

(p) ensure that adequate instruction/training is given to employees concerning any radiation hazards associated with their work, any precautionary measures necessary to limit

radiation exposure of persons and to avoid radiation accidents and injuries;

(q) ensure that necessary supervision is provided to all employees in the performance of their work in accordance with the provisions of this guide;

(r) in consultation with the RSO, investigate any case of exposure in excess of regulatory constraints received by individual workers and maintain records of such investigations;

(s) inform AERB promptly of the occurrence of actual or suspected radiation exposure of personnel in excess of regulatory constraints in prescribed format followed by reports of detailed investigations and follow up actions to prevent recurrence of such incidents;

(t) inform AERB, within twenty-four hours, of any accident involving a source or loss of source of which he/she is the custodian;

(u) ensure that all applicable requirements of other relevant regulatory authorities are met;

(v) make financial arrangement for disposal of disused sources;

(w) ensure that Standard operating procedures (SOP) are developed and adhered to, including the recommendations of the Manufacturer/ Supplier, for the safe operation and maintenance of the MCF.

(x) ensure that no person is permitted to operate the Medical Cyclotron Facility unless he/she has been adequately trained and qualified to operate the unit in accordance with the safety procedures;

(y) carry out physical verification of radioactive sources, if any, and maintain inventory;

(z) inform appropriate law enforcement agency in the locality, employer and AERB in case of any loss of source;

(aa) in case of permanent termination of the use of unit with radioactive source/radiation generator due to any reason, should decommission the unit and return the source to the supplier, or dispose off the source, as appropriate, with prior permission of AERB;

(bb) should obtain prior permission of AERB in case of transfer of Ownership of Medical Cyclotron unit or Facility; and

(cc) obtain prior approval from AERB for any modifications in location of installation.

(dd) The Employer should constitute a Local Safety Committee (LSC) for the medical cyclotron facility with the RSO as one of the members of the committee to review the safety status of the facility. LSC should be responsible for radiation safety as well as industrial safety having a bearing on radiation safety. The committee should meet periodically and the minutes of the meetings and action taken reports should be recorded and made available during inspection by AERB.

(ee) Employer should ensure adequate physical protection measures for sources within the facility and also during transport. Transport of radioactive materials should be in accordance with the guidelines in AERB Safety Guides for 'Security of Radioactive Sources in Radiation Facility' (No: AERB/RF-RS/SG-1, 2011) and 'Security of Radioactive Material during Transport' (No: AERB/NRF-TS/SG-10, 2008).

I.3 Responsibilities of the Radiological Safety Officer

The role and responsibilities of RSO are elaborated as below:

The RSO should:

(a) ensure that the relevant provisions of Atomic Energy (Radiation Protection) Rules, 2004, are implemented;

(b) advice and assist the Employer and Licensee in ensuring regulatory compliance for obtaining consent from the Competent Authority for procurement, use, transport or disposal of radioactive material;

(c) implement all radiation surveillance measures including display of radiation symbol and warning at the entrance door of room(s) where radioactive material is handled and at appropriate location;

(d) implement continuous display of the radiation symbol, warning, marking and labeling on the unit;

(e) advise the Licensee in establishing and maintaining an effective radiation protection programme to ensure safety of workers, members of the public and the environment;

(f) train the operators and associated servicing /maintenance personnel on basic radiation safety, hazard potential and biological effects of radiation;

(g) instruct all operators/users on relevant safety measures, provide adequate training in radiation protection and safety methodologies, use of personnel monitoring devices (eg. TLD badges);

(h) ensure that personnel monitoring devices are provided to radiation workers in the facility, as applicable, used as required and are securely stored in radiation-free zone;

(i) ensure that radiation monitoring instruments are kept in proper working condition and are periodically calibrated;

(j) assist the Licensee in developing suitable emergency response plans to deal with emergencies and ensuring appropriate emergency preparedness;

(k) conduct periodic radiation protection surveys and maintain records;

(l) maintain inventory of sources including initial and present activity, operational logbook and associated QA records;

(m) furnish to the licensee and AERB a periodic reports on safety status of the unit;

(n) investigate any situation that could lead to potential exposures and submit report to AERB;

(o) advice Employer on physical security measures;

(p) assist Licensee in maintaining personnel monitoring records, analyse personnel exposure records to ensure that there are no abnormal exposure trends;

(q) prepare the standard operating procedures (SOP) in-line with the instruction manual provided by manufacturer/supplier of the unit;

(r) assist Licensee for periodic servicing and preventive maintenance of the unit as prescribed by manufacturer/supplier and maintain records;

(s) ensure safe work practices during source replenishment and safe disposal of disused sources;

(t) report on all hazardous situations along with details of any immediate remedial actions taken are made available to the Employer and Licensee for reporting to the Competent Authority;

(u) advice the Licensee on the modification in the working condition of female worker after her notification about pregnancy; and

(v) inform the Competent Authority when he/she leaves the employment or is relieved of RSO role.

I.3 Responsibilities of the Cyclotron Operator / Machine Operator

Cyclotron Operator is the person who is directly involved in day-to-day operation/use of the unit. The Operator has recognized rights and duties in achieving radiation safety while handling the radiation source, which envisages awareness about the operational as well as safety requirements of the unit. Accordingly, the Cyclotron Operator should have requisite qualification and get training in safe operation, preventive maintenance aspects of the unit from authorized manufacturer/supplier.

The Cyclotron Operator should:

(a) be familiar with the basic design, operation and preventive maintenance of the Medical Cyclotron Facility including procedures for routine operation and handling emergency situations;

(b) operate the Medical Cyclotron Facility as per the standard operating procedures (SOP) prepared from detailed instruction manual provided by manufacturer/supplier;

(c) Ensure that there is no unauthorized bypass of the interlocks and other safety features mandatory for safe operation of cyclotron.

(d) Obtain the concurrence of the RSO, if required to carry out preventive, planned and emergency maintenance involving radioactive material.

(e) coordinate with the radiochemist to ensure that the cyclotron produced radioactive material is safely transferred and received in the desired synthesis module.

(f) maintain a logbook in respect of use, operation and maintenance of the medical cyclotron facility including inventory, production and transport of radioisotopes;

(g) make proper use of protective equipment, radiation monitors and personnel monitoring devices as provided;

(h) report to RSO and the licensee of any issues related to safe operation of the MCF, including the circumstances that could adversely affect safe operation of the unit;

(i) be familiar with the security safeguards in the area, such as locks, posting signs, warning lights and interlock systems; and

(j) in case of a female worker, on becoming aware that she is pregnant, notify the Employer, Licensee and RSO in order that her working conditions may be modified, as necessary.

I.4 Responsibilities of the Radiochemist

The radiochemist is the person who is directly involved in day-to-day operation of the Radiochemistry & Radiopharmacy lab of the facility. The radiochemist has recognized duties in achieving radiation safety while handling the radiation source, which envisages awareness about the operational as well as safety requirements of the facility. Accordingly, the radiochemist should have requisite qualification and get training in safe operation, preventive maintenance aspects of the Radiochemistry & Radiopharmacy lab from authorized manufacturer/supplier.

The radiochemist should:

(a) be familiar with the basic design, operation and preventive maintenance of the Medical Cyclotron Facility including procedures for routine operation and handling emergency situations;

(b) operate the Radiochemistry & Radiopharmacy lab as per the standard operating procedures (SOP) prepared from detailed instruction manual provided by manufacturer/supplier;

(c) should coordinate with the cyclotron operator for safe transfer of radioactive material from the medical cyclotron to the synthesis module.

(d) should ensure that the laboratory procedures required for the Quality Control (QC) of the product is done with due attention to radiation safety.

(e) In case radioactive material is transported outside the facility, he should do so with the concurrence of RSO

(f) make proper use of protective equipment, radiation monitors and personnel monitoring devices as provided;

(g) report to RSO/licensee of any issues related to safe operation of the MCF, including the circumstances that could adversely affect safe operation of the unit;

(h) be familiar with area security safeguards such as locks, posting signs, warning lights and interlock systems; and

(i) in case of a female worker(s), on becoming aware that she is pregnant, notify the Employer, Licensee and RSO in order that her working conditions may be modified, if necessary.

I.5 Responsibilities of radiation workers

(a) All personnel who are occupationally exposed to radiation in an MCF is termed as Radiation Worker. Other than the responsibilities as per their role, the radiation worker should: be familiar with the basic design, operation and preventive maintenance of the Medical Cyclotron Facility including procedures for routine operation and handling emergency situations;

(b) report to RSO/licensee of any issues related to safe operation of the Medical Cyclotron Facility, including the circumstances that could adversely affect safe operation of the unit;

(c) undergo training provided by the supplier, towards appropriate exposure parameters and dose reduction protocols.

I.6 Responsibilities of Manufacturer / Supplier

The supplier should:

(a) ensure that only approved Medical Cyclotron units are supplied in compliance with the terms and conditions of approval;

(b) in the case of indigenous manufacturers, obtain prior licence for commercial production of radioactive material or radiation generating equipment.

(c) adhere to the terms and conditions of the licence issued for manufacturing and authorization for supply of the MC.

(d) supply the unit only to the users authorized by AERB;

(e) install the unit only at authorized premises

(f) provide to the user instruction manual in understandable language (English/Hindi) for safe operation, periodic inspection, servicing, preventive maintenance including it's frequency, general description of the unit and detailed operating instructions and procedures;

(g) provide information to the user in respect of make, model, Sr. No. of the unit, dose rate & dose profile (both gamma & neutron)around the medical cyclotron unit;

(h) provide appropriate training to the personnel of user institution involved in operation, servicing and maintenance of the cyclotron unit.

(i) ensure availability of essential spare parts of the unit for its useful life;

(j) provide servicing and maintenance of the unit whenever required;

(k) provide safety accessories, as required to the user for the normal operation of the MC unit and for handling emergency situations;

(l) provide written instructions to the user specifying procedures to be followed in an emergency situation that has caused or may cause a radiation hazard to any individual, and

(m) provide technical support for eventual decommissioning of the facility as requested by the Licensee

II.7 Responsibilities of Medical Cyclotron Service Engineer

The Medical Cyclotron Service Engineer, with due adherence to the provisions of the current safety regulations or modified thereafter, has the following responsibilities;

a) involving in commissioning/service/maintenance/quality assurance/ decommissioning of Medical Cyclotron and associated equipment adhering to manufacturers specification, procedures and adhering to regulatory and radiation safety requirements;

b) ensuring that during commissioning of Medical Cyclotron equipment;
   i. the equipment is installed in approved room,
   ii. acceptance tests are carried out as per prescribed format,
   iii. installation of safety interlocks, emergency switches and other safety devices in compliance with prevailing regulatory requirements.

c) carrying out all repair and maintenance procedures as per the manufacturer' specifications or applicable standards;

d) ensuring that after repair or maintenance work, the functionality of the equipment is demonstrated and the equipment is handed over to the concerned technical person for carrying out necessary QA tests;

e) recording and communicating any design faults in the equipment, malfunction or non-availability of safety interlock etc. to the employer and RSO of the institution and the supplier for necessary corrective actions; and

f) providing operational safety training to the relevant staff to ensure operator safety.

Annexure-1: Layout diagrams (typical examples) of different type of Medical Cyclotron Facilities

The typical layouts are suggested keeping in mind radiation safety. However, other considerations such as GMP should be examined for actual layout of the facility without compromising radiation safety requirements.

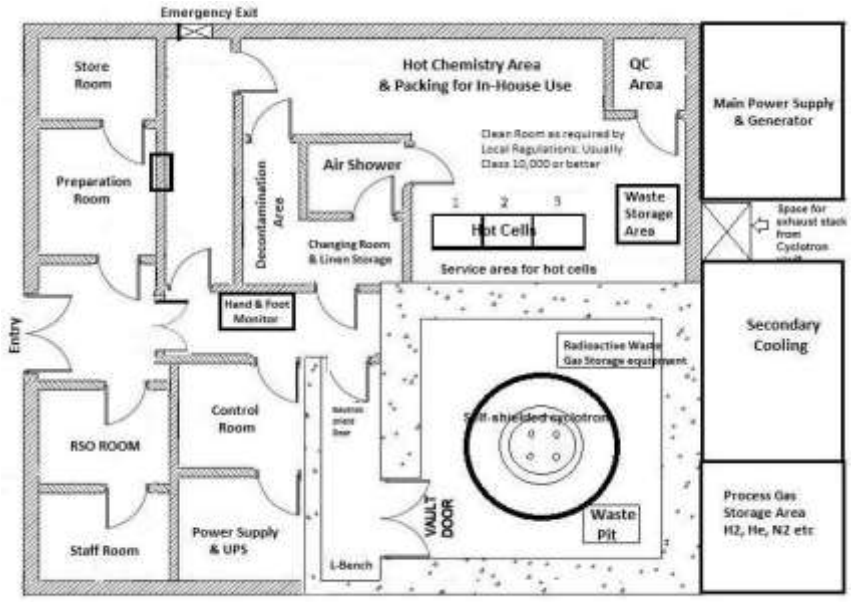

Fig A1.1: Floor plan of a typical Type I Medical Cyclotron Facility

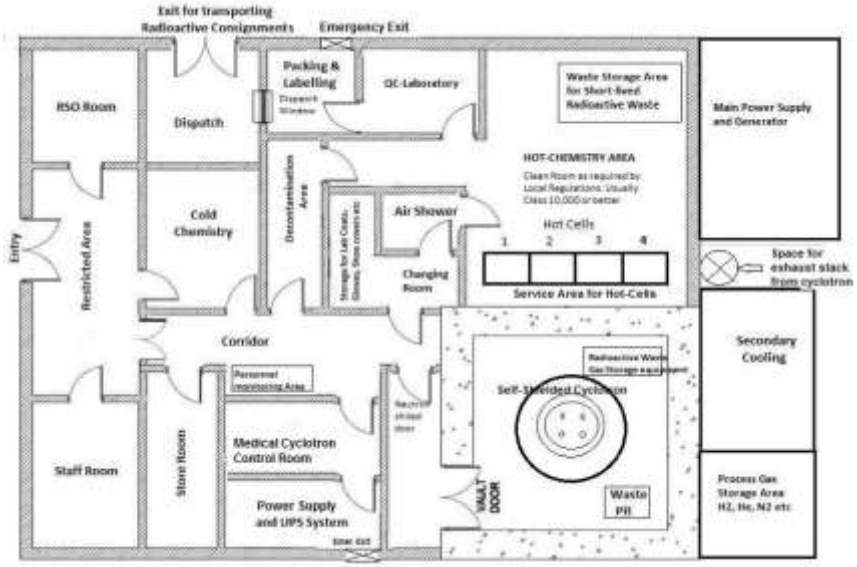

Fig A1.2: Floor plan of a typical Type II Medical Cyclotron Facility housing a self-shielded cyclotron

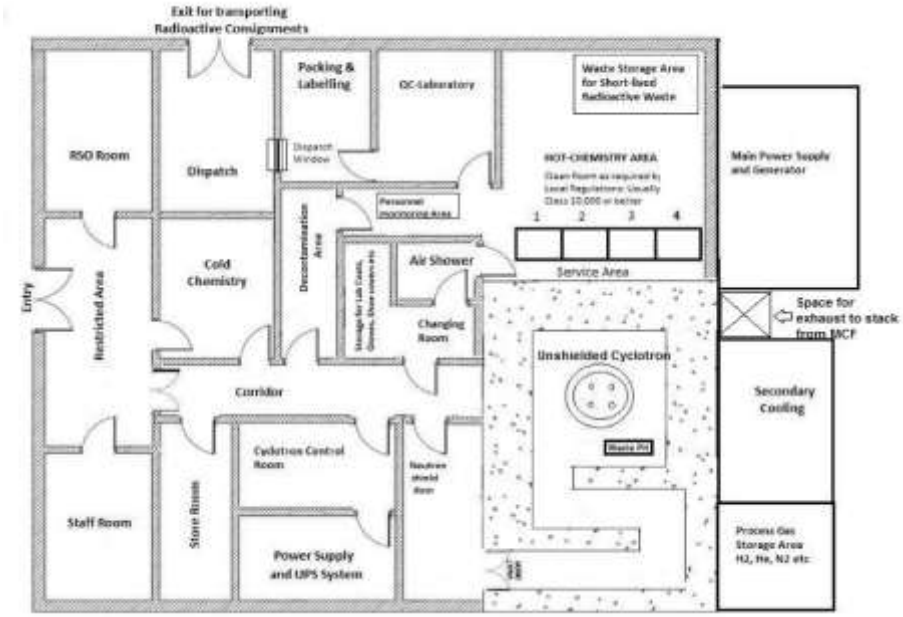

Fig A1.3: Floor plan of a typical Type II Medical Cyclotron Facility housing a Unshielded cyclotron in a vault with entry through a maze.

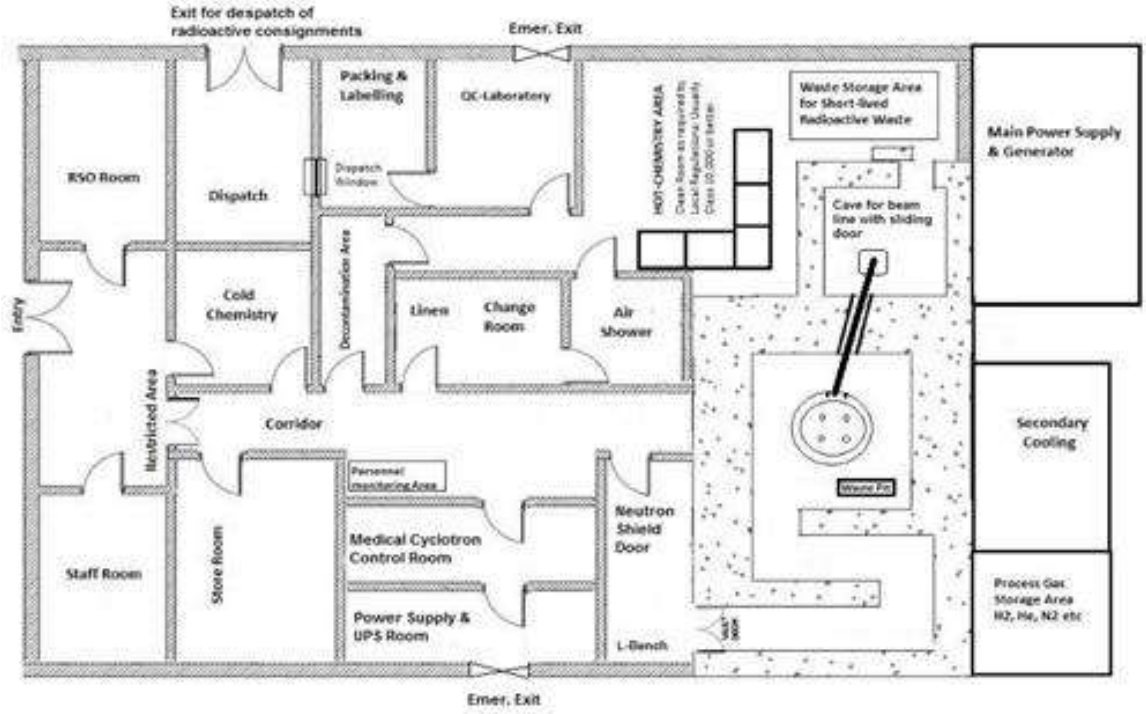

Fig A1.4: **Floor plan of a typical Type III Medical Cyclotron Facility housing a Unshielded cyclotron in a vault with entry through a maze.**

Annexure-2: Decommissioning of Medical Cyclotron Facilities

Medical Cyclotron facilities can function satisfactorily for over 20 years if maintained properly. However, there are reasons for which a cyclotron may be decommissioned if it is no longer viable or required, or damaged beyond repair due to corrosion etc., or the facility is planning to upgrade to a better model, which can be installed in the same vault without compromising on the safety aspects. Cyclotron manufacturers, wherever possible, choose components that have low cross section or the induced radioactivity has short half-life , $T_{1/2}$. However, some material like iron for the magnet yoke cannot be substituted. Similarly, there is no viable alternative to concrete for building the cyclotron vault.

It is advisable to make plans for decommissioning at the time of planning for the MCF and,

a. Provision should be made in the vault to take out the cyclotron, without having to cut it into pieces.

b. A budget may be set aside to cover the cost for dismantling the cyclotron

c. In facilities with self-shielded cyclotron, parts of the self-shield are expected to be radioactive and storage of this and the cyclotron should be planned for.

d. Provision of storage for anticipated radioactive waste that could be generated should be thought of. Waste will include the concrete scraped from the vault.

e. The magnet yoke is certainly expected to be radioactive for many years and, hence, it is desirable if it can be taken out as one piece and stored instead of cutting it into pieces, which will generate fines and dust and be more difficult to contain and also be very expensive.

f. Long lived radioactive products generated from Havar Foil, collimators and target components and need to be carefully disposed off.

Decommissioning issues are related to formation of radioactive isotopes with long half-lives due to activation with mostly neutrons. Long term activation due to protons will be only with those components that come in the path of the protons. Most cyclotron components are not exposed to proton beam. The Havar foil, collimators and target are irradiated directly and become radioactive.

However, these elements are of small volume and can be sent to radioactive waste repositories maintained by authorized bodies.

Typically, Havar foil, collimators of a medical cyclotron may contain induced long lived radioisotopes e.g. V-49, Cr-51, Mn-54, Fe-55, Co-56, Co-57, Zn-65 etc induced by proton beam.

Similarly, isotopes like Cr-51, Mn-54, Fe-55, Co-60, Ni-63 etc may also be induced due to neutron activation of various structural components of the cyclotron (e.g. cell, yoke etc).

Induced radioactivity in structural concrete by neutron activation depends on the content of the concrete. Typically, Co-60, Eu-152, Eu-154, H-3 & Ba-133 are expected.

Annexure 3: Emergency Scenarios Specific to MCF

The RSO should carry out detailed analysis of the MCF systems, structures and components and postulate all possible accident scenarios due to single or multiple failure(s) that may eventually lead to an emergency in the facility and prepare appropriate manual on handling emergency. It should also consider potential for off-site consequences, that is, the possibility of emergency scenarios extending beyond the facility as well. This manual should be readily available to all personnel in the facility. The facility should be prepared and equipped with necessary tools and safety gadgets to handle emergencies. The emergency response should adopt a graded approach that would ensure that the response measures are commensurate with the severity of the incident.

Incidents and accidents at a MCF can occur mainly as a result of operator error and/or equipment failure and may lead to a radiological emergency. Typical incidents and accidents which may lead to incidents / emergency situations are:

a) Loss of cooling of target

b) Fire incident inside the hot-cell/clean rooms/other production areas

c) Safety Interlock failure

d) Leaking source

e) Rupture of Havar Foil or target foil/disc of solid/liquid/gas targets

f) Loss of shielding integrity of hot-cell

g) Loss of supply air to the facility and/or loss of exhaust air from the hot-cells

h) Radioactive material stuck in transfer line

i) Abnormal radioactivity releases from stack

j) Unplanned/accidental exposures to maintenance personnel

k) Transfer of radioactive material from target to hot-cell without the consent from radio-chemist

l) Spillage of radioactive solutions/liquids within the facility or during transportation in public

domain.

m) Loss of control over radioactive material or the facility, such as theft or sabotage of radioactive material.

n) Power failure

o) Natural disasters (e.g. torrential rains, hurricane/cyclone) affecting the facility.

For emergencies involving MCF and radioisotope production, the following equipment should be considered, as appropriate:

a) Appropriate and functional survey meters to measure both high and low dose rates and contamination monitors;

b) Personal alarm dosimeters and direct reading dosimeters (preferably electronic personal dosimeters);

c) Additional personal monitoring badge (OSL dosimeters, thermoluminescent dosimeters and/or film badges);

d) Barrier materials and notices;

e) Lead bricks;

f) Suitable tool kit and source recovery equipment (long handling tongs, pliers, screwdrivers, bolt cutters, adjustable spanner, torch, lead source storage container);

g) Materials and reagents for decontamination;

h) Spare shielded container;

i) Plastic sheets, air tight bags for rupture of gaseous sources, swipe test kit, measuring tape;

j) Communication equipment (e.g. walkie-talkie, mobile phones);

k) Spare batteries for survey meters, electronic personal dosimeters, mobile phones and torches;

l) Pens, paper, calculator and an incident log book with first responder sheets;

m) Equipment manuals, procedures, instructions.

BIBLIOGRAPHY

1. Constitution Order of ATOMIC ENERGY REGULATORY BOARD by Government of India (Order No. 25/2/83-ER dated 15.11.83), S.O. 4772, 1983.

2. ATOMIC ENERGY REGULATORY BOARD, Safety Guide on 'Medical Cyclotron Facilities', No. AERB/RF-RS/SG-3, Mumbai, India (2016).

3. ATOMIC ENERGY REGULATORY BOARD, Safety Guide on 'Consenting Process for Radiation Facilities', No. AERB/RF/SG/G-3, Mumbai, India (2011).

4. ATOMIC ENERGY REGULATORY BOARD, Safety Guide on 'Security of Radioactive Sources in Radiation Facilities', No. AERB/RF-RS/SG-1, Mumbai, India (2011).

5. IAEA Technical Report Series no. 471, Cyclotron Produced Radionuclides: Guidelines for Setting up a Facility, Vienna, (2009).

6. INTERNATIONAL ATOMIC ENERGY AGENCY, 'Cyclotron Produced Radionuclides: Principles and Practice', Technical Report Series No. 465,Vienna (2008)

7. IAEA Safety Standards, on "Radiation Protection and Safety of Radiation Sources": International Basic Safety Standards, General Safety Requirements Part No. 3 (GSR Part 3), 2014

8. Atomic Energy (Radiation Protection) Rules, 2004

9. N.18/1(5)/91-ER/86 Jan 17,1992, DAE letter to Press [Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987]

10. ATOMIC ENERGY REGULATORY BOARD, Policies Governing Regulation of Nuclear and Radiation Safety, 2014

11. ATOMIC ENERGY REGULATORY BOARD, Safety Code on "Regulation of Nuclear and Radiation Facilities" (AERB/SC/G, 2000)

12. NCRP Report No 144, Radiation Protection for Particle Accelerator Facilities', NCRP (2003).

13. AERB ‘Safety Guidelines on Accelerators’, No. AERB/SG/IS-5, Mumbai, India (2005)

14. GRIFFITHS MATTHEW, ‘Hospital Cyclotrons: Radiation Safety Aspects’, RBWH Nuclear medicine, Queensland health, Queensland government, Australia (2004).

15. KAZUYOSHI MASUMOTO ET AL., ‘Effectiveness of self-shielding type cyclotrons’, Progress
in Nuclear Science and Technology, Volume4, pp. 223-227(2014)

16. IYER M. R, ‘Evaluation of Internal Hazards in Medical Cyclotron’, Radiat Prot Environ, Volume
35, pp 105-110 (2012)

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