No. AERB/RF-RS/SG-3

AERB SAFETY GUIDE

MEDICAL CYCLOTRON FACILITIES

ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY GUIDE NO. AERB/RF/RS/SG-3

MEDICAL CYCLOTRON FACILITIES

Atomic Energy Regulatory Board
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India

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FOREWORD

All activities involving the use of nuclear energy, nuclear radiation and radioactive sources in the country are to be carried out in accordance with the provisions of the Atomic Energy Act, 1962. In pursuance of the objective to ensure safety of members of the public and occupational workers, as well as protection of environment, the Atomic Energy Regulatory Board (AERB), India, is entrusted with the responsibility of laying down safety standards and framing rules and regulations for such activities. The Board has, therefore, undertaken a programme of developing safety standards, codes of practice and preparation of related guides and manuals for the purpose. These documents cover aspects such as siting, design, construction, operation, quality assurance, decommissioning and regulation of nuclear and radiation facilities.

Codes of practices and safety standards are formulated on the basis of internationally accepted safety criteria for design, construction and operation of specific equipment, systems, structures and components of nuclear and radiation facilities. Safety codes establish the objectives and set minimum requirements that shall be fulfilled to provide adequate assurance for safety. Safety guides elaborate various requirements and furnish approaches for their implementation. Safety manuals deal with specific topics and contain detailed scientific and technical information on the subject. These documents are prepared by experts in the relevant fields and are extensively reviewed by advisory committees of the Board before they are published. The documents are revised, when necessary, in the light of the experience and feedback from users as well as new developments in the field.

Medical cyclotron is a type of accelerator used for production of radioisotopes used in the field of medicine and research. However, the safety considerations in medical cyclotrons are different from those associated with high energy and high beam power accelerators. The safety considerations for the latter has been broadly discussed in ‘Safety Guidelines on Accelerators, AERB/SG/IS-5, Mumbai, India (2005)’.

This document is formulated for providing the regulatory framework incorporated during design, operation, maintenance and decommissioning of the medical cyclotron facility to the utilities. This also addresses responsibilities of the personnel and regulatory processes involved at various stages of the facility like siting, construction, commissioning, operation and decommissioning.

Consistent with the accepted practice, ‘shall’, ‘should’, and ‘may’ are used in the guide to distinguish between a firm requirement, a recommendation and a desirable option, respectively. Annexures are included to provide information that might be helpful to the user. A bibliography of the relevant documents referred to in the text is also included. Approaches for implementation, different to those set out in the guide may be acceptable, if they provide comparable assurance against undue risk to the health and safety of the occupational workers and the general public, and protection of the environment.

This guide has been prepared by a committee comprising of specialists in the field drawn from the Atomic Energy Regulatory Board, Bhabha Atomic Research Centre and relevant private institutions.

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

DEFINITIONS

Accelerator
A device in which charged particles are accelerated. Conventional X-ray tube is not considered as an accelerator.

Activation
The production of radionuclides by irradiation.

Activity
The quantity 'A' for an amount of radionuclide in a given energy state at a given time, defined as:

$$A = dN/dt$$

where, dN is the expectation value of the number of spontaneous nuclear transformations from the given energy state in a time interval dt. The SI unit of activity is the reciprocal of second (s^{-1}), termed as Becquerel (Bq).

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

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

Assessment
Systematic evaluation of the arrangements, processes, activities and related results for their adequacy and effectiveness in comparison with set criteria.

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

Classified workers
The employer shall designate as classified workers, those of his employees, who are likely to receive an effective dose in excess of three tenths of the average annual dose limits notified by the competent authority and shall forthwith inform those employees that they have been so designated.

Commissioning
The process during which structures, systems and components of a nuclear or radiation facility, on being constructed, are made functional and verified in accordance with design specifications and found to have met the performance criteria.

Competent Authority:
Any official or authority appointed, approved or recognized by the Government of India for the purpose of the Rules promulgated under the Atomic Energy Act, 1962.

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

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

Controlled Area
A delineated area to which access is controlled and in which specific protection measures and safety provisions are, or could be, required for
(a) controlling normal exposures or preventing the spread of contamination during normal working conditions; and
(b) preventing potential exposures or limiting their extent should they occur.

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

Decommissioning
The process by which a nuclear or radiation facility is finally taken out of operation, in a manner that provides adequate protection to the health and safety of the workers, the public and of the environment.

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

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

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.

Emergency
A situation which endangers or is likely to endanger safety of the site personnel, the nuclear/radiation facility or the public and the environment.

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

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

Exclusive Use (Transport of Radioactive Materials)
The sole use by a single consignor, of a conveyance or of a large freight container in respect of which all (initial, intermediate, and final) loading and unloading are carried out in accordance with the directions of the consignor or consignee.

Final Safety Analysis Report (FSAR)
Safety analysis report submitted to the regulatory body for obtaining consent for operation of a nuclear/radiation facility

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

Incident
Events that are distinguished from accidents in terms of being less severe. The incident, although not directly or immediately affecting plant safety, has the potential of leading to accident conditions with further failure of safety system(s).

Leak Tightness:
The ability of a component to maintain leakage rate within a prescribed value.

Licence
A type of regulatory consent, granted by the regulatory body for all sources, practices and uses for nuclear facilities involving the nuclear fuel cycle and also certain categories of radiation

facilities. It also means authority given by the regulatory body to a person to operate the above said facilities

Monitoring
The continuous or periodic measurement of parameters for determination/assessment in respect of structure, system or component in a facility or control of radiation.

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

Nuclear Medicine
The medical specialty that utilizes radiopharmaceuticals to investigate disorders of anatomy, physiology and patho-physiology, for diagnosis and/or treatment of diseases.

Occupational Exposure
All radiation exposures of personnel incurred in the course of their work.

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

Preliminary Safety Analysis Report (PSAR)
Safety analysis report submitted to regulatory body for obtaining consent for construction

Qualified Person
An individual who, by virtue of certification by appropriate authorities and through experience, is duly recognised as having expertise in a relevant field of specialisation like quality assurance, radiation protection, plant operation, fire safety or any relevant engineering or safety speciality

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

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

Radiation Worker
Any person who is occupationally exposed to radiation

Radiation Protection Survey / Radiological Survey
An evaluation of radiation safety, using appropriate radiation measuring instruments

Radiological Safety Officer
Any person who is so designated by the employer and who, in the opinion of the competent authority, is qualified to discharge the functions outlined in the Atomic Energy (Radiation Protection Rules), 2004.

Regulatory Body
See "Atomic Energy Regulatory Body"

Transport Index (TI)
A number assigned to a package, over pack, or freight container, or to un-packaged LSA-I or SCO-I used to provide control over radiation exposures

SPECIAL DEFINITIONS

Bunker Type Cyclotron
Cyclotron with no self-shielding.

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

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

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

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

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

Medical Cyclotron Facility
Medical Cyclotron Facility consists of cyclotron vault and control room, the radiochemistry and radiopharmaceutical production areas, Quality Control (QC) laboratory, radioactivity dispensing and packaging and dispatch areas, the cold-chemistry laboratory areas and personnel radiation surveillance area (such as decontamination area).

Medical Cyclotron Operator
A person duly trained and recognized by the employer for performing day to day operation of the medical cyclotron.

Note: Havar® is a heat treatable cobalt based alloy that provides very high strength at high temperatures. Havar® has excellent corrosion resistance and is non-magnetic. (Composition: Co 42.0%, Cr 19.5 %Ni 12.7% W 2.7%, Mo 2.2 %, Mn 1.6%, C 0.2% Fe –balance). Two thin Havar foils windows are used to separate the target chamber from the cyclotron vacuum. Havar foil forms the entrance of proton beam into a highly pressurized ^{18}O enriched water target used for the production of ^{18}F.

Off-normal
An operational process deviating from normal operation, which is expected to occur during the operating lifetime of a facility but which, in view of appropriate design provisions, does not cause any significant damage to items important to safety, nor lead to accident conditions.

Radio chemist / Radio pharmacist
A person duly trained and recognized by the employer for performing day to day preparation and handling of radiopharmaceuticals and carrying out QA of the same in a medical cyclotron facility.

Self-shielded Cyclotron
A cyclotron with additional shielding around the cyclotron tank and targetry as an integral part to minimize the neutron and gamma dose around the cyclotron.

Supplier
A person engaged in the supply of medical cyclotrons which are designed in conformance with the applicable safety standards and having responsibilities prescribed by the Competent Authority.

Target
The target in the medical cyclotron is the physical location where the accelerated protons or deuterons interact with the nucleus of the target atom to produce the radioisotope of interest.

Trial run
Provisional operation of the medical cyclotron facility approved by the Competent Authority to verify structures, systems and components of a medical cyclotron facility in accordance with approved design specifications, results are generated to submit to regulatory body in a specified format.

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

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

CONTENTS

1. INTRODUCTION

1.1 General

Medical cyclotrons are used to produce positron emitters, used for PET-imaging, as well as other radioisotopes used in SPECT imaging. In medical cyclotron, particles such as protons or deuterons are accelerated and made to bombard on suitable target material to produce radioisotopes, which are mostly positron emitters. Cyclotron produced radioisotopes are incorporated or tagged with chemicals to produce radiopharmaceuticals. Chemical processing is carried out in specific units built for the purpose. The Medical Cyclotron Facility (MCF) consists of cyclotron vault and control room, the radiochemistry and radiopharmaceutical production areas (R&R), Quality Control (QC) laboratory, radioactivity dispensing, packaging and dispatch areas, cold-chemistry laboratory areas, change rooms and personnel radiation surveillance area (such as decontamination area). Medical cyclotron facilities comes under the purview of regulation in accordance with Rule 3 (3) of the Atomic Energy (Radiation Protection Rules), 2004 and is regulated as per the relevant safety documents prescribed by the Competent Authority from time to time and in accordance with the Rule.

Different types of MCF are being operated in the country. 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.

Table 1.1: Classification of Medical Cyclotron Facilities

Type of MCF	**Medical Cyclotron proposed to be installed**	**Particle energy, beam current**	**Radiopharmaceuticals (RPs) proposed to be produced**	**Usage: In-house and/or Distribution**
I	Self-shielded	H^+ beam only up to 20 MeV Current ≤ 150 μA	[^{18}F]FDG	In-house[#]
II	Self-shielded or Bunker Type	H^+ and/or D^+ up to 20 MeV Current ≤ 150 μA	[^{18}F]FDG and other ^{18}F-RPs $^{13}NH_3$, ^{11}C-RPs ^{15}O-H_2O ^{18}F-RPs by electrophilic route	In-house and/or for distribution

III	Bunker Type with external beam line	H^+ and/or D^+ up to 20 MeV Current ~ 150μA	All those listed in Type-II above plus ^{124}I –RPs, ^{64}Cu-RPs	In-house and/or for distribution
IV	Bunker Type with one or more external beam lines	H^+ and/or D^+ 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.

In-house refers to supply of radioactivity 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 radioactivity is not envisaged.

1.2 Objective

This Guide is intended to apprise the utilities on the regulatory and radiation safety requirements that need to be ensured during the various stages such as setting up of a MCF, operation, maintenance and decommissioning.

1.3 Scope

The document provides requirements and guidance on radiological safety of a MCF for production of radioisotopes for use in nuclear medicine. It addresses medical cyclotrons of both types namely self-shielded and bunker type along with the safety requirements of the radiochemistry laboratories associated with the MCF. In addition to this, the document covers regulatory requirements for Types I-III categories of MCF while only broad guidelines are given for Type IV MCF.

2. CONSENTING PROCESS

2.1 General

The Consenting process involves a multi-tier safety review/evaluation of the facility progressing through the different stages. The applicant is required to obtain regulatory consents at various stages as follows:

a. Site Assessment
b. Layout, Design and Construction
c. Commissioning
d. Operation
e. Decommissioning

The information and formats for application to obtain regulatory consents at above stages is available in AERB Safety Guide on 'Consenting Process for Radiation Facilities', 2011 (AERB/RF/SG/G-3).

2.2 Site Assessment

The Medical Cyclotron Facility (MCF) should be located and installed either in a hospital or in industrial premises. The applicant is required to provide to the regulatory body the following site specific information:

a. Seismic zone as per IS-1893-1 (current version), 'Criteria for Earthquake Resistant Design of Structures' (Documentary evidence from relevant state/central govt. authority)
b. Maximum level of ground water and maximum flood level for past ten years as per the concerned central/state govt. records, along with documentary evidence.
c. Distance of site of installation of MCF from public and nearby residential localities, if any.
d. Documentary evidence from accredited geotechnical investigation agency that the soil and ground characteristics (e.g. soil profile, stratum, foundation type, soil and rock, elemental analysis of sub soil and ground water) will not cause deterioration in the strength and integrity of structure of irradiation cell.
e. Provision of suitable roads to approach the proposed site.
f. Details of any existing or planned auxiliary facilities such as ammunition dumps, and storage of inflammable and toxic substances within a radius of about 30 m from the proposed cyclotron vault of the MCF.

The applicant should take into account all above site-specific parameters and ensure that the design of the MCF adequately addresses safety of the systems, structures and components. The regulatory body may inspect the site for approval

2.3 Layout, Design and Construction

For obtaining Layout, design and construction approval, the applicant is required to submit application along with layout plan of the facility and Preliminary Safety Assessment Report (PSAR) in the specified format.

The major components of the PSAR are:

a. Organizational setup
b. Detailed system parameters of cyclotron, synthesis and dispensing units.
c. Design safety features of cyclotron, synthesis and dispensing units
d. Zoning and Ventilation
e. Auxiliary facilities
f. Identification of hazards and its evaluation
g. Emergency response planning and procedures
h. Quality Assurance (QA) Manual for construction
i. Physical security measures
j. Decommissioning manual

The approval for layout, design and construction may be granted after multi-tier review of the PSAR submitted for the installation of the MCF. The regulatory body may inspect the facility while under construction to ensure that the construction is as per the approved design and in accordance with QA Manual.

2.4 Commissioning

The process of Commissioning involves, a) making the MCF functional, b) Ensuring functioning of the MCF in accordance with the approved design specifications, c) Verification of structures, systems and components including safety systems as per performance criteria.

After completion of construction and installation, the applicant should approach the regulatory body for permission to carry out trial run for commissioning.

For this purpose, the applicant should submit the following to the regulatory body:

a) Radiation Protection Manual (RPM) as per the prescribed format
b) Details regarding availability of qualified and trained manpower – operator(s), radio pharmacist(s)/radiochemist (s) and AERB approved Radiological Safety Officer (RSO).

c) Personnel monitoring services for all radiation workers;
d) Appropriate radiation measuring and monitoring Instruments
e) Operational procedure manual
f) Safe handling tools and devices required for operation and maintenance of the medical cyclotron and auxiliary equipments.
g) Security Plan

After successful trial runs, the applicant becomes eligible for obtaining consent for operation.

2.5 Operation

For obtaining licence for regular operation, the applicant should submit the Final Safety Analysis Report (FSAR) in the prescribed format incorporating the results of commissioning and trial run operations.
Based on the review of all safety aspects and inspection by regulatory body, licence may be granted to operate the unit subject to terms and conditions.

2.6 Decommissioning

When the medical cyclotron is no longer to be used, the permission for decommissioning should be obtained from the Competent Authority and decommissioning should be carried out in accordance with an approved procedure laid down by the Competent Authority. The induced radioactivity in the cyclotron components and the structures should be considered during decommissioning/disposal as a radioactive waste. The licensee should submit a report on the completion of decommissioning, which includes, inter alia, safe disposal of sources and personnel exposures received during decommissioning.

2.7 Offences and Penalties

Any person who contravenes the provisions of the Atomic Energy (Radiation Protection) Rules, 2004, or any other terms or conditions of the Licence/Registration/Certification granted to him/her by the Competent Authority, is punishable under relevant sections of the Atomic Energy Act, 1962.

3. MEDICAL CYCLOTRON FACILITY DESIGN

3.1 General:

In an MCF, the cyclotron vault is the area with the highest amount of radioactivity, when the cyclotron beam is 'ON' for irradiation of the targets. After irradiation and transfer of produced radioactivity to the hot-cells, the radioactivity in the cyclotron vault decreases rapidly, while the radiochemistry laboratories will have the highest level of activity. After synthesis in the hot-cells, the radioactivity, in the form of the finished radiopharmaceutical is moved into the dispensing hot cell, packed and dispatched to the user. Small amounts of the finished product is sent to the QC laboratory for quality control.

The facility should have a proper layout and design to ensure safety of the workers, general public and environment during normal operation and off-normal incidents.

This section deals with overall design of the MCF and the specific design aspects to be considered for the Cyclotron vault and R&R. Several factors decide the design and layout of a medical cyclotron facility, of these, the type of the facility is the most important.

3.2 General design considerations of a Medical Cyclotron Facility (MCF)

3.2.1 Layout considerations:

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

a. The layout of the MCF should be planned in such a manner so as to ensure that movement of radioactive material is minimized and contained. This is achieved by ensuring that the area for each step in the processing is in close proximity to the preceding step. A typical radiation field gradient in a MCF is given in Figure 3.1 below.

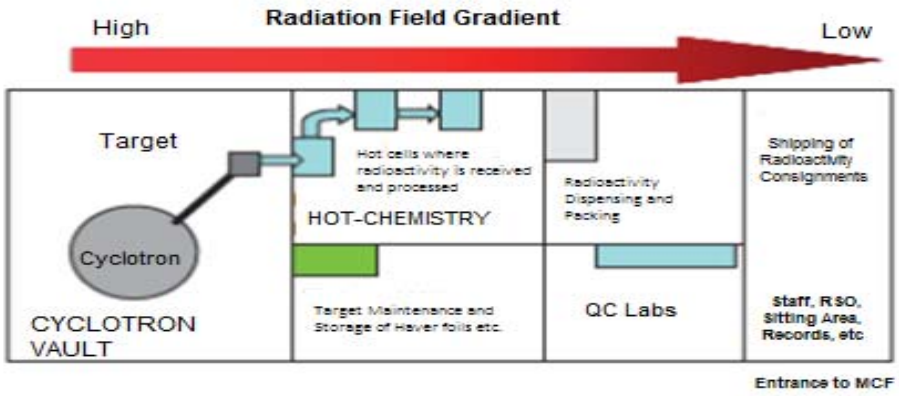

Figure 3.1: Typical radiation field gradient in a MCF

b. Adequate space should be available for ease in handling of radioactive material.
c. Shielded transport containers and pass boxes in the walls of adjoining rooms may be provided to minimize or eliminate the chance of the spread of contamination.
d. The facility should have restricted access to the areas where radioactive materials are either produced or handled.
e. Adequate security provisions as per the security plan should be in place to prevent unauthorized access to the facility and theft of radioactivity.
f. There should be suitable provision for safe storage of radioactive wastes.

3.2.2 Layout considerations for different types of MCFs:

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

a. In the Type-I MCF, since only [^{18}F] FDG is made, the layout is relatively simple. The cyclotron in such a facility could be a self-shielded and/or housed in a vault adequately shielded against gamma and neutron radiation.
b. A Type II facility has a larger scope than a Type I MCF. The floor plan should accommodate production, dispatch and shipping of isotopes.
c. A Type III MCF, is built around a cyclotron that is similar to that in a Type II, but in addition has a beam line for irradiating solid target to produce other radio-isotopes (in addition to C-11, N-13, O-15 and F-18). Since the scope of this facility is also to produce longer lived SPECT and PET isotopes, other than the four mentioned above, there are additional radiation safety requirements. There should be a provision for a small cave type vault, (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, 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.

d. 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. Unlike the cyclotrons in Type II and III, where the liquid and gas targets are mounted on the cyclotron itself, 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 as in the other types, where the cyclotrons will be 'OFF' for some time in a day. The floor plan for a Type IV cyclotron facility would be very individualized depending on the purpose and goals.

3.2.3 Ventilation requirements

In the design of a MCF, regardless of the type of facility, ventilation system plays a vital role.

a. The ventilation system should be in such a manner that the air-flow should be from low-activity area to potential high activity area.
b. It should also prevent microbial contamination to the areas where radiopharmaceuticals are produced and dispensed. Both goals should be achieved by proper design as indicated in Figure-3.2
c. The cyclotron vault should be at the lowest pressure in the building, and also the location from where the air from the premises will be exhausted.
d. 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.
e. Exhaust air should be passed through a filter bank consisting of a charcoal filter, pre filter, and a HEPA filter before release through a stack situated on top of the highest location in the building.
f. The radiochemistry area should be supplied with HEPA-filtered air to maintain the required high pressure vis-à-vis the QC-labs and the cyclotron vault. HEPA-filtering the inlet air ensures the required clean air quality.
g. The hot cells inside the R&R area should be maintained at a lower pressure than the surroundings. The hot cell exhaust should be released through stack.

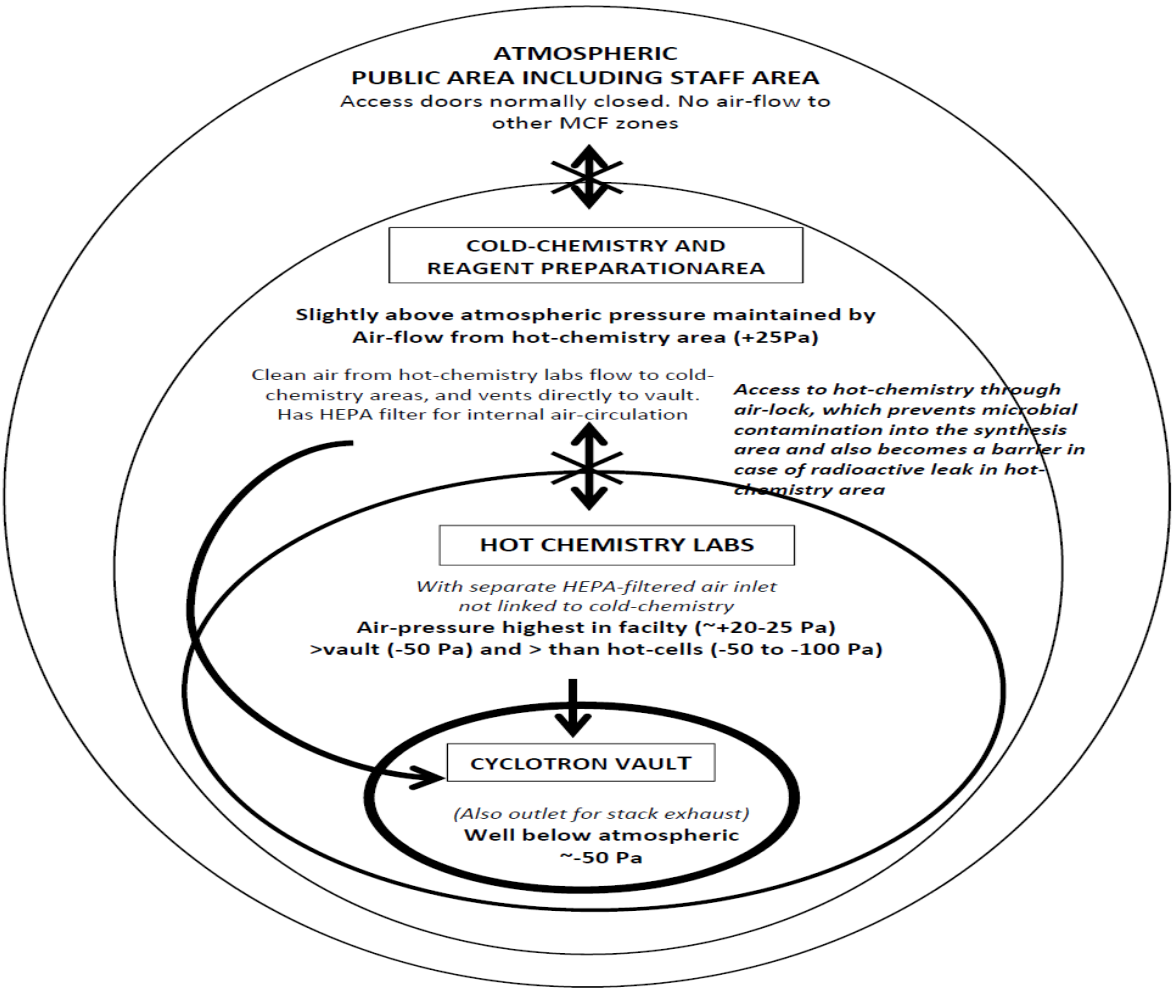

Figure 3.2: Air pressure in different zones in a Medical Cyclotron Facility (The values are with reference to Standard Atmospheric Pressure)

h. The stack should at least be at a height of 1.5 m from the nearest tallest building.
i. Another critical aspects in designing a MCF is the number of air-changes in the premises. The air pressure gradient would be the in the opposite direction to the radiation gradient, as described in Figure-3.2.

Typical air pressure and recommended number of air changes and room pressures for different functional area are shown in Table 3.1 below.

Table 3.1 Functional areas and recommended air pressure (The values are with reference to Standard Atmospheric Pressure)

Functional Area	Room Pressure (Pa)	No. of air changes (h^{-1})
General access areas	Atmospheric	NA
Corridors in MCF	-10	2 – 5
Control room	-10	2 – 5
Packaging room	-10	2 - 5
Personnel airlock for entering R&R	+5	10 – 20
R&R (Hot chemistry area)	+20	10 - 20
Hot cells	-50 to -100	>20
QC laboratory	-10	5 – 10
Cyclotron Vault	Below -50	10 – 20

3.3 Built-in safety:

3.3.1 Safety interlocks:

a. The facility should be equipped with installed area monitors, various interlocks and audio-visual alarm system.
b. Emergency scram switches or buttons to turn off the cyclotron should be available and must be placed inside and outside the cyclotron vault facility. All these scram switches should be clearly and conspicuously marked.
c. The entry of personnel into the Medical Cyclotron vault area or target caves should be through an access door having adequate shielding and equipped with interlock switches. These interlock switches should be such that any accidental or willful opening of the access door would stop or trip the machine. The interlock switches should be as ***"fail-safe"*** as possible.
d. Suitable interlocks should be available to ensure that the cyclotron cannot be operated when radiation shields (self-shielded cyclotron) are not in place or vault doors (bunker type cyclotron) are not closed.
e. Area gamma monitors located outside the vault door, should be interlocked in such a way that it will cause the cyclotron to trip, when in operation, if the radiation levels exceed the pre-set limit.
f. Area gamma monitors inside the vault, should be interlocked to the vault door so that they cannot be opened unless the level falls to permissible levels for workers to enter the vault.

3.3.2 Design safety provisions:

The facility should have suitable protection features to guard against following adverse conditions such as:

a. Main power supply instabilities
b. Fire
c. Mechanical damage
d. Target failure
e. Loss of coolant
f. Water ingress
g. High Radiation

3.3.3 Safety Indicators:

Indicators that warn of start-up conditions of the cyclotron like switching 'ON' of the magnet, the radiofrequency power and the beam, should be located at the entrance of the cyclotron vault. For self-shielded cyclotrons, separate indicators should be located inside the vault. In case of Type III & IV, the target caves should also have safety indicators at the entrance to 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" conditions.

3.4 Medical Cyclotron Vault Design & related aspects

3.4.1 Medical cyclotron vault

a. The medical cyclotron should have adequate shielding against both gamma and neutron radiations generated by the cyclotron during its operation. Bunker type cyclotrons generally require larger and wider vault. The dimension of the vault, its wall, ceiling and floor thickness should be such that all the structures and components to operate the cyclotron should be properly accommodated.

b. In self-shielded cyclotrons, the vault should provide adequate shielding from radioactivity build up in the self-shield as well as radiation from activation of inner components whenever the self-shield is opened for maintenance.

3.4.2 Structural Requirements:

a. The structures, systems and components should be built as per the relevant standards for earthquake resistant structures.
b. Standard concrete should be used for the cyclotron vault with required thickness to provide adequate shielding.

c. The use of boron in the concrete to absorb neutrons should be as boron carbide and not in the form of borate compounds. 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.
d. Cobalt content in the concrete should be kept as low as possible. Hence, the presence of iron or iron rich minerals with the high likelihood of presence cobalt and nickel as additives to the concrete, is to be avoided.
e. 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 from the cyclotron.
f. The concrete used in the vault walls for bunker type cyclotrons, should be built with about 20-30 cm strippable layer or as estimated by design, without affecting the concrete integrity, density etc.
g. 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 to the outside of the vault. Epoxy surface finish is now 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.
h. For the vaults housing bunker type cyclotrons, either a maze type structure or a concrete plug door should be provided with sufficient shielding to attenuate the γ and neutrons to acceptable dose limits at the entrance door. Since neutrons can stream through a maze, neutron shield doors should be fitted on hinges at the entrance to the maze and also at the entrance to the vault. These may be rigid steel shells filled with neutron absorbing material like polyethylene.
i. There should not be any water leakage, seepage and/or clogging from rain water or from any other source of water.

3.4.3 Target station requirements:

In case of Type III and Type IV Cyclotrons, having external beam lines, the target stations should be housed in a specially designed shielded target caves, which are designed to irradiate solid targets to produce large amount of radioisotopes. All the design requirements of the vault should be applicable for the target caves.

3.4.4 Provision for Utilities:

a. 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 (v) hydrogen, deuterium helium and nitrogen gas should be suitably housed

around the equipment and access into the vault for these utilities should be through curved/arched penetrations in the vault wall or floor trenches.

b. Cut-outs for the ventilation ducts for air inlet and air exhaust for maintaining the negative pressure and required number of air changes should be provided.
c. Lighting in the vault should be designed such as to facilitate critical inspection and maintenance.
d. The peripheral equipment for bunker type cyclotrons, should be installed in a separate area outside the vault, to avoid damage of sensitive electronic equipment due to radiation.
e. A work table with a shielded L-bench should be provided in the cyclotron vault for the routine service and maintenance of radioactive components. The work surfaces should be inert, non-absorbent, easy to clean and should not generate dust.

3.4.5 Floor design in the Cyclotron Vault:

a. A proper floor design is required for both self-shielded and bunker type cyclotrons. The floor should also have the sufficient load bearing capacity for the cyclotron, vault, walls and ceiling.
b. The concrete used for the floor should be of sufficient thickness to take the weight of the cyclotron and also provide adequate attenuation and absorption of neutrons (generated during cyclotron operations) so that the elements in the soil and groundwater below are not activated.
c. In addition, the floor of the cyclotron vault should have adequate space for other auxiliary equipment (vacuum pumps, waste gas compression systems, dehumidifiers, L-bench for target maintenance, lead shielded storage pits for long-lived radioactive waste, (e.g., Havar foils) etc.
d. Floor trenches are required for conduit of chilled water, electric cables, communication cables and the passage of radioactive product from target to the hot-cells in the radiochemistry labs. The trenches should be satisfactorily covered to facilitate easy servicing; and not to allow any seepage of spilled radioactivity during cyclotron and target maintenance activities. 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 to prevent direct streaming of neutrons and gamma radiation.
e. Like the walls in the vault, the floor should also have appropriate finishing to prevent it being a source of dust and fine. It should be non-absorbent, hard, washable and non-slippery.

3.4.6 Penetrations in the Vault:

a. Penetrations for power cables, cooling water lines, ventilation and air-conditioning, transfer of radioactivity, etc., into the vault should be designed to block radiation leaks to acceptable levels.
b. Penetrations in the vault walls should not be straight and should have bends to prevent direct streaming of gamma radiation. In addition, the gaps between the cables and tubing should be filled with high density polyethylene material and a layer of lead wool. The packing should be firm but not too tight so that removal of the cables should be possible if necessary.

3.4.7 Control Room:

A control room for operation of the medical cyclotron should be available near to the access to the vault. The display units of various online monitors and status of ventilation and exhaust systems should be available at the control desk or at least visible from the control desk. Provision should be made for storage of the radiation measuring and monitoring instruments inside or near to the control room. Access to cyclotron vault should have visual surveillance from the control room.

3.5 Transfer of Radioactivity

After irradiation, radioactive gases and liquids produced in the target will normally be transferred out of the cyclotron vault into the hot laboratory 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 radiation levels will allow normal occupancy during transfer. The composition of the tubing used to transport the radioactivity should be consistent with the chemical form of the radionuclide being transported.

3.6 Radiochemistry and Radio-pharmacy (R&R) Laboratory Area

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

3.6.1 General requirements:

a. The R&R-area should be, as far as possible, located adjoining to the cyclotron vault/target caves to ensure minimum length of tubing required to transport the radioactivity from the cyclotron target to the hot cells.
b. The R& R laboratory space should be physically separated from personal desk space, meeting space and eating areas.
c. The area available should be sufficient for arranging the required number of hot-cells, laminar 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.

d. If experimental production of radiopharmaceuticals is planned to be a regular feature, then, the R&R-area may be partitioned to separate an area dedicated for R&D purpose.
e. In Type III and IV facilities, the hot-chemistry lab for solid targets has to be adjacent to the target caves so that the transport of the solid target after irradiation is facilitated.
f. 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 equipped with shower in case of accidental spillage of radioactivity. Hand and foot monitor should be available at the exit from the R&R-area. There should be a provision for an eye-wash, in case of suspected contamination.
g. The R&R laboratory walls are to ensure physical security and hence, brick or concrete blocks may be used.
h. 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 in decontamination.
i. Table tops and other work surfaces should be finished with hard, impervious, heat resistant, stain resistant, chemically resistant which can easily be decontaminated, preferably in large sheets with a minimum of joints. Preferred materials are stainless steel and industrial grade grey polyvinylchloride.

3.6.2 Hot-cell design:

Hot-cells are the most effective way to contain and shield small amounts of open radioactive sources, which are to be chemically processed. 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 fulfill the following requirements

a. The frame should be sturdy to bear the load and the thickness of the shielding should be adequate for the type, energy and activity of radiation to keep doses received by the operators within the accepted limits.
b. The interior surface of the hot cells should be made of high quality stainless steel, preferably 316 grade, with smooth impervious joints.
c. Electrical and data communication cables should be through shielded ports with bends to prevent radiation streaming.

d. On closing the door, there should be an air-tight seal with the body of the hot-cell and should be tested for the leak tight behavior periodically.
e. Lead glass window of standard density with adequate thickness should be provided.
f. Hot cells constructed for the production of radiopharmaceuticals should maintain negative pressure to contain radioactivity.
g. There should be at least 20 air changes per hour during operation with HEPA filtered in-air and exhausted air should pass through HEPA filters to prevent introduction of dirt and exhaust of any contaminated particles.
h. 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 the pre-set critical value.
i. Hot-cells should be connected to radio-active waste gas compression systems, which maintain the required negative pressure in the hot-cells, ensures required number of air changes 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.

3.6.3 Shielded Laminar flow hoods

The laminar flow hoods used in the hot laboratory for handling radioactive products, should be sufficiently shielded to minimize the radiation exposure to the radio chemist.

3.7 Industrial Safety in the Design of MCF:

The facility should ensure industrial safety as per the applicable state/central 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 other 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 radioactivity or discharges into the environment.

3.7.1 Fire Safety

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

a. Local fire safety rules should be adhered to by the facility which may include provision for fire exits, fire protecting equipments, fire blankets etc to be kept in the facility. The facility should install smoke detectors & fire alarms in all

the rooms and have auto water sprinklers at suitable places to combat fire. Infrared (IR) sensors may also be put in suitable places where the chance of fire hazard is higher.

b. Suitable fire extinguishers should also be kept at suitable places inside the facility. The fire extinguisher should be appropriate to use on electrical fire as well as normal fire. It is better to have an automated gas based firefighting system which is non-toxic in nature. The cold chemistry lab or the preparation area should be equipped with fire extinguishers which can act on chemical fire. Moreover, it is advisable to store and use flammable chemicals in small quantity in these handling rooms. The bulk of the chemicals should be kept in steel vented cupboards suitable for storing chemicals.

In addition to the above, the facility should consider the following;

c. Hydrogen gas cylinders should be kept in a gas containment cabinet with a separate ventilating duct and a ventilation system to vent out any accidental release of gas.
d. During maintenance activities of the cyclotron, the power should be shut down for all other equipments except the electrical power required to run the cyclotron to avoid inadvertent ignition of flammable solvents and combustible materials used during routine maintenance of the cyclotron.
e. All electrical wiring and plastic tubing and metals should be insulated from contact with the conductive surfaces to avoid sparks.
f. It should be ensured that metal tubings & wirings should not make contact with magnetic parts or cables supplying low voltage to high amperage components while supplying power to the cyclotron.

All the employees/personnel should be trained periodically for fire safety procedures and handling firefighting equipments.

3.7.2 RF Safety

Radio frequency/microwave radiation is present in many accelerator facilities which is originated from klystrons, magnetrons, and backward wave oscillators. RF fields can interfere with some radiological survey instruments. To avoid exposure of persons to unacceptable levels of RF energy, engineered control measures, such as shielding, prevention of wave guide leakage, enclosures, interlocks preventing accidental energizing of circuits, and dummy load terminations should be given primary consideration. In addition personal protective equipment (PPE) should be used if required. RF leakage tests should be conducted when the system is first operated and periodically thereafter. It is advisable to conduct RF leakage tests at least once in a year.

3.7.3 Magnetic Field Safety

High magnetic fields are present at all accelerator facility during operation. The health risks from magnetic fields are not well understood till now. High magnetic fields may also present safety hazards from the forces they exert on ferromagnetic materials such as tools. Perceptible or adverse effects have been produced at higher flux densities on persons with implanted ferromagnetic medical devices (suture staples, aneurism clips, prostheses, etc.).

All radiological survey instruments should be properly stored to avoid interference from both magnetic fields and radio frequency fields. To avoid exposure of persons to unacceptable levels of RF energy, engineered control measures, such as shielding, interlocks preventing accidental energizing of circuits should be in place. RF leakage test should be conducted when the system is first operated and periodically thereafter. Appropriate caution boards warning of RF and magnetic fields should be displayed to avoid entry of unauthorized personnel.

4. OPERATIONS & MAINTENANCE

4.1 General:

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 also equally essential that the operations and maintenance of the MCF is carried out as per well established procedures.

The facility should have an appropriate organizational set up with well-defined line of command and responsibilities during operation, maintenance, safety and radiological protection activities.

All Administrative controls through policies and procedures indicating local safety rules should be displayed in the Medical Cyclotron facility in English and local language.

This section describes the requirements to be followed to ensure safety while operation and maintenance of Medical Cyclotron, the R&R and other associated equipment/facilities.

4.2 Personnel requirements and their qualification:

A MCF should be operated with adequate number of Cyclotron Operator(s), Radio chemist(s) and an RSO. Table 4.1 gives the recommended qualification for the required personnel. All personnel should undergo a specialized on-the-job supervised training to be certified by the manufacturer/supplier of the cyclotron or by an AERB recognized facility for the operation of the facility.

Table 4.1: Recommended Educational Qualification of Personnel working in a MCF

Staff	Minimum Educational Qualification
Cyclotron Operator	DMRIT/M. Sc. (Nuclear Medicine)/DNMT/BNMT/ Diploma in Engineering (Electrical /Mechanical/Instrumentation/Bio-medical) / B.Sc. (Physics)
Radio chemist	B. Sc. (Chemistry)/B. Pharm.
Radiological Safety Officer	Dip. R.P/M.Sc. (Medical Physics) or Equivalent

4.3 Operational requirements:

4.3.1 Medical cyclotron:

a. The medical cyclotron should be operated only after obtaining Licence for operation from the regulatory body and should adhere to the conditions stipulated therein. There should be a well-established program for training and qualifying the operator and the cyclotron should be operated only by such qualified and trained operator, duly authorised by the Employer.
b. All operators should undergo an appropriate radiation safety orientation course including emergency response plans. Radiation safety requirements as specified in the approved Radiation Protection Manual should be adhered to. Periodic conduct of radiation level measurements in and around the medical cyclotron facility before, during and after the routine operations should be conducted by the RSO.
c. The cyclotron should be operated as per the Standard Operating Procedure issued by the Manufacturer which includes amongst others
    i. The established operational sequence to ensure safe operation.
    ii. A "Search and Secure" procedure is to be conducted before closing the vault door before start of cyclotron operation to exclude the trapping of any personnel in hazardous area.
    iii. Possible off-normal situations and follow-up actions.
d. Transfer of produced radioactivity, to the intended hot cell should be ensured by the medical cyclotron operator while keeping the radio-pharmacist duly informed. If pneumatic chute system is used, its design and layout should be through the shortest possible route, through least occupancy areas. Also, in case of any accidental jamming or obstruction of the lead capsule containing radioactivity during transfer, it should be possible for safe removal or retrieval of the capsule.
e. There may be occurrences which demand bypass of safety/ interlock systems. Such bypass can only be carried out with approval of the Licensee and under the supervision of RSO. Bypass of interlocks should be permitted only under carefully controlled and monitored conditions and should be restored to its original intent.
f. Entry into the target cave should not be allowed if the radiation levels inside are above permissible levels, for e.g., after irradiation, until the radioactive target is safely transported into the hot-cell for processing or stored for cooling.
g. A log book should be maintained at the control room giving operational parameters and off normal incidents (including bypass of interlocks / safety systems) during the daily runs.

4.3.2 Radio-pharmacy & Radio-chemistry laboratory:

a. The preparation and dispensing of radiopharmaceutical should be carried out by qualified and trained Radio chemists / Radio pharmacists, duly authorised by the Employer.
b. All Radio chemists / Radio pharmacists should undergo an appropriate radiation safety orientation course including emergency response plans. It should be ensured that the hot-cells are not being used beyond their design capacity of handling of radioactive isotopes. . All radioactive materials should be stored/handled only in specially designated areas equipped with facilities to carry out such operations.
c. Before entering the R&R area, protective clothing and safety gears should be properly worn along with TLD badges. An inventory of all radioactive materials should be maintained by the facility and all sources or radioactivity would be accounted for. Any disposal of radioactive waste generated from operation of the facility should be made in accordance with the norms set by the regulatory body. The shielded door of the receiving hot cell should be properly closed and secured and the radiochemistry staff should be informed of the transfer of radioactivity about to be made.
d. Presence of adequate negative pressure inside the hot cell prior to the transfer of radioactivity should be confirmed. A pressure gauge indicating the presence of negative pressure in the hot cell should be conspicuously displayed and verified
e. Lead shielded containers should be used for transfer of radio-chemicals and radiopharmaceuticals produced in solid target from R & R lab to QC lab.
f. During QC proper radiation safety measures should be ensured such as:
    i. Handling of the radiopharmaceutical should be performed behind an L-bench assembly.
    ii. The transfer of syringe containing radioactivity should be undertaken in lead syringe carrier.
    iii. The staff should monitor for any personnel contamination and also monitor the tools and gadgets used during QC procedures for any detectable contamination.
g. The handling of waste should be as per proper procedures defined 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.
h. A log book should be maintained at the R& R Laboratory giving major operational parameters.

4.3.3 Record of Production and Despatch

The facility in charge should keep a record including the following

a. Total Amount of Radioisotope Produced per Batch of Irradiation
b. Total Amount of Radiopharmaceutical Synthesized per Batch of Synthesis
c. Total No. of Consignments with activity content
d. Radiopharmaceutical QC Records
e. Total amount of waste generated per batch.

4.4 Maintenance requirements:

4.4.1 Medical cyclotron

a. A programme of scheduled maintenance followed by safety inspection should be established, documented and followed for the cyclotron and its associated safety systems.
b. All planned or breakdown maintenance activities, should be carried out by trained personnel duly authorised by the Licensee.
c. RSO should ensure that all maintenance activities are carried out under radiologically conducive conditions.
d. All personnel accessing the vault during maintenance should be provided with Direct Reading Dosimeters.
e. The Licensee should be notified on any modifications that are made in the system during maintenance. The licensee should evaluate any implication on operational safety before carrying out the said modification.
f. The Licensee should seek prior permission from the Competent Authority for major design changes in the cyclotron and associated safety systems.
g. Before re-starting the cyclotron, suitable changes, if warranted, in the standard operation procedure should be effected.
h. The interlock switches must be tested periodically to ensure that they are functioning as designed.
i. Warning devices, both audible and visible, should be inspected and periodically tested to ensure that they are functioning properly as per the design intent.
j. Periodic routine checks should be performed for the monitoring instrumentation and safety systems in place in the facility. Any deviation or malfunction from the intended purpose should be corrected before starting up the medical cyclotron.

4.4.2 R & R:

a. A programme of scheduled maintenance followed by safety inspection should be established, documented and followed for the Hot Cells and Transfer lines and its associated safety systems.
b. All planned or breakdown maintenance activities, should be carried out by trained personnel duly authorised by the Licensee.

c. RSO should ensure that all maintenance activities are carried out under radiologically conducive conditions.
d. The interlock switches, if provided, must be tested periodically to ensure that they are functioning as designed.

4.4.3 Maintenance of the Targets:

a. The composition of induced activity in the target which should be identified and allowed to decay to acceptable levels before maintenance is carried out. The radioactive parts of the target should be handled with care and stored for decay or disposed of properly.
b. Targets should be maintained after specified hours of usage as prescribed by manufacturers.
c. Maintenance should be carried out behind a shielded L-bench with a suitable 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 radioactivity.
d. Havar foils should be replaced periodically as a part of preventive maintenance.
e. All the material used for cleaning the target, viz., solvents, solutions, absorbent paper, brushes etc., should be properly stored and discarded. Equipment like sonicator, which is used to clean the target and ion source parts should be dedicated for the purpose.
f. 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 established procedures.

4.5 Security Aspects

4.5.1 The licensee should be responsible for keeping the radioactive materials in his/her possession for safe custody and providing adequate physical security. The MCF should be kept under lock and key when not in use and the key should be kept in the custody of the certified personnel.

4.5.2 Radioactive sources should not be lent/leased, gifted or otherwise transferred to any other person except with the permission of the Competent Authority.

4.5.3 The licensee should submit periodically to the Competent Authority statement of sources in his/her custody in the format prescribed by the Competent Authority.

5. ROLES AND RESPONSIBILITIES

5.1 General

Responsibilities of individuals, who are directly or indirectly associated with the radiation safety of radiation workers and general public are stipulated in Atomic Energy (Radiation Protection) Rules, 2004. Additional responsibilities with respect to MCF practice are prescribed in this Guide.

5.2 Responsibilities of Employer

5.2.1 The ultimate responsibility of ensuring radiation safety in handling the MCF should rest with the employer.

5.2.2 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 shall be recorded and made available during inspection by the regulatory body.

5.2.3 Employer should ensure adequate security arrangements 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).

5.2.4 Comply with the terms and conditions of Licence.

5.3 Responsibilities of Licensee

5.3.1 Ensure periodic training in radiation safety for radiation workers towards performing their intended task.

5.3.2 Comply with the terms and conditions of Licence.

5.4 Responsibilities of Radiological Safety Officer

5.4.1 Advise the employer and licensee regarding

a. necessary steps to ensure that the dose of radiation workers are well within the dose limits prescribed by the Competent Authority. To this end he may establish in house dose constraints for the facility to ensure the limits are not exceeded.
b. the good work practices that ensure radiation doses are maintained As Low As Reasonably Achievable (ALARA).

c. promptly carrying out servicing and maintenance of the systems, structures and equipment, which can impact radiation safety.

5.5 Responsibilities of all Radiation Workers

Radiation workers shall undergo training provided by the supplier, towards appropriate exposure parameters and dose reduction protocols.

5.6 Responsibility of Student/Trainee

Trainees should work in the MCF only under direct supervision of authorized operating personnel and RSO.

In addition to the responsibilities as radiation workers, the cyclotron operator and the radio chemist are also responsible for the following:

5.7 Responsibilities of Medical Cyclotron Operators:

5.7.1 The operator should operate medical cyclotron as per the SOP and the operational requirements identified in this document.

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

5.7.3 Ensure that the filter banks and stack monitor are performing satisfactorily.

5.7.4 If the operator is required to carry out preventive, planned and emergency maintenance involving radioactive material, the operator should do so with the concurrence of RSO.

5.7.5 He should coordinate with the radio chemist to ensure that the cyclotron produced radioactivity is safely transferred and received in the desired synthesis module.

5.7.6 He should inform RSO/Licensee in case of any malfunctioning of the system and its components and make modifications if needed.

5.8 Responsibilities of Radio chemist(s):

5.8.1 The radio chemist should carry out all the activities in the R& R lab as per the SOP and the operational requirements identified in this document.

5.82 The Radio chemist should coordinate with the cyclotron operator for safe transfer of activity from the medical cyclotron to the synthesis module.

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

5.8.4 In case radioactive material is transported outside the facility, he should do so with the concurrence of RSO.

5.9 Unusual Incidences & Reporting:

5.9.1 In case of any Unusual Incidence in the facility the Licensee/Management shall intimate the regulatory body of the incident within 24 hours of its occurrence and submit a detailed report on the incident after carrying out investigations and measures initiated to prevent recurrence of such incident.

5.9.2 In the event of any loss or theft of any radioactive sources, a written complaint with the local law enforcing authorities should be lodged.

5.9.3 In case of any suspected excessive or over exposure to radiation, would arrange to promptly submit the monitoring badge of the concerned occupational radiation worker to the accredited Personnel Monitoring Service (PMS) provider, for immediate dose assessment and the personnel should be referred to a medical doctor for treatment if excessive or over exposure is suspected.

5.9.4 The RSO should immediately report to the Licensee/Management of any unusual incident and initiate prompt remedial actions to mitigate the consequences of the incident. Such unusual incident should be reported to the Competent Authority within 24 hrs of its occurrence and a detailed report thereafter.

5.9.5 The RSO should carry out prompt investigation on causes of the incident, initiate and recommend effective measures to prevent recurrence of such incident and submit a detailed report of the incident to the Licensee/Management.

5.9.6 The RSO should use radiation field measurement data, reconstruct the incident for dose evaluation, recommend in writing, measures to be initiated to prevent recurrence of such incident and submit the report to the Licensee/Management. The detailed report of the incident should be submitted to regulatory body by the Licensee/Management

6. Operational Radiation Protection

6.1 General

Operational radiation protection involves radiological surveillance during routine operations, maintenance and off-normal situations. Management and surveillance of radioactive waste is also an important component to ensure radiation safety.

This section deals with

i) Radiological surveillance
ii) Radioactive waste management which includes management of solid, liquid and gaseous radioactive waste generated during operation, maintenance and off-normal situations of MCF.
iii) Record keeping

6.2 Radiological Surveillance:

Radiological surveillance essentially includes area monitoring, personnel monitoring and contamination monitoring.

6.2.1 Area Monitoring:

The objective of area monitoring is achieved through use of installed gamma and neutron monitors as well as hand held survey meters.

a. Installed gamma and neutron radiation area monitoring devices with audio-visual alarm should be provided in all areas that can have continuous occupancy and where radiation levels are likely to rise above the permissible levels.
b. The output of all the fixed radiation monitors should be easily legible and measurement data from all locations should be displayed at a centralized control center in the facility preferably control room for the cyclotron.
c. The area monitors should have appropriate preset alarm conditions depending on the location of installation of the same.
d. Low and high range gamma radiation survey instruments, neutron survey meters should be available for measurement of ambient radiation fields.
e. The radiation monitoring and measuring instruments should undergo periodic calibration and performance checks.
f. A portable air sampler may also be made available at the facility to collect and measure air samples.

6.2.2 Personnel Monitoring

a. All radiation workers and trainees entering the controlled areas should be covered by personal monitoring services.
b. In addition the facility should also have sufficient numbers of Direct Reading Dosimeters (DRDs)/ Digital Pocket Dosimeters with alarm setting for instantaneous recording of personnel exposure.
c. Maintenance personnel should be issued with DRDs Ł1#˚ ˛˛ŁŁŁ1#Ł#ø˘ß¹Ł11˘˚# æ Ł1ŁŁßŁ1Æ#¸ ˚ ˛Æ˘¹ whenever they enter radiation areas.
d. In addition, wherever appropriate, extremity dose measurement using badges should also be undertaken.

6.2.3 Contamination Monitoring

a. Hand and Foot monitors at appropriate location interfacing the R & R room to other areas of the MCF should be provided to detect the presence of any radioactivity contamination on the skin, body, personnel protective clothing, personal clothing and foot wear etc.
b. 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.
c. Periodic surveillance for possible contamination from activation products either in the cyclotron vault or radiochemistry laboratory or QC labs should be ensured.
d. Provision of instruments and de-contamination facilities both for equipment and personnel should be made.
e. Contamination, should be promptly addressed through proper decontamination procedures.

6.3 Radioactive Waste Management

The radioactive waste management policies and procedures at the medical cyclotron facility should be as per the relevant Rules.

The licensee should put in place an appropriate procedures to ensure safe collection, segregation, storage, transfer/disposal of the radioactive waste generated during routine operations, maintenance and off-normal situations.

6.3.1 Solid Waste

a. 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 etc; which have induced radioactivity. Other solid radioactive waste that is generated is from components in the cyclotron tank that break during the wear and tear of normal use.

Solid radioactive waste are 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 radiopharmaceutical synthesis and dispensing operations

The radioactive waste generated during Quality Control procedures are paper chromatography strips, pipette tips, syringes, needles, tissue papers, rubber bungs, aluminum caps etc;

b. Management of solid waste:

i. All radiation safety precautions should be undertaken during handling, removal, collection, transfer and storage of generated radioactive waste. The contents inside the pit should be safely stored, adequately labeled with 'restricted access' to authorized personnel in order to prevent inadvertent handling by other staff.
ii. The entire procedure of radioactive waste handling, storage, removal and disposal should be carried out under the guidance and supervision of facility's RSO..
iii. Solid wastes generated during preventive maintenance should be collected and transferred to the dedicated lead lined storage pit inside the cyclotron vault in an impermeable polythene bag.
iv. 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 require long term storage.
v. The solid radioactive waste generated during the target cleaning process should be monitored and stored in the lead pit.
vi. Waste related to cyclotron components having induced radioactivity, may be characterized using a Multi-Channel Analyzer Gamma Ray Spectrometry System to identify and understand the typical profile of the induced radionuclides per μAh operation of the Medical Cyclotron. This will be beneficial in management of waste generated in subsequent operations.
vii. The waste generated during radiopharmaceutical synthesis and dispensing operations should be handled next day, collected and stored

for decay in a lead lined storage bin and stored inside the radiochemistry laboratory.

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

ix. The radioactive waste generated during Quality Control procedures should be stored in a lead lined foot operated waste bin inside the QC laboratory.

x. Short-lived ^{18}F, ^{11}C, and ^{13}N radioactive waste should be stored for decay to acceptable levels and discarded as non-radioactive waste. However, provision for interim storage of longer-lived radionuclides like Cu-64 and I-124, if produced should be made in addition to the short-lived radionuclides.

6.3.2 Liquid Waste

a. Generation of liquid waste:

The liquid radioactive wastes are generated during target maintenance and during synthesis of radiopharmaceuticals.

b. Management of liquid waste:

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

ii. Liquid waste collected during synthesis should be stored for interim period for decay, monitored and disposed off in laboratory sinks.

iii. Disposal of liquid waste should be such that the activity and concentration is well within the limits prescribed by regulatory body for disposal through sanitary sewerage.

6.3.3 Gaseous Waste

a. Generation of gaseous waste:

Gaseous radioactivity can be generated during cyclotron operation by activation of air in the cyclotron vault and chronic release of radioactivity particularly F-18 during synthesis operations in the radio-chemistry hot-cell.

b. Management of gaseous waste:

i. Radioactive gases generated during radiochemistry synthesis operations should be through a Waste Gas Compressor System, which will compress and store the radioactive waste air in leak proof cylinders for an appropriate period 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.

ii. Air-changes provided by design in the cyclotron vault should be such that there is a proper venting of gaseous radioactive waste through stack. The stack should be provided with a calibrated stack monitor to quantify the activity released through the stack and a record of such releases to be maintained and reported.

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

6.3.4 Disused, Spent Sources and long-lived radioactive waste

Sealed spent or disused calibration sources, if available, should be collected, stored and subsequently disposed off by taking necessary permissions from the regulatory body.

6.4 Record Keeping

RSO of the Medical Cyclotron should maintain a log of the following data;

a. Radiological Survey Data
b. Personnel Dose Records including DRDs
c. Unusual Incidents and Occurrences Record
d. Radioactive Waste Storage and Disposal Record
e. Preventive Maintenance Procedures
f. Logbook for Operation of Cyclotron

7. LABELLING, MARKING, PACKAGING AND DISTRIBUTION

7.1 Introduction

For commercial medical cyclotron facilities which are engaged in production and distribution of their products to other facilities for patient's use, proper packaging and transportation program should be established to ensure radiological safety. Licensee of medical cyclotron facility plays the role of consignor and he is primarily responsible for preparation of package including labelling, marking, packing, distribution and ensuring safe transport. The package should be prepared in accordance with national/ international regulations for safe transport of radioactive material currently in force. Type of package normally used to transport cyclotron generated PET radioisotopes is Type A package. Accordingly, all the applicable requirement of Type A package should be duly complied with by the consignor.

7.2 Design of Package

Type A package shall be designed in accordance with the design requirement of transport regulations and registered with the Competent Authority.

7.3 Preparation of Package

While preparing the package for distribution, it should be ensured that;

7.3.1 the package contains sufficient amount of absorbent material around the vial that can absorb twice the volume of radioactivity in the vial.

7.3.2 Radiation level at any point on the external surface of the package shall not exceed 2mSv/hour and Transport index shall not exceed 10.

7.3.3 Under normal conditions of transport, non-fixed contamination on the external surface of the package shall not exceed 4 Bq/cm^2. This limit is applicable when averaged over a surface area of at least 300 cm^2.

7.3.4 For packages to be transported by air, all applicable requirements for air transport shall be complied with.

7.4 Labelling and Marking

Following requirements should be ensured;

7.4.1 Category of the package should be determined on the basis of measured radiation levels, considering the package in isolation, in accordance with the following table:

Transport Index	Radiation level at external surface	Category
0	Not more than 0.005 mSv/h	I - White
0 – 1	More than 0.005 mSv/h but not	II - Yellow

	morethan 0.5 mSv/h	
1 – 10	More than 0.5 mSv/h but not more than 2 mSv/h	III – Yellow
More than 10	More than 2 mSv/h but not more than 10 mSv/h (under exclusive use)	III – Yellow

7.4.2 The packages should be appropriately labelled depending on the category of the package. The selected labels shall be filled with required information with respect to activity of radionuclide on date and transport index and shall be affixed on two opposite sides of the package.

7.4.3 The following markings should be durably and legibly inscribed on each package;

a) Address of consignor and consignee with their phone numbers
b) U.N number with proper shipping name. Applicable UN No. and proper shipping name is "UN 2915 Type A package, non-special, non-fissile".
c) gross mass of a package, if it exceeds 50 kg.
d) The inscription 'TYPE A'.

7.5 Transport Documents

Transport document should include the following;

7.5.1 Consignor's declaration in the format specified in Appendix - I.
7.5.2 Transport Emergency Card (TREM card) in the format specified in Appendix- II.
7.5.3 Instruction to carrier:

a. The consignor should provide a statement in the transport documents regarding actions, if any, which are required to be taken by the carrier. The statement should be in the languages deemed necessary by the carrier or the authorities concerned, and should include emergency arrangements appropriate to the consignment.

b. The consignor should inform the carrier about the need for segregation of packages containing radioactive material during transport and storage in transit from workers, members of the public, undeveloped photographic films and other dangerous goods.

7.6 General Guidelines

7.6.1 Licensee should prepare and implement radiation protection guidelines on labelling, marking and distribution of packages containing PET radionuclides.
7.6.2 Safe Operating Procedures (SOP) should be prepared for delivery of radioactive packages from the MCF to the user institution. The SOP should include, inter alia,

procedure for collection of packages at shipping ports (airports, sea ports etc), subsequent carriage and safe handing over the same to the user institution and detailed handling procedures during the entire activity. Personnel associated with the above activity should be suitable trained by the MCF.

7.6.3 Workers directly engaged in preparation of the packages should receive appropriate training from RSO, commensurate with their responsibilities.

7.6.4 In the event of any accident or incident during packing and transportation, appropriate remedial measures as per TREM card should be instituted and reported to the Emergency Control Room (ECR), DAE (Ph No: 022-2202 3978/1714) & AERB.

7.6.5 Packages should be transported only to the users authorised by regulatory body to receive the PET radionuclides.

8. SECURITY ASPECTS

8.1 Security of Sources:

The employer of the MCF is responsible for the safety and security of the source(s) 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 his possession at the MCF all the time. The security measures should include the following salient features:

a. General administrative measures
b. Quarterly accounting
c. Routine measures to ensure safe use and protect as an asset.

A detailed Security plan should be prepared as per the format prescribed in the AERB Safety Guide on 'Security of Radioactive Sources in Radiation Facilities', Safety Guide No. AERB/RF-RS/SG-1, (2011) and submitted to the Competent Authority along with PSAR to be submitted during regulatory stages as indicated in Chapter 2 of this Guide.

8.2 Security during Transport:

The employer of the MCF is responsible for security during transport of the source(s) supplied by him. The 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 the source(s) in his possession during transport.

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 individuals should be duly informed thereof.

9. EMERGENCY RESPONSE PLANS & PREPAREDNESS

9.1 Introduction

Emergency in a MCF can occur during normal operation, as a consequence of an accident or as a result of malicious act endangering the personnel working in the facility, premises or general public. The MCF should have necessary provisions to deal with all emergency situations that may be envisaged to arise from any initiating event**.**

9.2 Emergency Response Planning:

The facility should carry out detailed analysis of its systems, structures and components and envisage the possible accident scenarios due to single or multiple failure(s) that may eventually lead to an emergency.

Emergency situations could occur with limited consequences within the MCF. Certain situations could result in impact beyond the facility, such as unwarranted exposures to public. Emergency scenarios beyond the hospital/ industry premises are generally not envisaged.
Typical scenarios which may lead to emergency situations are:

a. Spillage of radioactive solutions/liquids within the facility.
b. Loss of cooling of target
c. Loss of negative pressure inside the cyclotron tank
d. Loss of negative pressure inside the hotcell
e. Activity build up in facility due to ventilation failure
f. Fire
g. Power failure
h. Safety Interlock failure
i. Havar foil or target foil rupture
j. Loss of shielding integrity
k. Radioactivity stuck in transfer line
l. Inadvertent radioactivity releases from stack
m. Unplanned/accidental exposures to maintenance personnel

In addition to the above mentioned possible accidental scenarios in facilities, accidents may also happen due to many reasons during transportation of sources, loss/unauthorized removal of sources, malevolent acts etc.

These may result in radioactive contamination, high radiation fields, and inadvertent exposures to personnel working in the facility.

The facility should be prepared and equipped to deal with all postulated onsite emergency situations.

A written emergency plan should be prepared and submitted as part of PSAR for obtaining approval from regulatory body towards design and construction of the facility.

The emergency plan should;

a. Identify all possible emergency scenarios and action plans to mitigate the consequences.
b. Clearly identify the role and responsibilities of management and other personnel in handling of the emergency.
c. Procedures to be adopted in case of high radiation exposure wherein specialised medical attention may be required.
d. Procedure for handling the situations that necessitate evacuation of personnel
e. The emergency plan should always be updated and maintained with the facility.

9.3 Training and Exercises

All personnel working in the MCF should be trained to identify off normal situations due to operation of cyclotron and handling of radioisotopes which may lead to emergencies. The personnel working in the MCF should be familiar with the communication channels and suitably trained on the procedures to be followed. The personnel should be periodically trained and updated on the emergency procedures. The facility should carry out periodic emergency exercises and maintain records of the same.

10. DECOMMISSIONING

10.1 General

The term decommissioning refers to set of actions 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, environment and public. The decommissioning process involves removal of radioactive materials and sources, decontamination and dismantling, subsequent waste management, final radiation survey and release of the facility for unrestricted use.

It is advisable to make plans for decommissioning at the time of planning for the MCF and keep in mind the following for the Decommissioning procedures:

a. Provision should be made to take out the cyclotron from the vault without having to cut it into pieces.
b. Provision should be made to cover the cost of decommissioning
c. Provision should be made to safely store the radioactive waste that could be generated during decommissioning.

10.2 Financial Provisions for Decommissioning

In case of the unlikely event of bankruptcy or other constraints, financial provision to meet the cost of safeguarding radioactive source and activated components in a MCF may be implemented. A separate fund may be earmarked by the employer in the form of bank guarantee towards the expenditure towards removal and transportation of radioactive sources/wastes to the supplier or any other agency approved by Regulatory Body for safe custody.

10.3 Regulatory Consent for Decommissioning

An MCF should be decommissioned upon completion of the authorised work at the approved location before it is released for other uses. Consent for decommissioning should be obtained from the Competent Authority when the facility is no longer to be used. A plan of the decommissioning operation should be submitted by the licensee to the Competent Authority while applying for the necessary consent from the Competent Authority. The decommissioning operation should be carried out in complete conformity with the plan approved by the Competent Authority. If it is necessary to modify the plan, prior approval should be obtained by the licensee from the Competent Authority.

10.4 Disposal of Radioactive Waste

The entire facility along with the cyclotron should be checked for the level of radioactive contamination. The contaminated components should be segregated depending on their half-

lives and properly disposed off as radioactive waste. For this purpose, the licensee shall obtain an authorisation 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 radiation level, fixed and non-fixed contamination level, if any, at the facility are within the limits stipulated by the Competent Authority.

10.5 Decommissioning Report

A report of the survey prepared by the RSO should be submitted by the licensee to the regulatory body on completion of decommissioning, detailing safe disposal of the source and other active components and personnel doses received during the decommissioning operation. Licensee upon receiving, from the Competent Authority, the final clearance of the decommissioning operation, issued based on the report submitted by the RSO, may release the decommissioned facility to the public.

More guidance on Decommissioning is given in Annexure - II

APPENDIX – I

DECLARATION OF RADIOACTIVE SHIPMENT

This is to certify that the package containing radioactive material as identified by the following details is safe for transport by rail, road, sea or air.

Package forwarded by (Consignor)	:	
Package addressed to (Consignee)	:	
Proper Shipping name	:	
UN Class of dangerous goods	:	7
United Nations No .	:	UN No.
Subsidiary risk	:	Nil
Name of Radioactive material	:	
Quantity/Activity of Radioactive material	:	
Package details Dimensions of the package Weight of the package Type of package*	 : : :	
Radiation level on the surface of the package in mSv/h		
Transport index of the package	:	
Category of the package	:	I-WHITE/ II-YELLOW/ III-YELOOW

* In case of Type B package, Competent Authority identification number should also be given.

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name and are classified, packed, marked and labelled, and are in all respects in proper condition for transport according to the applicable regulations.

Signature:

Name and address

Seal

Date:

APPENDIX –II

TREMCARD

Cargo	:	Radioactive material
Nature of Hazard	:	Radioactive material, Potential external and internal exposure
Protective device to be carried in the vehicle	:	One set each, for the driver and his assistant, of protective clothing (boots, gloves, overalls, caps). Six number of big polythene bags for collecting contaminated material
Emergency action	:	1. Inspect the package visually. If it is intact, ensure onward journey in the same or another vehicle. 2. In case of fire, fight from a distance 3. If the package appears to be damaged, cordon a distance of 3 m around the package 4. Obtain the names and addresses of persons who might have been exposed to radiation and convey the particulars to the Head, RSD, AERB and to the Head, RP&AD, BARC
First aid	:	Thoroughly wash the affected skin with plenty of water.
Contact telephone numbers for advice and assistance	:	a) Contact the consignor at the address given on the package b) Emergency Control Room, Crisis Management Group, DAE, Mumbai-400 001 TF: 022-2202 3978 Telefax- 022-22021714 Fax-022-22830441 Mobile- +919969201364 Email- daeecr@dae.gov.in **Alternate CMG - DAE Emergency Control Room (ECR)** located at Anushakti Nagar (VSB) 022-2599 1070 *Telefax – 022-25515283** Fax- 022-25991080/022-25993080 Mobile- +919969201365 Email- vsbecr@npcil.co.in

ANNEXURE-1

Layout diagrams of different type of Medical Cyclotron Facilities

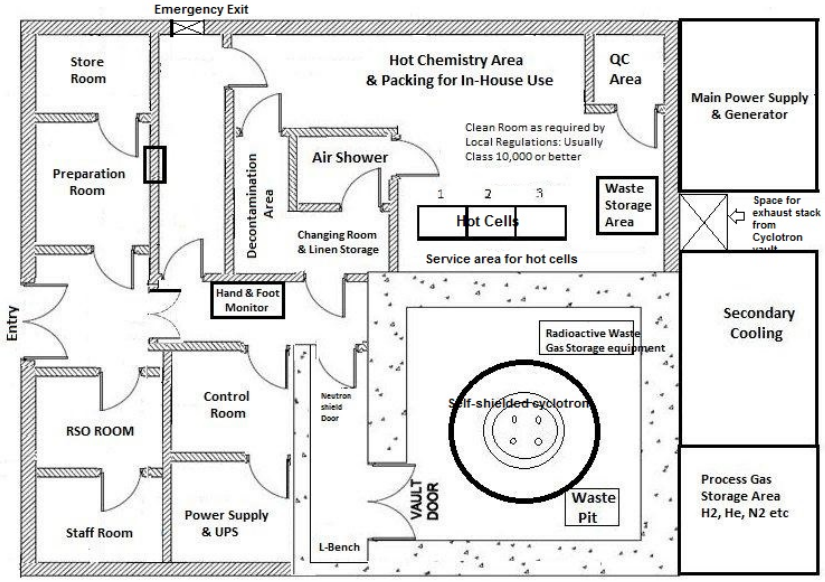

Fig 1: Floor plan of a typical Type I Medical Cyclotron Facility

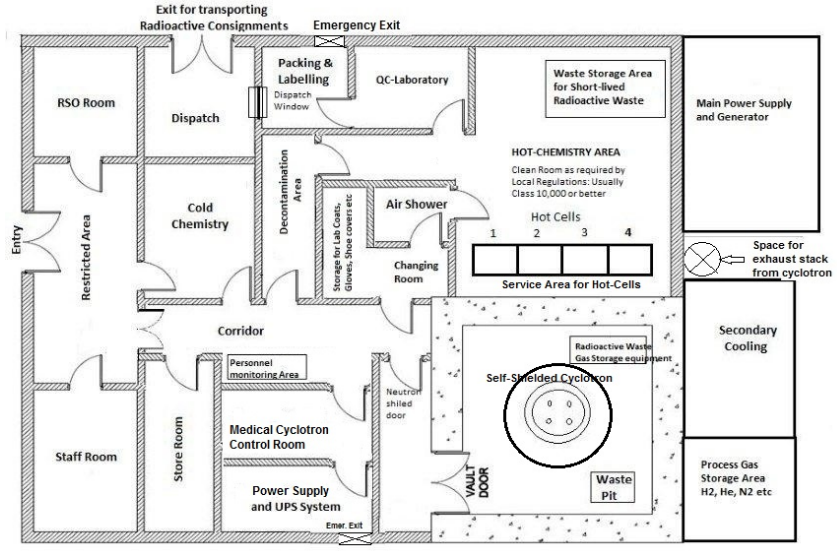

Fig 2: Floor plan of a typical Type II Medical Cyclotron Facility housing a self-shielded cyclotron

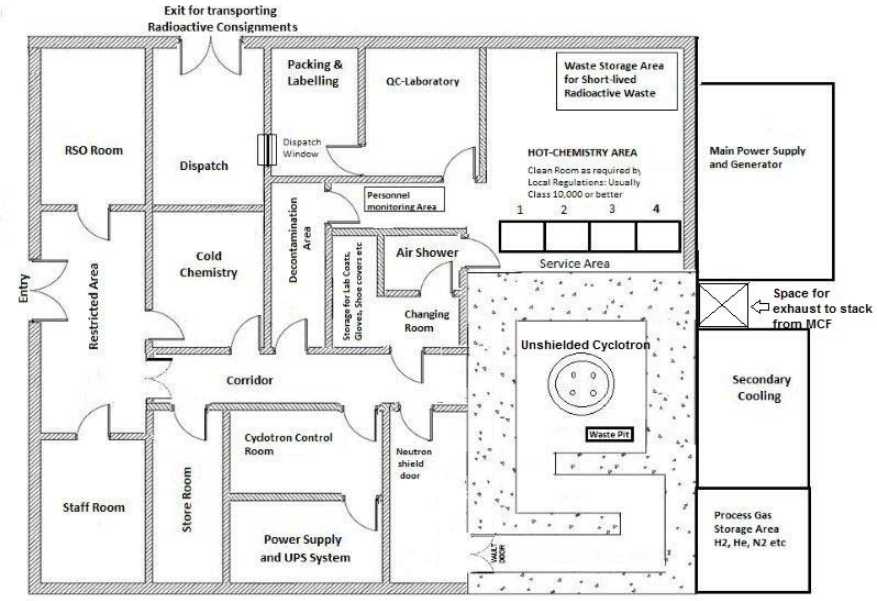

Fig 3: Floor plan of a typical Type II Medical Cyclotron Facility housing a Bunker Type cyclotron in a vault with entry through a maze.

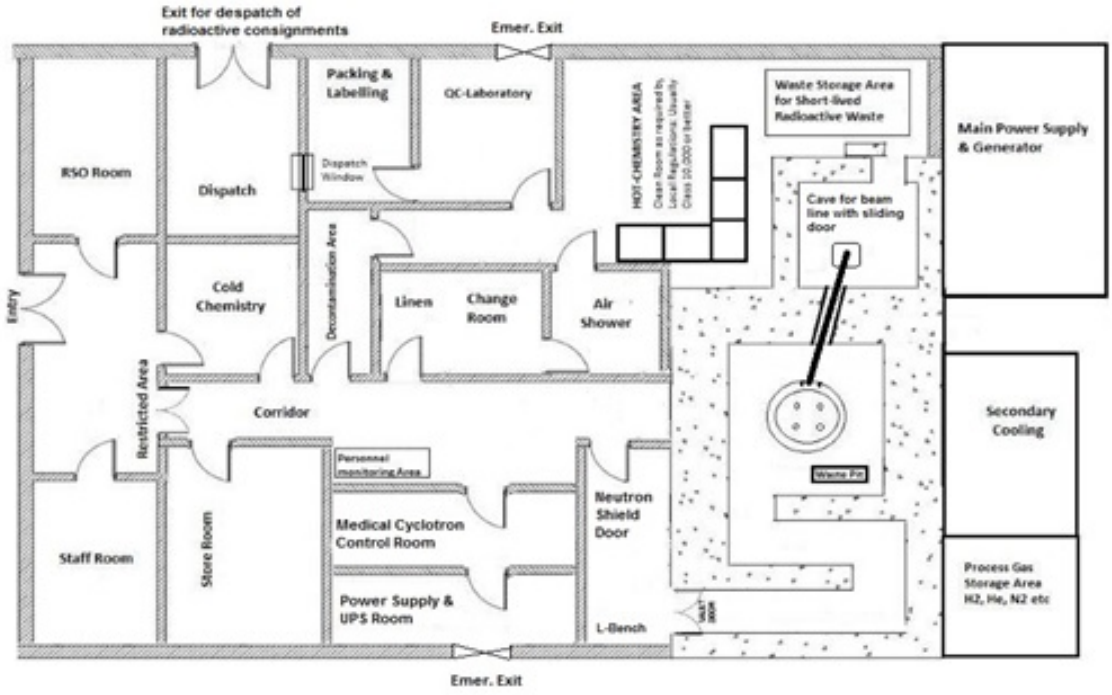

Fig 4: **Floor plan of a typical Type III Medical Cyclotron Facility housing a Bunker Type cyclotron in a vault with entry through a maze.**

ANNEXURE - II

Decommissioning of Medical Cyclotron Facilities

Medical Cyclotron facilities can function satisfactorily for over 20 years if maintained properly. There are reports of a 20 year old medical cyclotron that has been refurbished by changing the control electronics, targets and it is expected that the refurbished cyclotron will have several years of further operational usefulness. Essentially, this implies that the hardware in a cyclotron, viz., the magnet yoke and coils, dees, target bodies, etc., do not go bad and if these are maintained well without corrosion, then the system can be refurbished. 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 $T_{1/2}$. However, some material like iron for the magnet yoke cannot be substituted. Similarly there is no viable alternative to concrete for 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 since the accelerated particle is H^- ions and not protons. The Havar foil, collimators and target are irradiated directly and become radioactive. However, these are small volume and can be sent to radioactive repository maintained by authorized bodies.

The tables below give some of the long lived radioactivity expected to be induced in a typical cyclotron operating for 20 years with a 20% utilization and after a 30 day cooling period.

Table 2.Long Term Activation while using proton beam in a typical cyclotron

Isotope	Half Life	Activity [Bq]	Main Components
Al-26	717 ky	1.3E+03	Silica, Alumina
V-49	330 d	1.4E+08	Havar foil
Cr-51	27.7 d	3.8E+07	Havar foil
Mn-52	5.51 d	2.2E+08	Havar foil
Mn-53	3.74 My	4.5E+03	Havar foil
Mn-54	312.3 d	2.5E+09	Havar foil
Fe-55	2.73 y	7.9E+07	Havar foil
Co-56	77.27 d	7.2E+09	Havar foil
Co-57	271.74 d	2.5E+08	Havar foil
Co-58	70.86 d	1.8E+08	Havar foil
Ni-57	6.077 d	1.4E+06	Havar foil
Ni-59	76 ky	4.4E+06	Havar foil
Ni-63	100.1 y	7.6E+04	Havar foil
Zn-65	244.26 d	3.4E+08	Copper
Ta-179	1.82 y	4.7E+05	Ta Collimator
W-181	121.2 d	1.7E+10	Ta Collimator

Table 3.Long Term Activation due to neutrons in an bunker type cyclotron

Isotope	Half Life	Activity [Bq]	Main Components
Cr-51	27.7 d	2.5E+07	Aux. Equipment
Mn-54	312.3 d	4.8E+07	Acc. Cell, Iron yoke
Fe-55	2.73 y	5.4E+08	Acc. Cell, Iron yoke
Fe-59	45.1 d	1.3E+07	Acc. Cell, Iron yoke
Co-58	70.86 d	1.1E+07	Aux. Equipment
Co-60	5.27 y	9.8E+07	Aux. Equip., Iron yoke
Ni-59	76 ky	1.6E+04	Aux. Equipment
Ni-63	100.1 y	3.7E+06	Aux. Equipment
Ag-108m	418 y	7.9E+05	Target holder (Ag)
Ag-110m	249.9 d	7.2E+07	Target holder (Ag)

Table 4.Long Term Activation due to neutrons in a shielded cyclotron

Isotope	Half Life	Activity [Bq]	Main Components
H-3	12.33 y	7.8E+07	Concrete floor
Be-10	1.6 My	8.0E+01	Polyethylene (3% B)

C-14	5730 y	1.5E+03	Concrete floor
Ca-41	103 ky	2.0E+04	Concrete floor
Cr-51	27.7 d	2.0E+07	Aux. Equipment
Mn-54	312.3 d	3.7E+07	Acc. Cell, Iron yoke
Fe-55	2.73 y	4.3E+08	Acc. Cell, Iron yoke
Fe-59	45.1 d	1.0E+07	Acc. Cell, Iron yoke
Co-58	70.86 d	8.8E+06	Aux. Equipment
Co-60	5.27 y	8.0E+07	Aux. Equip., Iron yoke
Ni-59	76 ky	1.3E+04	Aux. Equipment
Ni-63	100.1 y	2.9E+06	Aux. Equipment
Ag-108m	418 y	6.1E+05	Target holder (Ag)
Ag-110m	249.9 d	5.6E+07	Target holder (Ag)
Eu-152	13.32 y	2.3E+06	Concrete floor
Eu-154	8.6 y	2.1E+05	Concrete floor

The table below gives the long term activation products expected in the concrete. The units are activity per kg and considering the inside 20 cm layer of a cyclotron vault is to be treated as radioactive waste, this amounts to 10% of 2 m thick vault. It is estimated that an average size vault weighs 300 tonnes, so this 30 tonnes of rubble that has to be stored as radioactive waste till it decays to permissible levels.

Table 5.Long Term Activation: Neutrons in a bunker type typical cyclotron Vault Walls Specific Activity [Bq/kg]

Nuclide	**Reaction**	**$T_{1/2}$**	**0-20 cm**	**20-40 cm**	**40-60 cm**	**Total**
Co-60	59Co(n,γ)60Co	5.27 y	3.1E+03	1.0E+03	2.3E+02	2.2E+08
Cs-134	133Cs(n,γ)134Cs	2.06 y	5.0E+02	1.1E+02	2.2E+01	3.2E+07
Eu-152	151Eu(n,γ)152Eu	13.4 y	4.2E+03	1.5E+03	3.6E+02	3.2E+08
Eu-154	153Eu(n,γ)154Eu	8.5 y	2.8E+02	8.0E+01	1.7E+01	1.9E+07
H-3		11 y	6.3E+04	2.3E+04	5.2E+03	4.7E+09
K-40	39K(n, γ)40K		6.2E+02	6.2E+02	6.2E+02	3.9E+08
Th-232			3.2E+01	3.2E+01	3.2E+01	2.0E+07
U-238			2.5E+01	2.5E+01	2.5E+01	1.5E+07
Ba-133	132Ba(n,γ)133Ba	10.5 y	(depends on the amount of barite used in concrete)			
Total			**8.5E+04**	**3.1E+04**	**7.6E+03**	**6.7E+09**

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Working Group Details

Task Group for Safety Guide on Medical Cyclotron

Dates of Meeting:	April 24, 2012
	May 13, 2012
	June 04, 2012
	August 08, 2012
	July 10, 2013
	August 14, 2013
	September 19, 2013
	February 12, 2014

Members:

Dr. M. G. R Rajan (Chairman)	BARC
Shri P.K. Nema	BARC (Former)
Dr. Rajashekharrao. B	Nueclear, Mumbai
Dr. Pankaj Tandon	AERB
Shri SoumyajyotiKar (Member Secretary)	AERB
Dr. Sunil C.(Co-opted Member)	BARC

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

Date(s) of meeting : December 10, 2014
March 12, 2015

Members :

Shri A.R. Sundararajan (Chairman)	:	Atomic Energy Regulatory Board, Mumbai (Formerly)
Dr. D.N. Sharma	:	National Disaster Management Authority, New Delhi
Dr. B.C. Bhatt	:	Bhabha Atomic Research Centre, Mumbai (Formerly)
Shri P.K. Nema	:	Bhabha Atomic Research Centre, Mumbai (Formerly)
Dr. M.G.R. Rajan	:	Bhabha Atomic Research Centre, Mumbai
Shri D.A.R. Babu	:	Bhabha Atomic Research Centre, Mumbai
Dr.A.U. Sonawane	:	Atomic Energy Regulatory Board, Mumbai
Shri V. Mohan	:	Atomic Energy Regulatory Board, Kalpakkam
Dr. (Smt.) Jain Reji George	:	Board of Radiation & Isotope Technology, Mumbai
Smt. V. Anuradha	:	Atomic Energy Regulatory Board, Mumbai
Shri R.K. Chaturvedi (Member Secretary)	:	Atomic Energy Regulatory Board, Mumbai

ADVISORY COMMITTEE ON RADIOLOGICAL SAFETY (ACRS)

Date(s) of meeting : July 17, 2015
March 04, 2016

Members :

Dr. U.C. Mishra (Chairman)	:	Bhabha Atomic Research Centre, Mumbai (Formerly)
Shri A.R. Sundararajan (Vice Chairman)	:	Atomic Energy Regulatory Board, Mumbai (Formerly)
Dr. M.R. Iyer	:	Bhabha Atomic Research Centre, Mumbai (Formerly)
Dr. D.N. Sharma	:	National Disaster Management Authority, New Delhi
Dr. Sudhir Gupta	:	Directorate General of Health Services, New Delhi
Shri S.P. Agarwal	:	Atomic Energy Regulatory Board, Mumbai (Formerly)
Dr. B.C. Bhatt	:	Bhabha Atomic Research Centre, Mumbai (Formerly)
Dr. S.K. Srivastava	:	Tata Memorial Hospital, Mumbai
Dr. A.U. Sonawane (Member Secretary)	:	Atomic Energy Regulatory Board, Mumbai

PROVISIONAL LIST OF REGULATORY DOCUMENTS ON
MEDICAL FACILITIES INVOLVING RADIATION

Sr. No.	Document No.	Titles
1	AERB/RF-MED/ SC-1 (Rev. 1)	Radiation Therapy Sources, Equipment and Installations
2	AERB/RF-MED/ SC-2 (Rev. 2)	Nuclear Medicine Facilities, Mumbai, India
3	AERB/SC/MED-2(Rev. 1)	Medical Diagnostic X-ray Equipment and Installations