GUIDE NO. AERB/RF/SG/G-3 (Vol. 2 of 4)

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GOVERNMENT OF INDIA

AERB SAFETY GUIDE

CONSENTING PROCESS FOR RADIATION FACILITIES

(VOLUME - 2)

ATOMIC ENERGY REGULATORY BOARD

APPENDIX-3C

(Refer section 3.2.2.4 for IARPF and PARF<10 MeV)
(Refer section 3.7.8.3 for IAF-NDT)

FORMAT FOR ACCEPTANCE TEST REPORT (ATR) FOR ACCELERATOR FACILITIES
[IARPF, IAF-NDT AND PARF<10MeV]

(All the safety systems/ sensors/ signals/ interlocks should be tested atleast 15-20 times, with accelerator ON and OFF condition and consolidated report in the format prescribed herewith shall be submitted)

1. General

Name and address of the operating institution :

Telephone No. :
Fax :

Facility-in-charge :
Radiological safety officer :

AERB approval details and reference :
Date of expiry : _____
Type of Facility : Radiation processing/ Research (<10MeV)/NDT :

2. Accelerator Specifications

Maximum voltage (MV)	
Maximum beam current (mA)	
Particles accelerated	
Vacuum (Torr)	
Maximum beam dimensions (mm)	
Scan amplitude/Scan angle	

3. Performance of Beam Calibration Devices

	Type of calibration	**Expected response of control system**	**Observed response of the control system**
Energy calibration			
Current calibration			

4. Performance of Safety System/Interlocks

Safety System/ Interlock with location	Test conducted	Expected response of control system	Observed response of the control system

5. Radiation Survey of the Facility during the Beam ON Condition at Maximum Parameters

Location	Nature of occupancy	Radiation level	Detector used

6. Performance of Installed On-line Radiation Monitors and Contamination Monitor

Installed location	Detector type	Make & model	Range	Date of calibration	Alarm level	Functional performance

7. Performance of Warning Indicators

Location	Type of warning indicator(s)	Posted procedures	Functional performance

8. Performance of Various Monitors and Associated Systems

Type of monitor	Functional performance
Ozone monitor	
Cryogenic leak monitor	
Instruments to monitor prompt high energy radiation	
Pulsed beam monitor	
RF monitor	

9. Availability of In-house Facilities (details may be furnished in separate pages)

Type of facility	**Available/Not available/ Not applicable**
Decontamination facility	
Personal dosimetry rack facility	
Storage of radioactive material	
Monitor for coolant system	
Monitoring of coolant filter	
Radioactive waste management facility	
Dosimetry faciity	
Ventilation system	
Others, if any	

10. Availabiliy of the Records

Type of record	**Available/ Not available/ Not applicable**
Record of training and experience of persons working in the accelerator facility	
Search and secure procedure	
Controlled access procedure	
Operating procedures	
Periodic radiation survey of facility	
Periodic contamination surveys	
Periodic air sampling	
Personnel monitoring records	
Unusual occurrences	

We hereby certify that the above information is correct to the best of our knowledgeand belief.

Place:

Date:

Signature:

Name:

Designation:

Name and Designation
of Facility-in-charge:

Signature:

APPENDIX-3D-I & II

(Refer section 3.2.2.5)

FORMAT OF THE FINAL SAFETY ANALYSIS REPORT FOR IARPF
(This format can also be used for PARF with beam energy <10 MeV)

[FSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer)]

A. ORGANISATION AND ADMINISTRATION :

(i) Name and Address of Institution :

(ii) Telephone No. :

(iii) Fax No. :

(iv) Purpose of the Plant (Industrial Application) :

(v) Design Approval of the Device obtained from AERB

Model :
Technical Specification : Maximum energy _____
Maximum current _____
Particles Accelerated : _____
Ref. No. :
Date of issue :
Valid up to :

(vi) Site, Layout and Construction Approval of the facility obtained from AERB

Ref. No. :
Date of issue :
Valid up to :

B. SAFETY PERSONNEL

(i) Head of Institution :

(ii) Facility-in-charge :

(iii) Radiological Safety Officer :
AERB Approval ref. :
Date of issue :
Valid up to :

DETAILS OF DOCUMENTS TO BE SUBMITTED

Required documents
Technical description of accelerator design and working procedure with drawings
Precommissioning test reports with results
Shielding design and of installation survey (along with drawings and layout)
Electrical circuit diagram and other interlocks of the accelerating device (inbuilt safety features)
Electrical circuit diagram and other interlocks of the accelerator vault
Provisions and procedures for particle beam energy and beam current calibration and periodic checks
Quality assurance manual (operation)
Arrangements for personal and environmental monitoring system
Periodic surveys of radioactive contamination if applicable
Radiation safety manual
Availability of local safety committee and their safety evaluation report
Details deviations from approved beam line components, accelerator vessel, layout, etc.
Decommissioning procedures of the accelerator facility (if applicable)

We certify that all the information provided by us is true and correct to the best of our knowledge and belief.

Place: Signature:

Date: Name:

Designation:

Documents to be attached : as mentioned above

APPENDIX-3D-III

(Refer section 3.7.8.3)

FORMAT OF THE FINAL SAFETY ANALYSIS REPORT FOR INDUSTRIAL ACCELERATOR FACILITY (IAF) FOR NDT

[FSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer)]

A. ORGANISATION AND ADMINISTRATION :

(i)	Name and Address of Institution	:	
(ii)	Telephone No..	:	
(iii)	Fax No.	:	
(iv)	Head of Institution	:	
(v)	Facility-in-charge	:	
(vi)	Purpose of the Plant (Industrial Application)	:	
(vii)	Site Layout and Construction Approval obtained from AERB		
	Ref. No.	:	
	Date of issue	:	
	Valid up to	:	
(viii)	Design Approval of the Device obtained from AERB		
	Model	:	
	Technical Specification	:	Maximum energy_____ Maximum current _____
	Particles Accelerated	:	_____
	Ref. No.	:	
	Date of issue	:	
	Valid up to	:	

B. SAFETY PERSONNEL

(i)	Radiological Safety Officer	:	
	AERB Approval ref.	:	
	Date of issue	:	
	Valid up to	:	

DETAILS OF DOCUMENTS TO BE SUBMITTED

Required documents
Summary of accelerator design and general working principles with drawings
Precommissioning test reports with results
Shielding design and of installation survey (along with drawings and layout)
Safety assessment reports
Facility operational and interlocks procedures
Calibration and daily checks (beam calibration/monitors)
Changes in operation, equipment, occupancy etc.
Arrangements for personal and environmental monitoring system
Periodic surveys of radioactive contamination if applicable
Radiation safety manual
Emergency scenarios and its response procedures
Organisational setup with responsibilities
Availability of local safety committee and their safety evaluation report
Details deviations from approved beam line components, accelerator vessel, layout etc.
Decommissioning procedures of the accelerator facility (if applicable)

We certify that all the information provided by us is true and correct to the best of our knowledge and belief.

Place: Signature:

Date: Name:

Designation:

Documents to be attached : as mentioned above

APPENDIX-3E

(Refer section 3.2.2.5 for IARPF and PARF<10 MeV)
(Refer section 3.7.8.3 for IAF-NDT)

FORMAT FOR RADIATION PROTECTION MANUAL FOR ALL ACCELERATOR FACILITIES [IARPF, IAF-NDT AND PARF <10MeV]

(OPERATION, MAINTENANCE, EMERGENCY ASPECTS)

A. ADMINISTRATION AND SAFETY ASSURANCE

(a) Administrative hierarchy/organisational set up

(b) Authorised personnel - Training and qualification of facility personnel, their knowledge in radiation safety, responsibilities of each of personnel, their availability in adequate number, policies in case of long leave/absence of certified personnel

(c) Local safety committee: constitution, functions and responsibilities

(d) Procedures for reporting to the regulatory agency on unusual occurrences and periodic radiation safety status

(e) Procedures in case of change or repairs of H.V. system, safety system/ interlocks, certification of log book entry by RSO

(f) Record of maintenance - maintenance schedule, radiation monitoring, and calibration of survey meters, etc.

(g) Industrial safety aspects - fire equipment, safety accessories etc.

(h) Facility security arrangements, fencing and personnel movement control etc.

(i) Removal and storage of contaminated material, if any.

(j) Medical assistance - First aid facility, location, periodic medical examination (once a year), medical facilities and treatment facilities for radiation incidents

B. MONITORING

(a) Radiation monitoring - Type of area monitors, sensitivity range, location, interlock alarm set levels

(b) Contamination monitoring - On line monitoring and sample measurement, method of collecting samples

(c) Personnel monitoring - Number of PM badges, procedure for their issuance, safe place for storage, etc.

C. OPERATION PROCEDURES

'Beam ON' procedures be established, documented and displayed in the console area

D. MAINTENANCE PROCEDURE FOR SAFETY SYSTEMS/INTER-LOCKS

(a) Periodic maintenance - Daily/weekly/monthly/quarterly/yearly (Items, procedures and schedules)

(b) Procedure for maintenance of cooling water used for cooling target beam line components, etc

(c) Procedure for maintenance of air cooling mechanism maintenance and checking of alarm/warning devices

E. EMERGENCY PLANNING AND PROCEDURES

(a) Organisational structure and communication links

(b) Name, address and telephone numbers of agencies to be contacted in case of emergency

(c) Emergency contact telephone/ telex nos. and address of

(i) Head of Institution

(ii) Facility-in-charge

(iii) Radiological safety officer (RSO)

(iv) Regulatory agency (AERB)

(v) Fire safety officer (Local)

(vi) Local fire station

(vii) Local police station

(viii) Local medical hospital, radiation therapy hospitals (nearest)

(d) Type of emergencies envisaged - Prevention/handling of emergencies, investigation methods, etc. during explosion or fire or smoke, radiation emergency, crisis management in case of emergency, earthquake, floods, other natural calamities.

APPENDIX-3F

(Refer sections 3.2.2.3 for IARPF.and PARF<10 MeV)
(Refer section 3.7.8.2 and 3.7.8.3 for IAF NDT)

QUALITY ASSURANCE MANUAL (QAM) FOR ACCELERATOR FACILITIES [IARPF, IAF-NDT, PARF<10MeV]

A. QUALITY ASSURANCE PROGRAM (QAP)

An adequate quality assurance (QA) program, including appropriate quality control measures, shall be established for the design and manufacture, construction and operation of accelerator. Compliance with the ISO 9000 or IS 14000 series is desirable. Records of all QA procedures shall be maintained for the entire life of the accelerator.

B. QUALITY ASSURANCE IN DESIGN:

1.1 Quality Assurance Programme

The responsible organisation shall develop and implement a QA programme, which describes the overall arrangements for the management, performance and assessment of the accelerator. This programme should also provide the means to ensure that all work is suitably planned, correctly performed and properly assessed. Procedures should be defined by the responsible organisation for control of design activities to ensure that the design of the accelerator fulfils specified requirements.

1.2 Grading

A graded approach based on the relative importance to radiological safety of each item, service or process shall be used.

1.2.1 The design activities, which could be graded, include:

(a) The level and detail of analysis of design

(b) The need for and level of design review and approval

(c) The degree of verification of design

(d) The controls applied to design change

(e) The detail of design records and their retention times

(f) The need for alternative calculations to be carried out

(g) The need to qualify or test the design output

(h) The need for qualification tests for design

1.3 Organisation

The responsible organisation shall identify the principal designer who has responsibility for specifying the design requirements and for approving the design output on its behalf.

1.4 Interfaces

Interface arrangements shall be agreed between organisations involved in design activities. Interface that should be addressed are for example:

(a) Interfaces between technical disciplines within the design organisation

(b) Principal designer with:

(i) Siting organisation

(ii) Construction organisation

(iii) Commissioning organisation

(iv) Operating organsiation

(v) Decommissioning organsiation

(vi) Regulatory body

1.5 Planning

Plans used in design should include the following where appropriate:

(a) Scope of work, including work carried out by other organisations

(b) Design methods

(c) Software requirements (software to be developed or software codes to be validated for use)

(d) Test requirements, including qualification tests, prototype, seismic, etc.

(e) Design review, verification and validation requirements

(f) Resource requirements

(g) Special training requirements

(h) Schedule of activities

(i) Points at which checks of the design process will take place and the frequency of such checks

(j) Inputs from safety, reliability, maintainability, human factors, standardisation and other disciplines.

1.6 Non-conformance Control and Corrective Actions

A system for the control of non-conformances and their corrective actions should be established.

1.7 Document Control and Records

Procedures for the preparation, review, approval, issue, modification and control of documents shall be established.

C. QUALITY ASSURANCE DURING CONSTRUCTION OF CIVIL ENGINEERING STRUCTURES OF ACCELERATOR

1.1 Quality Assurance Programme

The responsible organisation shall develop and implement a QA programme, which describes the overall arrangements for the management, performance and assessment of civil engineering structures for industrial processing accelerators during construction. This programme should provide the means to ensure that all work is suitably planned, correctly performed and properly assessed in order to implement design intent in the construction.

1.2 Grading

Work procedures should be defined for control of construction activities at site and it should be reviewed and approved before use. A graded approach based on the relative importance to safety of each item, service or process shall be used. The construction activities, which could be graded, include:

(a) Qualification of special construction processes and the personnel to carry them out

(b) Detail and need for inspection plans

(c) Level of traceability

(d) Level of in process controls and need for hold points

(e) Records and archived samples

1.3 Organisation

The responsible organisation should formally appoint a person on its staff to be responsible for construction activities. The appointed person should have the necessary resources within the construction organisation to discharge the following responsibilities:

(i) Ensuring that construction and installation work is carried out in accordance with design specifications, drawings, procedures and instructions, including the implementation of specified QA requirements.

(ii) Ensuring that construction and installation work undertaken, including work by suppliers, is co-ordinated, conducted and completed in accordance with planned programmes of work.

(iii) Controlling access to the construction site.

1.4 Interfaces

Interface arrangements should be agreed between the construction organisation, suppliers and other organisational units performing the work. They should be defined in writing and should be included in procurement documents. Interfaces that should be addressed are:

(a) Construction organisation with supplier

(b) Construction organisation with operating organisation

(c) Suppliers with sub-suppliers

(d) Construction organisation with the principal designer

(e) Construction organisation with siting organisation

(f) Interfaces between construction organisation and the AERB

1.5 Planning

All construction activities should be planned. The plan should define:

(a) The activities to be performed in manageable units

(b) The planned sequential order and duration of these activities

(c) The resource allocation for each activity

1.6 Non-conformance Control and Corrective Actions

The non-conformances that are required to be reported to the construction organisation should be identified. Suitable corrective action should also be recorded.

1.7 Document Control and Records

Procedures for the preparation, review, approval, issue, modification and control of documents should be established. The record system should be established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, storage, retrieval and disposal of construction records. Records should include all those, which record the as-built condition of structures, systems and components.

1.8 The civil engineering construction should be carried out following the relevant Indian standard codes/specifications. Quality of civil construction should satisfy the requirements of appropriate Indian standard codes/specifications

and that of product specifications. Typical list of topics to be covered in QA programme for the civil engineering construction is given as below:

(a) Formwork, shuttering and pre-construction activities

(b) Concreting and curing

(c) Post concrete inspection

(d) Repair

(e) Fabrication and erection of embeded parts (EP)

(f) Fabrication and erection of structural steel

(g) Brick work

(h) Grounding network

(i) Painting for steel structure

(j) Finishing and repair control

(k) Painting of main plant structures/concretes faces

(l) List of procedures

(m) Miscellaneous items such as organisation chart of QA civil, flow chart showing production of good uniform concrete, schematic diagram on procedure of concrete mix design etc.

(n) Density of the concrete in construction of walls and roof of irradiation cell/accelerator/beam hall shall be maintained at least 2.5 g/cc and it shall be ensured that no voids or air gaps are present during concrete filling.

(APPENDICES 4A, 4B-4D, 4C, 4F ARE FOR ACCELERATOR FACILITIES>10 MeV)

APPENDIX-4A

(Refer section 3.3.2)

FORMAT FOR SITE EVALUATION REPORT FOR PARTICLE ACCELERATOR RESEARCH FACILITY (PARF>10MeV)

1. Description of the Facility
   - (a) Specifications of the machine with maximum power
   - (b) Safety features
   - (c) End use of the facility.
2. Details of Proposed Site (a radius of 2 km around the site) Covering the Following Aspects:
   - (a) Location, area map, topography, terrain, rock, soil, rivers, water bodies, ocean in the vicinity
   - (b) A layout diagram of the proposed site, indicating all the units and the distances between them inside the boundary and the vicinity of the site in all directions
   - (c) Geological characteristics of the site-floods, storms, rain
   - (d) Soil survey report with reference to load bearing of the structure, elemental analysis of soil including lithium activation of the sub soil and ground water wherever applicable
   - (e) Meteorological data of the site
   - (f) Seismic data (seismic zone) of the site
   - (g) Meteorological data on wind speed, wind direction, temperature, rainfall, water logging, flood levels and other factors which might affect the safety aspects in the operation of the accelerator
   - (h) Availability of adequate water supply for cooling under all conditions including fire fighting
   - (i) Reliability and quality of electrical power available to the accelerator facility
   - (j) Population distribution (demography).
3. Justification for and Evaluation of the Particular Site for Locating the Facility

4. Hazard Assessment

   (a) Identification of hazards

   (b) Probable effects on workers, public and the environment, from normal operation and off-normal operations, accidental conditions and situation arising out of natural or disruptive factors

   (c) Means of mitigation of these hazards

   (d) Expected radioactive waste generation in solid, liquid and gaseous forms; their handling, effluent treatment and disposal method

   (e) Radiological impact assessment studies.

5. Facilities Available Near the Site, to Deal with Emergency Situations

6. Details of any existing or planned auxiliary facilities handling radioactive materials/radiation/industrial toxicants within the site or located nearby.

7. Other Supporting Documents, if any.

APPENDIX-4B, 4D

(Refer section 3.3.3, 3.3.4, 3.3.5)

FORMAT FOR (PRELIMINARY/FINAL) SAFETY ANALYSIS REPORT FOR PARF (>10MeV)

The purpose of Safety Analysis Report (SAR) is to ensure that the measures taken to minimise the consequences of hazards present in the proposed activity, or to mitigate their consequences, are sufficient to make the risks of the proposed activity acceptable. It should contain the following:

1. Introduction

   This Chapter should provide a basic understanding of the facility function and the protection features to the public, workers (health and safety), and the environment.

2. Executive Summary

   The summary should provide an overview of the results and conclusions of the analysis. The summary should address the results of Chapter 4 and Chapter 5 of the SAR.

3. Site, Facility and Operations Description

   (a) This section should describe the accelerator site location and provide specific data for characterising the site.

   (b) This section should also describe the accelerator by providing design criteria and as-built characteristics for the accelerator, for its supporting systems, and for components with safety-related functions.

   (c) For new facilities and those to undergo major modifications, a fire hazards analysis is to be included.

   (d) How the facility fits into the contractor's organisation, is to be described.

   (e) The experiments which will use the accelerator should be described, including those design criteria and characteristics of the experimental equipment, systems and components, having safety-related functions.

   (f) An operation/process description of the accelerator facility should be provided. Both potential accident and normal operation conditions for the machine and the experimental program should be appropriately detailed.

   (g) The design process and SAR should consider the worker safety conditions.

(h) Details of ventilation system for removal of noxious gases generated should be provided.

4. Safety Analysis

(a) This section should document the accident analysis, including any systematic methodology (i.e. failure mode and effects analysis, fault trees, etc.) used for the identification and mitigation of potential hazards.

(b) This section should discuss the methods used at the accelerator facility to control and mitigate the potential hazards.

(c) Analysis of design basis or postulated emergency conditions, including those due to natural or disruptive factors. Demonstration of adequacy of protective measures provided in the design.

(d) The residual risk to the facility, workers, the public, and the environment should be discussed.

5. Accelerator Safety Envelope

This section should provide the accelerator safety envelope (ASE) that will establish and define the limits of operation for the facility/operation.

6. Quality Assurance

This section should describe the quality assurance (QA) program to be applied to the accelerator facility (Give broad guidelines. In addition QA manual should be made separately as per **Appendix 4F** of AERB safety guide AERB/RF/SG/G-3)

7. Decommissioning and Decontamination Plan

A description of structural and internal features which would facilitate decommissioning and decontamination of the accelerator complex should be provided in this section. Waste management of radiological and hazardous material generation from the decommissioning and decontamination operation should be discussed. Provisions including adequate financial arrangement for safe disposal of spent/disused sources should be made.

8. References/Glossary/Abbreviations

In short, the FSAR (SAD) shall contain the following:

(a) A description of (or a reference to) the facility's function, location, and management organisation, as well as details of major facility components and their operation.

(b) Hazards from both normal operation and credible accidents in the facility and associated onsite and offsite impacts to workers, the public, and the environment.

(c) Sufficient descriptive information and analytical results pertaining to specific hazards and risks identified during the safety analysis process, and to provide an understanding of the risks presented by the proposed operations.

(d) A detailed description of engineered controls (e.g. interlocks and physical barriers) and administrative controls (e.g. training) implemented to eliminate, control, or mitigate risks associated with the operation.

(e) The set of physical and administrative bounding conditions for safe operations, based on the safety analysis documented in the SAR. These bounding conditions are known as the accelerator safety envelope (ASE). Any activity violating the ASE shall be terminated and immediately notified to AERB.

APPENDIX-4C

(Refer section 3.3.4)

FORMAT FOR THE ACCEPTANCE TEST REPORT (ATR) FOR PARTICLE ACCELERATOR RESEARCH FACILITIES (PARF >10MeV)

S. No.	Safety system	Observations/ Remarks	Signature with name and designation for accepting the performance
1.	Door Interlock - Power cutoff after opening - Signal in control room - Manual resetting		
2.	Scram Switches - Power cut-off after pressing the scram switch - Signal in control room - Manual resetting		
3.	Area Radiation Monitors Interlock - Power cut-off after radiation field increases more than specified - Signal in the control room - Local sound alarm - Calibration of monitors		
4.	Vacuum Failure - Identification of loss of vacuum - Functioning of gate valve - Response time		
5.	LCW Cooling System - Functioning of sensor for temperature, flow etc. - Indication in the control room - Tripping of plant system		

APPENDIX-4C (CONTD.)

(Refer section 3.3.4)

FORMAT FOR THE ACCEPTANCE TEST REPORT (ATR) FOR PARTICLE ACCELERATOR RESEARCH FACILITIES (PARF >10MeV)

S. No.	Safety system	Observations/ Remarks	Signature with name and designation for accepting the performance
6.	Public Address System (PAS) - Functioning of mike - Functioning of speakers at all locations		
7.	Fire Detection System - Power supply to fire detection system - Detection of fire - Alarm local and in control room - Resetting of alarm		
8.	Beam Shutter Response - Functioning - Response time		
9.	Beam Loss Monitor - Functioning of interlock with bending magnet - Signal in control room		
10.	Other safety systems [Add as applicable]		

APPENDIX-4F

(Refer section 3.3.2 to 3.3.4)

QUALITY ASSURANCE (QA) MANUAL FOR PARTICLE ACCELERATOR RESEARCH FACILITY [PARF] (BEAM ENERGY >10MeV)

A. QUALITY ASSURANCE PROGRAMME DURING CONSTRUCTION OF PARF>10 MeV

The Licensee shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of structures/ systems/components related to civil, mechanical, electrical and instrumentation aspects of PARF during design and construction. This programme should specify means to ensure that all work is suitably planned, correctly performed and properly assessed in order to implement design intent in the construction.

The QA manual (QAM) should be prepared addressing the following aspects:

A.1 INTRODUCTION

This section should include applicability and scope of the QAM.

A. 2 MANAGEMENT FUNCTIONS

This section should specify the management's Policy Statement and Organisation plan. Organisational plan should be documented addressing the following aspects:

(a) Organisational structure

(b) Functional responsibility

(c) Levels of authority

(d) Lines of internal and external communication.

It should also address requirements related to competent manpower for construction activities of the facility. The functional responsibilities of all the personnel distinguishing task including their assigned administrative powers should be identified and documented.

The Licensee should formally identify a person to be responsible for implementation of QA programme during construction activities. Responsibilities of key personnel in the organisation should be defined in writing. The person appointed should have the necessary resources to discharge the following responsibilities:

(a) Ensuring that construction and installation work is carried out in accordance with design specifications, drawings, procedures and instructions, including the implementation of specified QA requirements.

(b) Ensuring that construction and installation work undertaken, including work by manufacturers/suppliers, is coordinated, conducted and completed in accordance with planned programmes.

(c) Controlling access to the construction site.

Appropriate controls reflecting safety regulations shall be established for all personnel, including suppliers and visitors. These shall be in line with applicable statutes and shall include arrangements for effective planning, organisation, monitoring and review of the preventive and protective measures. Management shall provide all necessary support to the contractor to ensure health and safety of the construction personnel and quality assurance requirements of construction.

A. 2.1 Grading

A graded approach based on the relative importance to safety of each item, service or process should be adopted. Activities, which should be graded during construction include:

(a) Qualification of special construction processes and the personnel to carry them out

(b) Details and need for inspection plans

(c) Level of traceability of construction material and related records

(d) Level of in-process controls and need for hold points

(e) Complexity involved in equipment handling/ erection and post-erection preservation

A.2.2 Interfaces

Licensee should ensure that interface arrangements shall be agreed among the construction agencies, suppliers and other organisational units performing the work. These should be defined in writing and be included in relevant documents. Appropriate references of the same should be made in the QA programme. Handover/ transfer responsibilities after completion of construction/ installation to operating organisation.

A.3. PERFORMANCE FUNCTIONS

A.3.1 Document Control

Procedures for the preparation, review, approval, issue, modification and control of documents should be established. The record system should be

established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, storage, retrieval and disposal of construction records. Document control system should also include records of as-built condition of structures, systems and components.

A. 3.2 Procurement Control

Measures shall be established and documented to ensure that relevant standards/specifications and other requirements necessary to assure adequate quality are included or referenced for procurement of items and services required during construction of PARF.

Procurement requirements for assuring quality shall be covered by a procurement document. The document shall include items such as scope of work, technical requirements, and test, inspection and acceptance requirements.

Procedures for the preparation, review, approval, issue, modification and control of documents pertaining to activities affecting construction should be established. Document release and distribution system shall be established utilising up-to-date distribution lists. Individuals responsible for issue of documents shall be identified.

A.3.3 Supplier Evaluation and Selection

Supplier evaluation shall be carried out to assess the capability to provide items and services in accordance with the requirements of procurement document(s). The supplier evaluation includes as appropriate:

(a) evaluation of current technical capability, availability of expertise and resources,

(b) analysis of product samples, and

(c) review of historical quality performance data.

A.4 PROCESS CONTROL

Documented procedures should be established for all construction related activities of the PARF such as receiving and storing components, civil construction, equipment erection, cleaning/flushing, inspection, testing, modification etc. Provision should be made for verification, review and audit of activities affecting quality of construction.

Site construction activities should be planned and documented in adequate detail and approved by designated persons/agencies. The plan shall define:

(a) The planned sequential order and duration of activities

(b) The resource allocation for each activity

(c) Work planning and supervision

(d) Implementation of safety requirement during construction including fire safety and first aid

Preventive maintenance and preservation of items in stores or installed should be carried out in accordance with manufacturers' recommendations and good engineering practices, and documented.

A.5 VERIFICATION FUNCTIONS

A.5.1 Verification Programme

A comprehensive documented verification programme to be prepared to assure conformance of construction of the PARF as per the relevant codes and standards. Verification programme should comprise external (third party) as well as internal verification at specified stages/periodicity.

A.5.2 Inspection and Test Controls

A plan for inspection and testing of the materials/components used for construction, should be established. These should include identification of characteristics to be checked, type of check, acceptance norms etc. These should specifically include:

(a) Inspection of soil rocks, earthworks and foundation piles

(b) Testing of concrete

(c) Inspection of civil and steel structures

A.5.3 Audit

Provisions need to be prescribed detailing the establishment and implementation of a comprehensive system of planned and documented audits to verify the implementation and effectiveness of the various elements of the quality assurance programme. It should address the audit performance, audit personnel, audit plan and audit timing etc. The requirement for QA audit and extent of its application should be based on the safety significance of the system.

A.6 CORRECTIVE FUNCTIONS

A.6.1 Non-conformity Control and Corrective Actions

A system for the control of non-conformances and their corrective actions should be established. Non-conformances, deviations or inadequacies affecting quality should be identified and controlled. The persons responsible for review and disposition of non-conformances should be identified. The programme should provide that appropriate action be taken to ensure that

conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective or incorrect material, equipment and any other non-conformances are identified, corrected and recurrences are prevented.

A.7 RECORDS

Records should be prepared and maintained to provide objective evidence of quality to meet the requirements of applicable codes, standards and specifications to include details such as:

(a) Certificates of each component from the supplier/manufacturer; and the test and inspection records

(b) Non-conformance reports, corrective/preventive actions carried out

(c) Certificates about raw material such as cement, sand, iron, steel used during constructions

(d) Records of the test results, acceptance criteria and as-built condition of structures.

(e) Design reports and drawings

(f) Safety analysis reports

The record system shall be established which includes the arrangements and responsibilities for the categorization, receipt, indexing, preservation/storage, retrieval, inspection and disposal of records after expiry of the specified retention period of non-permanent records.

B. QUALITY ASSURANCE DURING COMMISSIONING AND OPERATION OF PARF (>10MeV)

Licensee shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of the PARF. This programme shall also provide means to ensure that all work is suitably planned, correctly performed and properly assessed. Procedures shall be defined by the Employer to ensure that the commissioning and operation of PARF fulfils specified requirements.

The QAM should be prepared in following format addressing the different aspects of the facility.

B.1. INTRODUCTION

This section should include Applicability and Scope of the QAM.

B. 2. MANAGEMENT FUNCTIONS

This section should specify the management's policy statement and organisation plan. Organisational plan should be documented addressing the following aspects:

(a) Organisational structure

(b) Functional responsibility

(c) Levels of authority

(d) Lines of internal and external communication.

It should also address requirements related to availability of competent manpower for commissioning and operation of the facility. The functional responsibilities of all the personnel distinguishing task including their assigned administrative powers should be identified and documented. The necessary resources required by these personnel to discharge the following responsibilities need to be identified:

(a) Commissioning and operation of the facility is carried out in accordance with approved procedures, design specifications, designers' instructions.

(b) Controlling access to the operating facility.

Procedures need to be documented for formal reviews of QA programme by management as often as necessary or any changes in the regulatory requirements that may have been introduced after the previous approval of QA programmes. Identification and control of compliance with applicable codes, standards, specification and practices; acceptance criteria (qualitative and/or quantitative as appropriate) for determining satisfactory completion of the commissioning and operation activity should be described in the QAM.

B.2.1 Interfaces

The interface arrangements should be agreed with the licensee and various agencies involved (namely design, construction, commissioning, operation, decommissioning, AERB and statutory agencies as applicable). Handover/ transfer responsibilities after completion of construction/ installation to operating organisation.

B.3 PERFORMANCE FUNCTIONS

B.3.1 Document Control

(a) Procedures for the preparation, review, approval, issue, modification and control of documents pertaining to activities affecting commissioning and operation should be established.

(b) Document release and distribution system shall be established utilising up-to-date distribution lists. Individuals responsible for issue of documents shall be identified.

(c) Documents important for commissioning and operation include, among others, final safety analysis report (FSAR), acceptance test

report (ATR), and radiation protection manual (RPM), commissioning reports and technical specifications for operation.

(d) Procedures for making interface with various components and systems should be prepared. Verification and validation of software used for operational control should be done by the independent agencies.

B.3.2 Process Control

B.3.2.1 Commissioning Control

Procedures should be established to ensure that appropriate tests are performed during commissioning to demonstrate that design intent and, regulatory and other statutory requirements are met. Satisfactory demonstration of functional capability of safety systems is a prerequisite for considering the PARF to be suitable for the operating phase.

Measures shall be established to ensure that all commissioning activities including beam extraction, transport and dumping are planned, controlled and implemented in accordance with approved documents such as procedures, instructions and checklists, and results documented.

Commissioning activities shall commence only after due completion of respective construction activities supported by certified documents. Inspection and surveillance shall be performed by the facility and documented to verify compliance with specification requirements.

Measures shall be established to identify, review, resolve and document all non-conformances and design changes.

A system for audit of commissioning, follow-up and record of corrective actions shall be established.

B.3.2.2 Operation Control

Documented procedure shall be established for safe operation of the PARF in accordance with the design intent and specified operational limits.

Provisions should be included to ensure interface among agencies for operation, maintenance, technical services, plant management, design, inspection, testing, verification and audit.

Provision shall exist for regular verification of operation activities related to safety. Preventive and maintenance schedule should be prepared for all safety systems as per the applicable codes.

Inspection and testing/surveillance during operation of safety equipment as well as subsequent to maintenance, modification or procedural changes should be performed to specified requirements and documented.

Trained and authorised operator should be available for operation of PARF.

Measures should be established to

(i) identify emergency situations and to develop and implement procedures for coping with emergencies; and

(ii) to hold emergency exercises at specified intervals to identify inadequacies, if any.

B.4 VERIFICATION FUNCTIONS

B.4.1 Verification Programme

A comprehensive documented verification programme should be prepared and verification conducted accordingly to assure conformance of commissioning and operation of the PARF as per the relevant specified codes and procedures. Verification programme should comprise external as well as internal verification

B.4.2 Inspection and Test Controls

Measures should be established to ensure that testing and measuring devices used in determining conformance to acceptance criteria are of proper range, type, accuracy and precision.

Testing and measuring devices should be controlled, calibrated and adjusted at specified intervals, or before use, to maintain accuracy within necessary limits.

Controls shall be established to ensure proper handling, storage and use of calibrated instruments.

B.4.3 Audit

Provisions need to be prescribed detailing the establishment and implementation of a comprehensive system of planned and documented audits to verify the implementation and effectiveness of the various elements of the quality assurance programme. It should address the audit performance, audit personnel, audit plan and audit timing etc. The requirement for QA audit and extent of its application should be based on the safety significance of the system.

B. 5 CORRECTIVE FUNCTIONS

B.5.1 Non-conformity Control and Corrective Actions

A system for the control of non-conformances and their corrective actions should be established. Non-conformances, deviations or inadequacies affecting quality should be identified and controlled. The persons responsible

for review and disposition of non-conformances should be identified. The programme should provide appropriate actions to be taken to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective or incorrect material, equipment and any other non-conformance are identified and corrected.

Preventive actions should also be identified based on the review of non-conformances.

B.6 RECORDS

Records should be prepared and maintained to provide objective evidence of quality to meet the requirements of applicable codes, standards and specifications.

Records should include:

(a) results of reviews, inspections, tests and audits,

(b) operation logs,

(c) non-conformance reports, repairs carried out,

(d) training, qualifications and certification of personnel,

(e) information pertaining to 'as built' condition of items in the plant,

(f) copies of design drawings, PSAR, FSAR, RPM, QAM, licence/ consents/certificates, etc.,

(g) radiation dose records, emergency exercises and maintenance records.

The record system shall be established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, preservation/storage, retrieval, inspection and disposal of records after expiry of the specified retention period of non-permanent records.

(APPENDICES 5B,5D, 5E, 5F REFER TO MEDICAL CYCLOTRON FACILITY)

APPENDIX-5B

(Refer section 3.4.1.3)

FORMAT OF THE PRELIMINARY SAFETY ANALYSIS REPORT (PSAR) FOR MEDICAL CYCLOTRON FACILITIES

[PSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer) along with the application for the layout and construction approval of Medical Cyclotron Facility]

INTRODUCTORY INFORMATION

1.	Name and address of the applicant	:	
	Institution profile	:	
	Purpose and scope of the project	:	
2.	Details of Supplier	:	
	Name and address of the applicant/local supplier with PIN code (in block letters)	:	
3.	Details of System Parameters		
	Model/Type designation of the medical cyclotron	:	
	Year and country of manufacture	:	
	Type of the medical cyclotron (shielded/non self- shielded)	:	
	Maximum beam energy	:	MeV
	Maximum beam current	:	μA
	Number of targets	:	
	Operational life of the device (in hours)	:	
	Radiation levels at a distance of one metre from the cyclotron under beam 'ON' condition (specify for maximum energy and mode) (Please attach dose contours around the cyclotron and cyclotron vault)	:	

Leakage radiation and other parameters .... :

Built-in safety features/operation procedures to prevent any radiologically unsafe malfunction of the equipment (Please attach relevant documents such as installation manual, operation/ servicing manual) :

Specify the standards to which the medical cyclotron comply :

Details of beam energy and current calibration facility :

4. Number of Synthesis and Dispensing Units :

5. Design Manual of the Medical Cyclotron which includes

(a) Drawing and functional description of the accelerating chamber and target systems along with radiation shielding

(b) Drawings along with the functional description of safety related control systems and devices

(c) National standards to which the equipment conforms (English translation of the Standard is to be provided)

(d) Test report on performance of the medical cyclotron demonstrating the compliance with the National standard

(e) Certificate from the competent authority of country of design/ manufacture to the effect that the equipment is approved for isotope production use

6. Layout of the Medical Cyclotron Vault and Associated Facilities, Indicating the following details

(a) Radiation shielding details : Concrete blocks, earth beams (barrier or insulation), lead bricks, iron plates etc.

(b) Barriers : Fences, locked gates, doors etc.

(c) Facility specific : Control console facility to view active and passive engineered controls

(d) Area radiation monitors

(e) Ventilation facility

(f) Caution and alert system

(g) Access sensors or interlocks : Electrical, magnetic and mechanical

(h) 'Crash' or 'Scram' buttons either mounted on walls or at doors and gates

(i) Search and rescue control

(j) Warning indicators (status lights, alarms, posted procedures)

7. Details of Documents with Details (to be submitted)

Design detail	:	Summary of medical cyclotron design and general working principles, specifications and physical parameters of the system and user objectives.
Site characteristics	:	Location, occupancy in site area as well as surrounding population up to 30 meters radius, geology, load bearing capacity of soil and rock, structural design criteria, foundation, meteorology, seismology, water table, flood level, plinth level (with respect to nearest accessible road), AERB site approval reference, etc.
Medical cyclotron	:	Description of general layout, details of buildings, pressure vessels, vacuum system, radio frequency system, magnetic field, beam injection, acceleration, transport and target system including their design, construction and testing and quality assurance manual for the equipment.
Synthesis and dispensing units	:	Name and address of the Manufacturer and supplier, make and model of the synthesis and dispensing unit, maximum activity to be handled, material and thickness of shielding.
Biological shield	-	Final sketch giving details of shielding wall surrounding the source, wall thickness, labyrinth access, openings, voids, reinforcements, embedment etc. in the biological shield. Method of shielding calculation and the dose limits followed
	-	Shield material, density, and quality control measures followed during shield construction
	-	Maximum and minimum shield thickness, roof thickness
	-	Drawings and layout of the device location installed

- Dose rate profiles anticipated at various locations: (maximum and minimum values). Indicate them on a sketch of the facility - control room, roof, access doors, openings and where personnel are expected to be stationed for work or otherwise.
- Radiation shielding evaluation including sky shine
- Maximum dose rate anticipated

  Locations: (Indicate also in a sketch)

8. Documentation Details of Auxiliary Services

   (a) Electrical power and power supply systems (including emergency power supply), major electrical equipment, illumination, lift, hoist, cranes etc.

   (b) Air conditioning and ventilation system (including treatment of noxious gases produced, if any)

   (c) Cooling water supply system

   (d) Compressed air system

   (e) Communication system

   (f) Target gas handling system - system description, characteristics of the gas (properties, specifications, purification etc.)

   (g) Laboratory, workshops, stores, etc.

   (h) Other services- please specify.

   (i) Controls of various subsystems, description, operation etc.

9. List of Potential Hazards and Safety Measures to be taken

   (a) During precommissioning trials of all systems and subsystems

   (b) During commissioning

   (c) During operation and maintenance

10. Safety Features Including Hazard Evaluation

    (a) Design safety of buildings and equipment

    (b) Structural design: Seismic and wind load parameter details

    (c) Accelerator facility

    (d) Electrical system and equipment

        (i) Power and control cables-specifications

        (ii) Cable ducting

(iii) Safety fencing of high voltage locations

(iv) Earthing

(v) Electromagnetic interference and suppression

(e) Air conditioning and ventilation

(f) Vacuum system

(g) Cooling water supply system

(h) Compressed air system

(i) Dry nitrogen supply system

(j) Communication system

(k) Control system

(l) Fail safe (any defect or component failure, which prevents the cyclotron operation) and operational independent

(m) Inventory and labeling of control devices

(n) Others, please specify.

11. Radiation Safety

(a) Radiation safety policy

(b) Dose equivalent limits

(c) Planned exposure (operational hours/week)

(d) Planned special exposure

(e) Design features - shielding etc.

(f) Radiation monitoring and alarm system (including interlocks)

(g) Induced activity estimation - radiation levels due to induced activity, induced gaseous airborne activity (if applicable)

(h) Radiation sensitive components installed inside the facility and their durability

(i) Induced activity in cooling water

(j) Other radiation safety considerations - radioactive waste, postulation of radiation accident (target rupture, loss of shielding integrity), analysis and action, administrative considerations (if applicable)

(k) Analysis of potential radiation exposure scenarios

12. Chemical Safety

List of chemicals used with quantities, their toxicity and hazards, safety considerations, analysis of potential release scenarios and preventive and

other action to be taken (e.g. Ozone production and ozone depleting substance, flammable gases, liquids, oxygen deficiency hazard (SF6), biologically hazardous material, cryogenic fluids, etc.)

13. Fire Safety

Fire and explosion hazards, means of escape, access, fire detection and alarm system, fire fighting system-fire hydrants, dry risers, fire extinguishers etc.

14. Personnel Safety

Safety policy, organisation, functions of safety personnel, responsibilities, general safety rules, accident prevention program, safety equipment and procurement, safety inspection, housekeeping, accident reporting, investigation, preventive measures, training, medical facilities including first aid.

15. Safety in Operation and Maintenance

(i) Startup procedure

(ii) Shutdown procedure

(iii) Emergency shutdown procedure

(iv) Search and secure

(v) Procedure for entry into cyclotron vault

(vi) Others (eg. gas handling procedure), please specify

16. Emergency Planning and Procedures
(types of emergencies envisaged, preventive measures, handling of emergencies, investigation etc.)

(i) During major leaks, foil rupture, contamination, target rupture, loss of shielding integrity

(ii) During explosion and fire

(iii) During general fires

(iv) During emergency in tanks and equipment etc.

(v) During radiation emergency

(vi) Crisis management in case of major emergency

17. Pre-operational Radiation Survey Report (background radiation in and vicinity of the medical cyclotron facility)

18. Quality Assurance Manual for Construction of the Facility (as per format given in item A of **Appendix-6A** of AERB/RF/SG/G-3)

19. Details of waste disposal pocedures and provisions including adequate financial arrangement for safe disposal of spent/ disused sources.

20. Details of storage facility for activated components and procedure (identifying long half life radioisotopes)

21. Details to be furnished regarding the decommissioning of the facility.

We certify that all the information provided by us is true and correct to the best of our knowledge and belief.

Place: Signature:

Date: Name:

Designation:

APPENDIX-5D

(Refer section 3.4.1.4)

FORMAT OF THE FINAL SAFETY ANALYSIS REPORT (FSAR) FOR MEDICAL CYCLOTRON FACILITIES

[FSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer) along with the application for the commissioning and operation of Medical Cyclotron Facility]

A. INTRODUCTORY INFORMATION

1. Name and address of the applicant :

   Head of Institution :

2. Institution profile :

3. Purpose and scope of the project :

4. Details of Supplier :

   Name and address of the applicant/local supplier with PIN code (in block letters) :

5. Details of AERB Site Approval

   Ref. No. :
   Date of issue :
   Valid up to :

6. Details of AERB Layout and Construction Approval

   Ref. No. :
   Date of issue :
   Valid up to :

7. Detail of System Parameters :

   Model/Type designation of the medical cyclotron :
   Year and country of manufacture :
   Type of the medical cyclotron (shielded/non shielded) :
   Maximum beam energy - : MeV
   Maximum beam current - : μA
   Number of targets - :

Operational life of the device (in hours) :

Radiation levels at a distance of one metre from the cyclotron under beam 'ON' condition (specify for maximum energy and mode) (Please attach dose contours around the cyclotron and cyclotron vault) :

Leakage radiation and other parameters .... :

Built-in safety features/operation procedures to prevent any radiologically unsafe malfunction of the equipment (Please attach relevant documents such as installation manual, operation/servicing manual) :

Specify the standards to which the medical cyclotron comply :

Details of beam energy and current calibration facility :

Number of synthesis and dispensing units :

8. Design Manual of the Medical Cyclotron which includes

   (a) Drawing and functional description of the accelerating chamber and target systems along with radiation shielding

   (b) Drawings along with the functional description of safety related control systems and devices

   (c) National standards to which the equipment conforms (English translation of the Standard is to be provided)

   (d) Test report on performance of the medical cyclotron demonstrating the compliance with the National standard

   (e) Certificate from the competent authority of country of design/ manufacture to the effect that the equipment is approved for isotope production use

9. Layout of the Medical Cyclotron Vault and Associated Facilities, indicating the following details

   (a) Radiation shielding details : concrete blocks, earth beams (barrier or insulation), lead bricks, iron plates etc.

   (b) Barriers: fences, locked gates, doors etc.

(c) Facility specific : Control console facility to view active and passive engineered controls

(d) Area radiation monitors

(e) Ventilation facility

(f) Caution and alert system

(g) Access sensors or interlocks: Electrical, magnetic and mechanical

(h) 'Crash' or 'Scram' buttons either mounted on walls or at doors and gates

(i) Search and rescue control

(j) Warning indicators (status lights, alarms, posted procedures)

10. Details of Documents with Details (to be submitted)

Design detail	:	Summary of medical cyclotron design and general working principles, specifications and physical parameters of the system and user objectives.
Site characteristics	:	Location, occupancy in site area as well as surrounding population up to 30 meters radius, geology, load bearing capacity of soil and rock, structural design criteria, foundation, meteorology, seismology, Water table, flood level, plinth level (with respect to nearest accessible road), AERB site approval reference, etc.
Medical cyclotron	:	Description of general layout, details of buildings, pressure vessels, vacuum system, Radio frequency system, Magnetic field, beam injection, acceleration, transport and target system including their design, construction and testing and quality assurance manual for the equipment.
Synthesis and dispensing units	:	Name and address of the manufacturer and supplier, make and model of the synthesis and dispensing unit, maximum activity to be handled, material and thickness of shielding.
Biological shield	-	Final sketch giving details of shielding wall surrounding the source, wall thickness, labyrinth access, openings, voids, reinforcements, embedment etc. in the biological shield. Method of shielding calculation and the dose limits followed

- Shield material, density, and quality control measures followed during shield construction
- Maximum and minimum shield thickness, roof thickness
- Drawings and layout of the device location installed
- Dose rate profiles anticipated at various locations: (Maximum and minimum values). Indicate them on a sketch of the facility - control room, roof, access doors, openings and where personnel are expected to be stationed for work or otherwise.
- Radiation shielding evaluation including sky shine
- Maximum dose rate anticipated

  Locations : (indicate also in a sketch)

11. Documentation Details of Auxiliary Services

    (a) Electrical power and power supply systems (including emergency power supply), major electrical equipment, illumination, lift, hoist, cranes etc.

    (b) Air conditioning and ventilation system (including treatment of noxious gases produced, if any)

    (c) Cooling water supply system

    (d) Compressed air system

    (e) Communication system

    (f) Target gas handling system - system description, characteristics of the gas (properties, specifications, purification etc.)

    (g) Laboratory, workshops, stores, etc.

    (h) Other services (please specify)

    (i) Controls of various subsystems, description, operation etc.

12. List of Potential Hazards and Safety Measures to be Taken

    (a) During precommissioning trials of all systems and subsystems

    (b) During commissioning

    (c) During operation and maintenance

13. Safety Features Including Hazard Evaluation

    (a) Design safety of buildings and equipment

(b) Structural design: Seismic and wind load parameter details

(c) Accelerator facility

(d) Electrical system and equipment

  (i) Power and control cables-specifications

  (ii) Cable ducting

  (iii) Safety fencing of high voltage locations

  (iv) Earthing

  (v) Electromagnetic interference and suppression

(e) Air conditioning and ventilation

(f) Vacuum system

(g) Cooling water supply system

(h) Compressed air system

(i) Dry nitrogen supply system

(j) Communication system

(k) Control system

(l) Fail safe (any defect or component failure, which prevents the cyclotron operation) and operational independent

(m) Inventory and labeling of control devices

(n) Others, Please specify.

14. Radiation Safety

(a) Radiation safety policy

(b) Dose equivalent limits

(c) Planned exposure (operational hours/week)

(d) Planned special exposure

(e) Design features - shielding etc.

(f) Radiation monitoring and alarm system (including interlocks)

(g) Induced activity estimation - radiation levels due to induced activity, induced gaseous airborne activity (if applicable)

(h) Radiation sensitive components installed inside the facility and their durability

(i) Induced activity in cooling water

(j) Other radiation safety considerations - radioactive waste, postulation of radiation accident (target rupture, loss of shielding integrity), analysis and action, administrative considerations (if applicable)

(k) Analysis of potential radiation exposure scenarios

15. Chemical Safety

List of chemicals used with quantities, their toxicity and hazards, safety considerations, analysis of potential release scenarios and preventive and other action to be taken [e.g. ozone production and ozone depleting substance, flammable gases, liquids, oxygen deficiency hazard (SF6), biologically hazardous material, cryogenic fluids, etc.]

16. Fire Safety

Fire and explosion hazards, means of escape, access, fire detection and alarm system, fire fighting system- fire hydrants, dry risers, fire extinguishers etc.

17. Personnel Safety

Safety policy, organisation, functions of safety personnel, responsibilities, general safety rules, accident prevention program, safety equipment and procurement, safety inspection, housekeeping, accident reporting, investigation, preventive measures, training, medical facilities including first aid.

18. Safety in Operation and Maintenance

(i) Startup procedure

(ii) Shutdown procedure

(iii) Emergency shutdown procedure

(iv) Search and secure

(v) Procedure for entry into cyclotron vault

(vi) Others (eg. gas handling procedure), please specify.

19. Emergency Planning and Procedures
(types of emergencies envisaged, preventive measures, handling of emergencies, investigation etc.)

(i) During major leaks, foil rupture, contamination, target rupture, loss of shielding integrity

(ii) During explosion and fire

(iii) During general fires

(iv) During emergency in tanks and equipment etc.

(v) During radiation emergency

(vi) Crisis management in case of major emergency

20. Pre-operational radiation survey report (background radiation in and vicinity of the medical cyclotron facility)

21. Quality assurance manual for construction of the facility (as per format given in item A of **Appendix 6A** of AERB/RF/SG/G-3)

22. Details of waste disposal pocedures and provisions including adequate financial arrangement for safe disposal of spent/ disused sources.

23. Details of storage facility for activated components and procedure (identifying long half life radioisotopes)

24. Details to be furnished regarding the decommissioning of the facility.

B. OPERATING AND SAFETY PERSONNEL

(i) Cyclotron operator :

(ii) Radiopharmacist :

(iii) Radiological safety officer :

AERB Approval Ref. :

Date of issue :

Valid up to :

DETAILS OF DOCUMENTS TO BE SUBMITTED

Required documents
Technical description of medical cyclotron design and working procedure with drawings
Electrical circuit diagram and other interlocks of the medical cyclotron device (inbuilt safety features)
Electrical circuit diagram and other interlocks of the medical cyclotron vault
Calibration and periodic checks
Provisions and procedures for (particle beam energy, beam current)
Quality assurance manual (operation)
Arrangements for personal and environmental monitoring system
Periodic surveys of radioactive contamination if applicable
Availability of local safety committee and their safety evaluation report
Details of deviations from approved medical cyclotron components, medical cyclotron vault, shielding design, etc.
Decommissioning procedures of the medical cyclotron facility

We certify that all the information provided by us is true and correct to the best of our knowledge and belief.

Place:

Date:

Signature:

Name:

Designation:

Encl : Documents attached as per the above requirement

APPENDIX-5E

(Refer section 3.4.1.4)

RADIATION PROTECTION MANUAL FOR MEDICAL CYCLOTRON FACILITY

(OPERATION, MAINTENANCE, EMERGENCY ASPECTS)

A. ADMINISTRATION AND SAFETY ASSURANCE

(a) Administrative hierarchy/organisational set up

(b) Authorised personnel - Training and qualification of facility personnel, their knowledge in radiation safety, responsibilities of each of personnel, their availability in adequate number, policies in case of long leave/ absence of certified personnel

(c) Local safety committee: constitution, functions and responsibilities

(d) Procedures for reporting to the regulatory agency on unusual occurrences and periodic radiation safety status

(e) Procedures in case of change or repairs of H.V. system, safety system/ interlocks, certification of log book entry by RSO

(f) Records of maintenance - maintenance schedule, radiation monitoring, and calibration of survey meters, etc.

(g) Industrial safety aspects - fire equipment, safety accessories etc.

(h) Facility security arrangements, fencing and personnel movement control etc.

(i) Removal and storage of contaminated material, if any.

(j) Medical assistance - first aid facility, location, periodic medical examination (once a year), medical facilities and treatment facilities for radiation incidents

B. MONITORING

(a) Radiation monitoring - Type of area monitors, sensitivity range, location, interlock alarm set levels

(b) Contamination monitoring - On line monitoring and sample measurement, method of collecting samples

(c) Personnel monitoring - Number of PM badges, procedure for their issuance, safe place for storage, etc.

C. OPERATION PROCEDURES

'Beam ON' procedures be established, documented and displayed in the console area

D. MAINTENANCE PROCEDURE FOR SAFETY SYSTEMS/ INTERLOCKS

(a) Periodic maintenance - Daily/weekly/monthly/quarterly/ yearly (items, procedures and schedules)

(b) Procedure for maintenance of cooing water used for cooling target beam line components, etc

(c) Procedure for maintenance of air cooling mechanism, maintenance and checking of alarm/ warning devices

E. EMERGENCY PLANNING AND PROCEDURES

(a) Organisational structure and communication links

(b) Name, address and telephone numbers of agencies to be contacted in case of emergency

(c) Emergency contact telephone/ telex nos. and address of

(i) Head of Institution

(ii) Facility-in-charge

(iii) Radiological safety officer (RSO)

(iv) Regulatory agency (AERB)

(v) Fire safety officer (Local)

(vi) Local fire station

(vii) Local police station

(viii) Local medical hospital, radiation therapy hospitals (nearest)

(d) Type of emergencies envisaged - Prevention/handling of emergencies, investigation methods, etc. during major leaks of water, explosion or fire or smoke, radiation emergency, crisis management in case of emergency, earthquake, floods, other natural calamities.

APPENDIX-5F

(Refer section 3.4.1.3, 3.4.1.4)

QUALITY ASSURANCE MANUAL (QAM) FOR MEDICAL CYCLOTRON FACILITIES

A. QUALITY ASSURANCE PROGRAMME DURING CONSTRUCTION OF MEDICAL CYCLOTRON FACILITIES

The Employer/Licensee shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of structures/systems/components related to civil, mechanical, electrical and instrumentation aspects of medical cyclotron facilities during construction. This programme should specify the means to ensure that all work is suitably planned, correctly performed and properly assessed in order to implement design intent in the construction.

The QA manual (QAM) should be prepared addressing the following aspects:

A.1 INTRODUCTION

This section should include applicability and scope of the QAM.

A.2 MANAGEMENT FUNCTIONS

This section should specify the management's policy statement and organisational plan. Organisational plan should be documented addressing the following aspects:

(a) Organisational structure

(b) Functional responsibility

(c) Levels of authority

(d) Lines of internal and external communication.

It should also address requirements related to competent manpower for construction activities of the facility. The functional responsibilities of all the personnel distinguishing task including their assigned administrative powers should be identified and documented.

The Licensee should formally identify a person to be responsible for implementation of QA programme during construction activities. Responsibilities of key personnel in the organisation should be defined in writing. The person appointed should have the necessary resources to discharge the following responsibilities:

(a) Ensuring that construction and installation work is carried out in accordance with design specifications, drawings, procedures and instructions, including the implementation of specified QA requirements.

(b) Ensuring that construction and installation work undertaken, including work by manufacturers/suppliers, is coordinated, conducted and completed in accordance with planned programmes.

(c) Controlling access to the construction site.

Appropriate controls reflecting safety regulations shall be established for all personnel, including suppliers and visitors. These shall be in line with applicable statutes and shall include arrangements for effective planning, organisation, monitoring and review of the preventive and protective measures. Management shall provide all necessary support to the contractor to ensure health and safety of the construction personnel and quality assurance requirements of construction.

A.2.1 Grading

A graded approach based on the relative importance to safety of each item, service or process should be adopted. Activities, which should be graded during construction include:

(a) Qualification of special construction processes and the personnel to carry them out

(b) Details and need for inspection plans

(c) Level of traceability of construction material and related records

(d) Level of in-process controls and need for hold points

(e) Complexity involved in equipment handling/erection and post-erection preservation.

A.2.2 Interfaces

Employer/Licensee should ensure that interface arrangements shall be agreed among the construction agencies, suppliers and other organisational units performing the work. These should be defined in writing and be included in relevant documents. Appropriate references of the same should be made in the QA programme. Handover/transfer responsibilities after completion of construction/installation to operating organisation.

A.3. PERFORMANCE FUNCTIONS

A.3.1 Document Control

Procedures for the preparation, review, approval, issue, modification and

control of documents should be established. The record system should be established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, storage, retrieval and disposal of construction records. Document control system should also include records of as-built condition of structures, systems and components.

A.3.2 Procurement Control

Measures shall be established and documented to ensure that relevant standards/specifications and other requirements necessary to assure adequate quality are included or referenced for procurement of items and services required during construction of medical cyclotron facilities.

Procurement requirements for assuring quality shall be covered by a procurement document. The document shall include items such as scope of work, technical requirements, and test, inspection and acceptance requirements.

Procedures for the preparation, review, approval, issue, modification and control of documents pertaining to activities affecting construction should be established. Document release and distribution system shall be established utilising up-to-date distribution lists. Individuals responsible for issue of documents shall be identified. Records important for construction include PSAR, civil structure design documents etc.

A.3.3 Supplier Evaluation and Selection

Supplier evaluation shall be carried out to assess the capability to provide items and services in accordance with the requirements of procurement document(s). The supplier evaluation includes as appropriate:

(a) evaluation of current technical capability, availability of expertise and resources,

(b) analysis of product samples, and

(c) review of historical quality performance data.

A.4 PROCESS CONTROL

Documented procedures should be established for all construction related activities of the medical cyclotron facilites such as receiving and storing components, civil construction, equipment erection, cleaning/flushing, inspection, testing, modification etc. Provision should be made for verification, review and audit of activities affecting quality of construction.

Site construction activities should be planned and documented in adequate detail and approved by designated persons/agencies. The plan shall define:

(a) The planned sequential order and duration of activities

(b) The resource allocation for each activity

(c) Work planning and supervision

(d) Implementation of safety requirement during construction including fire safety and first aid

Preventive maintenance and preservation of items in stores or installed should be carried out in accordance with manufacturers' recommendations and good engineering practices, and documented.

A.5 VERIFICATION FUNCTIONS

A.5.1 Verification Programme

A comprehensive documented verification programme to be prepared to assure conformance of construction of the medical cyclotron facilities as per the relevant codes and standards. Verification programme should comprise external (third party) as well as internal verification at specified stages/ periodicity.

A.5.2 Inspection and Test Controls

A plan for inspection and testing of the materials/components used for construction, should be established. These should include identification of characteristics to be checked, type of check, acceptance norms etc. These should specifically include identification of characteristics to be checked, type of check, acceptance norms etc. Provisions to test construction equipment, calibration of testing and measuring instruments etc. prior to their use need to be established.

A.5.3 Audit

Provisions need to be prescribed detailing the establishment and implementation of a comprehensive system of planned and documented audits to verify the implementation and effectiveness of the various elements of the quality assurance programme. It should address the audit performance, audit personnel, audit plan and audit timing etc. The requirement for QA audit and extent of its application should be based on the safety significance of the system.

A.6. CORRECTIVE FUNCTIONS

A.6.1 Non-conformity Control and Corrective actions

A system for the control of non-conformances and their corrective actions should be established. Non-conformances, deviations or inadequacies affecting quality should be identified and controlled. The persons responsible

for review and disposition of non-conformances should be identified. The programme should provide that appropriate action be taken to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective or incorrect material, equipment and any other non-conformances are identified, corrected and recurrences are prevented.

A.7. RECORDS

Records should be prepared and maintained to provide objective evidence of quality to meet the requirements of applicable codes, standards and specifications to include details such as:

(a) Certificates of each component from the supplier/manufacturer; and the test and inspection records

(b) Non-conformance reports, corrective/preventive actions carried out

(c) Certificates about raw material such as cement, sand, iron, steel used during constructions

(d) Records of the test results, acceptance criteria and as-built condition of structures.

(e) Design reports and drawings

(f) Safety analysis reports

The record system shall be established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, preservation/storage, retrieval, inspection and disposal of records after expiry of the specified retention period of non-permanent records.

B. QUALITY ASSURANCE DURING COMMISSIONING AND OPERATION OF MEDICAL CYCLOTRON

Employer/Licensee shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of the medical cyclotron facilites. This programme shall also provide means to ensure that all work is suitably planned, correctly performed and properly assessed. Procedures shall be defined by the Employer to ensure that the commissioning and operation of medical cyclotron facilites fulfils specified requirements.

The QAM should be prepared in following format addressing the different aspects of the facility.

B.1. INTRODUCTION

This section should include Applicability and Scope of the QAM.

B.2. MANAGEMENT FUNCTIONS

This section should specify the management's policy statement and organisation plan. Organisational plan should be documented addressing the following aspects:

(a) Organisational structure

(b) Functional responsibility

(c) Levels of authority

(d) Lines of internal and external communication.

It should also address requirements related to availability of competent manpower for commissioning and operation of the facility. The functional responsibilities of all the personnel distinguishing task including their assigned administrative powers should be identified and documented. The necessary resources required by these personnel to discharge the following responsibilities need to be identified:

(a) Commissioning and operation of the facility is carried out in accordance with approved procedures, design specifications, designers' instructions.

(b) Controlling access to the operating facility.

Procedures need to be documented for formal reviews of QA programme by management as often as necessary or any changes in the regulatory requirements that may have been introduced after the previous approval of QA programmes. Identification and control of compliance with applicable codes, standards, specification and practices; acceptance criteria (qualitative and/or quantitative as appropriate) for determining satisfactory completion of the commissioning and operation activity should be described in the QAM.

B.2.1 Interfaces

The interface arrangements should be agreed with the licensee and various agencies involved (namely design, construction, commissioning, operation, decommissioning, AERB and statutory agencies as applicable). Handover/ transfer responsibilities after completion of construction/ installation to operating organisation.

B.3 PERFORMANCE FUNCTIONS

B.3.1 Document Control

(a) Procedures for the preparation, review, approval, issue, modification and control of documents pertaining to activities affecting commissioning and operation should be established.

(b) Document release and distribution system shall be established utilising up-to-date distribution lists. Individuals responsible for issue of documents shall be identified.

(c) Documents important for commissioning and operation include among others, final safety analysis report (FSAR), acceptance test report (ATR), and radiation protection manual (RPM), commissioning reports and technical specifications for operation.

(d) Procedures for making interface with various components and systems should be prepared. Verification and validation of software used for operational control should be done by the independent agencies.

B.3.2 Process Control

B.3.2.1 Commissioning Control

Procedures should be established to ensure that appropriate tests are performed during commissioning to demonstrate that design intent and, regulatory and other statutory requirements are met. Satisfactory demonstration of functional capability of safety systems is a prerequisite for considering the medical cyclotron facilites to be suitable for the operating phase.

Measures shall be established to ensure that all commissioning activities including beam extraction, transport and dumping are planned, controlled and implemented in accordance with approved documents such as procedures, instructions and checklists, and results documented.

Commissioning activities shall commence only after due completion of respective construction activities supported by certified documents. Inspection and surveillance shall be performed by the facility and documented to verify compliance with specification requirements.

Measures shall be established to identify, review, resolve and document all non-conformances and design changes.

A system for audit of commissioning, follow-up and record of corrective actions shall be established.

B.3.2.2 Operation Control

Documented procedure shall be established for safe operation of the medical cyclotron facilites in accordance with the design intent and specified operational limits.

Provisions should be included to ensure interface among agencies for operation, maintenance, technical services, plant management, design, inspection, testing, verification and audit.

Provision shall exist for regular verification of operation activities related to safety. Preventive and maintenance schedule should be prepared for all safety systems as per the applicable codes.

Inspection and testing/surveillance during operation of safety equipment as well as subsequent to maintenance, modification or procedural changes should be performed to specified requirements and documented.

B.4 VERIFICATION FUNCTIONS

B.4.1 Verification Programme

A comprehensive documented verification programme should be prepared and verification conducted accordingly to assure conformance of commissioning and operation of the medical cyclotron facilites as per the relevant specified codes and procedures. Verification programme should comprise external as well as internal verification

B.4.2 Inspection and Test Controls

Measures should be established to ensure that testing and measuring devices (e.g. radiation survey meters, area monitors, tools, gauges and other devices) used in determining conformance to acceptance criteria are of proper range, type, accuracy and precision.

Testing and measuring devices should be controlled, calibrated and adjusted at specified intervals, or before use, to maintain accuracy within necessary limits.

Controls shall be established to ensure proper handling, storage and use of calibrated instruments.

B.4.3 Audit

Provisions need to be prescribed detailing the establishment and implementation of a comprehensive system of planned and documented audits to verify the implementation and effectiveness of the various elements of the quality assurance programme. It should address the audit performance, audit personnel, audit plan and audit timing etc. The requirement for QA audit and extent of its application should be based on the safety significance of the system.

B.5 CORRECTIVE FUNCTIONS

B.5.1 Non-conformity Control and Corrective Actions

A system for the control of non-conformances and their corrective actions should be established. Non-conformances, deviations or inadequacies affecting quality should be identified and controlled. The persons responsible

for review and disposition of non-conformances should be identified. The programme should provide appropriate actions to be taken to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective or incorrect material, equipment and any other non-conformance are identified and corrected.

Preventive actions should also be identified based on the review of non-conformances.

B.6 QA RECORDS

Records should be prepared and maintained to provide objective evidence of quality to meet the requirements of applicable codes, standards and specifications.

Records should include:

(a) results of reviews, inspections, tests and audits,

(b) operation logs,

(c) non-conformance reports, repairs carried out,

(d) training, qualifications and certification of personnel,

(e) information pertaining to 'as-built' condition of items in the plant,

(f) copies of design drawings, PSAR, FSAR, RPM, QAM, licence/ consents/certificates, etc.,

(g) radiation dose records, emergency exercises and maintenance records.

The record system shall be established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, preservation/storage, retrieval, inspection and disposal of records after expiry of the specified retention period of non-permanent records.

(APPENDICES 6A.6B,6D, 6E, 6F ARE FOR IFRT)

APPENDIX-6A

(Refer section 3.4.3.2)

FORMAT FOR SITE ASSESSMENT REPORT OF INTEGRATED FACILITY FOR RADIATION TECHNOLOGY (IFRT)

GEOLOGICAL AND GEOTECHNICAL INVESTIGATIONS

1. Site investigations for Integrated Facility for Radiation Technology are necessary to determine the geotechnical characteristics of the site that affect the design, performance and safety of the IFRT. The investigations should produce the information needed to define the overall site geology to a degree that is necessary for an understanding of the subsurface conditions in order to ensure stability against natural hazards like earthquake, flood etc.

2. Site investigations should also provide information needed to define ground water conditions as well as the geotechnical parameters needed for analysis and design of foundations. These include parameters to evaluate the subsurface characteristics for safe engineering of IFRT, such as bearing capacity of foundation material, lateral earth pressure, the stability of cuts and slopes in rock, the effects of earthquake induced motions transmitted through underlying deposits on the response of soils and structure (including the potential for inducing liquefaction in soils) and also those needed to estimate the expected settlement of the structure.

3. Requirements of geotechnical investigations depend on the site specific conditions. However, the following investigations are the minimum, which should be carried out for the evaluation of parameters required for safe design:

   (a) Field Work

      (i) Drilling of bore holes

      (ii) Collection of disturbed/undisturbed soil and water samples

      (iii) Standard penetration tests

      (iv) Plate load tests

      (v) Electrical receptivity tests

   (b) Laboratory Tests on Soil Samples

      (i) Grain size analysis (Coarse and fine)

      (ii) Consistency limit test

(iii) Specific gravity of soil

(iv) Proctor density test

(v) Permeability test

(vi) Consolidation test

(vii) Modulus of elasticity and poisons ratio

(viii) Unconfined/confined compression test

(ix) Direct shear test (consolidated drained)

(x) Chemical tests on soil

(c) Laboratory Tests on Rock Samples

(i) Petrographic study

(ii) Porosity

(iii) Unconfined/confined compression test

(iv) Modulus of elasticity and poisons ratio

(d) Test on Ground Water Samples

Chemical analysis of ground water sample

4. Following requisites should be met in connection with geotechnical investigations:

(i) Prior to commencement of geotechnical investigation, a comprehensive plan of the work should be chalked out. Geological status of the site should be examined based on available information. Additional investigation may be required if site specific conditions warranted so for the safety of the plant.

(ii) Minimum depth of boreholes should be three times the larger dimension of the footing.

(iii) Number of boreholes should be such that subsurface profile of the plant area can be drawn with reasonable certainty in any direction. At least four data points should be available, in any direction, for plotting of sub surface profile.

(iv) Geological mapping of the foundation pit should be carried out after completion of excavation.

(v) Appropriate rectification/stabilisation measures shall be adopted if it is found necessary after excavation.

4.1 Report on geotechnical investigation with the following details:

(i) Geological status of the site based on available information

(ii) Details of bore logs and trial pit logs

(iii) Permeability test results

(iv) Ground water observations

(v) Results of soil and rock tests

(vi) Chemical test results of water

(vii) Sub surface profiles

(viii) Electrical resistivity logging

(ix) Petrographic study results

(x) Evaluation of foundation design parameters

APPENDIX-6B

(Refer section 3.4.3.3)

FORMAT OF THE PRELIMINARY SAFETY ANALYSIS REPORT FOR INTEGRATED FACILITY FOR RADIATION TECHNOLOGY (IFRT)

[PSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer)]

A. INTRODUCTORY INFORMATION

1(a)	Name of the utility/institution setting up the IFRT	:
	Mode of communication	:
	Telephone No.	:
	Fax. No.	:
	E-mail	:
(b)	Postal address of the utility/institution	:
2.	Name, designation and address of the applicant officially representing the utility/institution	:
3.	Name and address of the designer(s) of IFRT (with e-mail and fax)	:
4.	Name and address of the manufacturer of IFRT (with e-mail and fax)	:
5.	Project Details	:
	(a) Type of nuclear/radiation facility	:
	(b) Objective/purpose	:
	(c) Nature of the facility	:
6.	Design class of hot cell structure	:
7.	Type of radioactive sources to be handled	:
8.	The Maximum activity to be handled in the facility	: ———— PBq (——— kCi)
9.	State whether similar plant is operating elsewhere by applicant	:

B. TECHNICAL DESCRIPTION OF THE INTEGRATED FACILITY FOR RADIATION TECHNOLOGY (IFRT)

1. Brief Description of the Facility

2. Design details : Design philosophy, defence-in-depth concept, redundancy. independence and diversity in the design, built-in-safety features provided in the design.

3. Site of Installation of IFRT : Geotechnical and geological information, Field investigations, water table, weather, soil profile, laboratory investigations, allowable bearing pressure/safe bearing capacity, chemical analyses of water and soil, site lay out, documentary evidence of the ownership of the site, Regulatory Consent issued by AERB for site approval

   - Structural details - type and depth of foundation and precautions against flooding
   - Seismic considerations and IS Tec. doc. proposed to be followed for construction
   - Buildings and residential complexes, occupancy, etc. within 30m radius of the facility location; give layout and height of the adjacent tallest building in the vicinity of 100 m.
   - Access roads to the facility : road strength and width to carry transport flasks containing radioation sources (culvert/bridge, if any, on the way - specify)
   - Any additional information

4. Biological Shield

   - Sketch giving details of shielding wall surrounding the hot cell and its thickness, openings, voids, reinforcements, embedment etc. in the biological shield.
   - Sketch of low bay area design details
   - Shield material, density, quality assurance during construction
   - Maximum and minimum shield thickness, roof thickness

- Dose rate profiles anticipated at various locations: (maximum and minimum values). Indicate them on a sketch of the facility - control room, roof, access doors, openings and where personnel are expected to be stationed for work or otherwise.
- Maximum dose rate anticipated at various locations : (Indicate also in a sketch)
- Shielding thickness of lead glass window and its light transmission efficiency

5. Different Systems of the High Bay Area and Safety Systems/Interlocks

5.1 Hot cell

- Design details of Hot Cell with drawing providing all dimensions
- Details of SS lining inside wall of Hot cell and roof.

Source cask handling crane

- Technical specification of components of EOT cranes to be installed for source cask handling
- Details of mechanical arrangement (include drawing) of source handling cranes.
- No. and locations of the cranes
- Load carrying capacity of the crane, prevention of source cask from crane, Dimensions of wire used in crane.
- Safety provisions for operational controls and interlocking mechanism.

Master slave manipulator (MSM)

- Technical details of master-slave manipulator (MSM)
- Operating procedures of MSM
- Lifting capacity of MSM
- Installation and testing procedures

5.2 Water pool

- Detailed sketch or drawing of water pool for source storage showing dimensions, water proofing, lining details, penetrations, piping,

fittings, embedment, locations of level measuring devices, inlet-outlet water piping

- Water level monitoring system for maximum-minimum water levels, normal level and abnormal levels; Total volume of water.
- Buffer storage tank details, overhead water storage tank details, provision of emergency water discharge into pool, provision of overflow/ drainage of water from the pool to any municipal sewerage lines.
- Municipal water supply quality - TSD, TSS, hardness and conductivity
- Rate of water supply in emergency
- Quantity of water maintained in pool, conductivity maximum/minimum, method of assuring water quality, PH of water.
- Leakage from pool - prevention and assessment
- Normal evaporation water losses from pool with and without ventilation related to humidity and temperature
- System to prevent water flooding in the cell
- Method of cleaning water pool
- Pool grill cover strength - prevention of accidental fall into the pool - during routine operations like source container handling operations
- Pool bottom surface plan - loading conditions, provisions for transport container, intermediate source storage, if any.
- Corrosion- intermetallic/galvanic, specification of metals coming in contact with pool water prevention thereof.
- Maximum water height above sources when it is taken out from storage containers under water and expected radiation profiles on the pool surface, both at normal and abnormal water levels
- Underwater lights, location, voltage use, prevention of shocks and electrocution.

		- Prevention of accidental fall of person and material into the pool
		- Prevention of syphoning action in pool
		- Prevention of accidental entry into the room, when the water level in the pool is low and when the sources are in storage position.
		- DM water plant capacity and type (anion, cation, mixed bed etc.)
5.3	Ventilation	- Volume of hot cell, including and excluding high bay and low bay area
		- Ventilation rate provided, anticipated minimum air changes in the hot cell, high bay area, water pool, low bay area
		- Location and routing of ventilated ducts, fans, duct size, etc. (give sketch), air handling units, HEPA filters.
		- Methods of monitoring ventilation and action on ventilation failure
		- Location of ventilation exhaust and the height of stack above the hot cell roof. Prevention of water flooding through ventilation ducts from roof (sketch)
		- Ozone concentration (maximum) anticipated in the cell with ventilation ON and OFF. Time duration in minutes for safe concentration of ozone in the cell (0.1ppm) after the exhaust is switched off.
		- Prevention of entry to the hot cell when unsafe limit of ozone concentration exists
		- Details of safety interlock interlocks to retract in case of ventilation failure
		- Provisions for standby ventilation exhaust fans, if any
5.4	Access door	- Design details of access door with material used, thickness, its shielding adequacy
		- Information on safety interlocks provided to prevent human access to the hot cell when the radiation sources are handled.

- Interference to interlocks and source safety and protection against exposure to radiation or accidental entry.
- Cautions, visual display and audio alarm against entry into the cell

5.5 Low bay area
- Purpose of the area
- Design details of the area
- Access control to the this area

6. Radioactive Waste and DecontAmination:
- Different types of waste generated; provision and procedure made for the safe disposal of the same
- Details of decontamination procedures for hot cell, tools used in hot cell, flasks and floors, washbasins
- Collection and storage of solid waste, sump with stainless steel (SS) lining for collection of liquid waste
- Discharge methods of gaseous waste from hot cell, high bay area, filters used and monitoring methods of gaseous discharge to atmosphere.

7. Radiation Monitoring Instruments:
- Personnel monitoring, contamination monitoring and area monitoring equipment, personnel protective equipment
- Locations of area monitors, zone monitors and the preset values
- Interlocking mechanism of radiation area monitors with access into the Hot cell.
- Different types of radiation survey meters

8. Detailed Access Control Procedure and Operating Procedures in the Hot Cell :

9. Fire Detection System :
- Detection methods of excessive temperature rise, smoke, fire, and interlock if any in cell area, high bay and low bay area.

- Type of detectors used and their sensitivity, location of detectors.
- Validity certification for detectors
- Direction escape route for fire - fire fighting system, fire hydrants, extinguishers, dry risers, etc.

10. Control System :

- Give control system description in brief
- Voltage and currents employed, emergency power standby power, battery backup if any,
- Control logic and flow of command
- Interlock systems for fail-safe operation

11. Audio-visual Alarms/Anunciators :

- Describe the list of audio visual alarms provided, their location, purpose and effectiveness - against exposure to radiation, fire, smoke, toxic gases, radioactive gaseous waste discharge etc.

12. Electrical System and Emergency Power Supply :

- Provisions made when power failure occurs, ratings of normal and emergency power systems, status of systems like manipulators and cranes
- Emergency power supply caters to cell ventilation, access door, cell instruments, remote hoist, cell lights and emergency alarms

13. Design Basis Accident Analysis and Safety Provisions:

Abnormal events mentioned below shall be analysed and methods for achieving safety under these events shall be described.

(a) Release of radioactivity or accidental exposures in hot cell and water pool area

(b) Jamming of master-sleeve manipulators

(c) Failure of crane

(i) Failure of cranes brakes during handling of the flask cover inside cell

(ii) Breaking of wire rope of overhead crane

(d) Slug(s) is missing or rolled from the hot cell table

(e) Heavy contamination of hot cell, contamination of pool water pool

(f) High activity of gaseous waste discharge in air

(g) Failure of access door interlocks

(h) Fire in the IFRT

(i) Failure of ventilation system

(j) Failure of power supply

(k) Failure of PLC

(l) Earthquake at the IFRT site

(m) Flooding of hot cell with water

(n) Leakage of water from pool

(o) Breakage of pool lining

(p) Fall of person in the water pool

The designer/manufacturer shall carry out such analysis to demonstrate means provided to prevent and handle above situations safely.

14. Decommissioning of IFRT:

- Procedure to be followed when decision is made to close down the facility permanently.
- Provisions including adequate financial arrangement for safe disposal of spent/disused sources.

APPENDIX-6D

(Refer section 3.4.3.4)

FORMAT OF THE FINAL SAFETY ANALYSIS REPORT FOR INTEGRATED FACILITY FOR RADIATION TECHNOLOGY (IFRT)

[FSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer) along with the application for obtaining the licence for commissioning/operation of IFRT]

A. INTRODUCTORY INFORMATION

1(a)	Name of the utility/institution setting up the IFRT	:	
	Mode of communication	:	
	Telephone No.	:	
	Fax. No.	:	
	E-mail	:	
(b)	Postal address of the utility/ institution	:	
2.	Name, designation and address of the applicant officially representing the utility/institution	:	
3.	Name and address of the designer(s) of IFRT (with e-mail and fax)	:	
4.	Name and address of the manufacturer of IFRT (with e-mail and fax)	:	
5.	Project Details :		
	(a) Type of nuclear radiation facility	:	
	(b) Objective/purpose	:	
	(c) Nature of the facility	:	
6.	Design class of hot cell structure	:	
7.	Type of radioactive sources to be handled	:	
8.	The maximum activity to be handled in the facility	:	——— PBq (——— kCi)
9.	State whether similar plant is operating elsewhere by applicant	:	

B. TECHNICAL DESCRIPTION OF THE INTEGRATED FACILITY FOR RADIATION TECHNOLOGY (IFRT)

1. Brief description of the facility

2. Design details : Design philosophy, defence-in-depth concept, redundancy. independence and diversity in the design, built-in-safety features provided in the design.

3. Site of installation of IFRT: Geotechnical and geological information, Field investigations, water table, weather, soil profile, laboratory investigations, allowable bearing pressure/safe bearing capacity, chemical analyses of water and soil, site lay out, documentary evidence of the ownership of the site, Regulatory Consent issued by AERB for site approval

   - Structural details - type and depth of foundation and precautions against flooding
   - Seismic considerations and IS Tec. doc. 1893 (curent revision) proposed to be followed for construction
   - Buildings and residential complexes, occupancy, etc. within 30m radius of the facility location; give layout and height of the adjacent tallest building in the vicinity of 100m.
   - Access roads to the facility : road strength and width to carry transport flasks containing radioation sources (culvert/ bridge, if any, on the way - specify)
   - Any additional information

4. Biological shield of hot cell

   - Sketch giving details of shielding wall surrounding the hot cell and its thickness, openings, voids, reinforcements, embedment etc. in the biological shield.
   - Sketch of low bay area design details
   - Shield material, density, quality assurance during construction
   - Maximum and minimum shield thickness, roof thickness

- Dose rate profiles anticipated at various locations: (maximum and minimum values). Indicate them on a sketch of the facility - control room, roof, access doors, openings and where personnel are expected to be stationed for work or otherwise.
- Maximum dose rate anticipated at various locations : (Indicate also in a sketch)
- Shielding thickness of lead glass window and its light transmission efficiency

5. Different systems of the high bay area and safety systems/interlocks

5.1 Hot cell

- Design details of hot cell with drawing providing all dimensions
- Details of SS lining inside wall of Hot cell and roof.

Source cask handling crane

- Technical specification of components of EOT cranes to be installed for source cask handling
- Details of mechanical arrangement (include drawing) of source handling cranes.
- No. and locations of the cranes
- Load carrying capacity of the crane, prevention of accidental fall of source cask from crane, Dimensions of wire used in crane.
- Safety provisions for operational controls and interlocking mechanism.

Master slave manipulator (MSM)

- Technical details of master-slave manipulator (MSM)
- Operating procedures of MSM
- Lifting capacity of MSM
- Installation and testing procedures

5.2 Water pool

- Detailed sketch or drawing of water pool for source storage showing dimensions, water proofing, lining details, penetrations, piping,

fittings, embedment, locations of level measuring devices, inlet-outlet water piping

- Water level monitoring system for maximum-minimum water levels, normal level and abnormal levels; total volume of water.
- Buffer storage tank details, overhead water storage tank details, provision of emergency water discharge into pool, provision of overflow/drainage of water from the pool to any municipal sewerage lines.
- Municipal water supply quality - TSD, TSS, hardness and conductivity
- Rate of water supply in emergency
- Quantity of water maintained in pool, conductivity maximum/minimum, method of assuring water quality, PH of water.
- Leakage from pool - prevention and assessment
- Normal evaporation water losses from pool with and without ventilation related to humidity and temperature
- System to prevent water flooding in the cell
- Method of cleaning water pool
- Pool grill cover strength - prevention of accidental fall into the pool - during routine operations like source container handling operations
- Pool bottom surface plan - loading conditions, provisions for transport container, intermediate source storage, if any.
- Corrosion-intermetallic/galvanic, specification of metals coming in contact with pool water prevention thereof.
- Maximum water height above sources when it is taken out from storage containers under water and expected radiation profiles on the pool surface, both at normal and abnormal water levels
- Underwater lights, location, voltage use, prevention of shocks and electrocution.

		-	Prevention of accidental fall of person and material into the pool
		-	Prevention of syphoning action in pool
		-	Prevention of accidental entry into the room, when the water level in the pool is low and when the sources are in storage position.
		-	DM water plant capacity and type (anion, cation, mixed bed etc.)
5.3	Ventilation	-	Volume of hot cell, including and excluding high bay and low bay area
		-	Ventilation rate provided, anticipated minimum air changes in the hot cell, high bay area, water pool, low bay area
		-	Location and routing of ventilated ducts, fans, duct size, etc. (give sketch), air handling units, HEPA filters.
		-	Methods of monitoring ventilation and action on ventilation failure
		-	Location of ventilation exhaust and the height of stack above the hot cell roof. Prevention of water flooding through ventilation ducts from roof (sketch)
		-	Ozone concentration (maximum) anticipated in the cell with ventilation ON and OFF. Time duration in minutes for safe concentration of ozone in the cell (0.1ppm) after the exhaust is switched off.
		-	Prevention of entry to the hot cell when unsafe limit of ozone concentration exists
		-	Details of safety interlock interlocks to retract in case of ventilation failure
		-	Provisions for standby ventilation exhaust fans, if any
5.4	Access Door	-	Design details of access door with material used, thickness, its shielding adequacy
		-	Information on safety interlocks provided to prevent human access to the hot cell when the radiation sources are handled.

- Interference to interlocks and source safety and protection against exposure to radiation or accidental entry.
- Cautions, visual display and audio alarm against entry into the cell

5.5 Low Bay Area
- Purpose of the area
- Design details of the area
- Access control to the this area

6. Radioactive Waste and Decontamination:
- Different types of waste generated; provision and procedure made for the safe disposal of the same
- Details of decontamination procedures for hot cell, tools used in hot cell, flasks and floors, washbasins
- Collection and storage of solid waste, sump with stainless steel (SS) lining for collection of liquid waste
- Discharge methods of gaseous waste from hot cell, high bay area, filters used and monitoring methods of gaseous discharge to atmosphere.

7. Radiation Monitoring Instruments:
- Personnel monitoring, contamination monitoring and area monitoring equipment, personnel protective equipment
- Locations of area monitors, zone monitors and the preset values
- Interlocking mechanism of radiation area monitors with access into the Hot cell.
- Different types of radiation survey meters

8. Detailed Access Control Procedure and Operating Procedures in the Hot Cell :

9. Fire Detection System :
- Detection methods of excessive temperature rise, smoke, fire, and interlock if any in cell area, high bay and low bay area.

- Type of detectors used and their sensitivity, location of detectors.
- Validity certification for detectors
- Direction escape route for fire - fire fighting system, fire hydrants, extinguishers, dry risers, etc.

10. Control System :

- Give control system description in brief
- Voltage and currents employed, emergency power standby power, battery backup if any,
- Control logic and flow of command
- Interlock systems for fail-safe operation

11. Audio-visual Alarms/ Anunciators :

- Describe the list of audio visual alarms provided, their location, purpose and effectiveness - against exposure to radiation, fire, smoke, toxic gases, radioactive gaseous waste discharge etc.

12. Electrical System and Emergency Power Supply :

- Provisions made when power failure occurs, ratings of normal and emergency power systems, status of systems like manipulators and cranes
- Emergency power supply caters to cell ventilation, access door, cell instruments, remote hoist, cell lights and emergency alarms

13. Design Basis Accident Analysis and Safety Provisions:

Abnormal events mentioned below shall be analysed and methods for achieving safety under these events shall be described.

(a) Release of radioactivity or accidental exposures in hot cell and water pool area

(b) Jamming of Master-sleeve manipulators

(c) Failure of crane

(i) Failure of cranes brakes during handling of the flask cover inside cell

(ii) Breaking of wire rope of overhead crane

(d) Slug(s) is missing or rolled from the hot cell table

(e) Heavy contamination of hot cell, contamination of pool water pool

(f) High activity of gaseous waste discharge in air

(g) Failure of access door interlocks

(h) Fire in the IFRT

(i) Failure of ventilation system

(j) Failure of power supply

(k) Failure of PLC

(l) Earthquake at the IFRT site

(m) Flooding of hot cell with water

(n) Leakage of water from pool

(o) Breakage of pool lining

(p) Fall of person in the water pool

The designer/manufacturer shall carry out such analysis to demonstrate means provided to prevent and handle above situations safely.

14. Acceptance test reports after installation of safety systems:

(a) Dose rate profile measurement in the entire facility, strength of radiation source.

(b) Performance of radiation monitoring and control interlocks

(c) Performance of personnel monitors

(d) Dose concentration measurement with and without ventilation fan functioning

(e) Assurance and effectiveness of control functions and interlocks

Sketch of the facility and location of dose rate monitoring points and maximum/minimum dose rate levels should include :

(a) Name of persons carrying out the measurement

(b) Instrument used in the radiation survey

(c) Confidence limits of radiation level measurements

(d) Background radiation levels in each location of measurement

15. Decommissioning of IFRT:

Procedure to be followed when decision is made to close down the facility permanently.

Provisions including adequate financial arrangement for safe disposal of spent/ disused sources.

16. List of critical safety components:

The manufacturer of IFRT shall provide to the operating organisation a complete list of components as per following classification:

Group A : Replaceable by manufacturer or with his explicit Consent

Group B : Replaceable to exact specifications

Group C : Replaceable without restriction

AERB SAFETY GUIDE NO. AERB/RF/SG/G-3 (Vol. 2 of 4)

CONSENTING PROCESS FOR RADIATION FACILITIES

(VOLUME - 2)

Atomic Energy Regulatory Board
Mumbai-400 094
India

March 2011

Price

Order for this guide should be addressed to:

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

FOREWORD

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

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

AERB issued a safety code on 'Regulation of Nuclear and Radiation Facilities' (AERB/SC/G) to spell out the requirements/obligations to be met by a nuclear or radiation facility for the issue of regulatory Consent at every stage. This safety guide apprises the details of the regulatory requirements for setting up the radiation facility. such as consenting process, the stages requiring consent, wherever applicable documents to be submitted and the nature and extent of review. The guide also gives information on methods of review and assessment adopted by AERB.

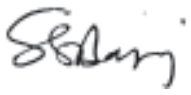
Consistent with the accepted practice, 'shall' and 'should' are used in the guide to distinguish between a firm requirement and a desirable option respectively. Appendices are an integral part of the document, whereas annexures, bibliography and list of participants are included to provide further information that might be helpful to the user. 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.

For aspects not covered in this guide, applicable national and international standards, codes and guides acceptable to AERB should be followed. Non-radiological aspects

such as industrial safety and environmental protection are not explicitly considered in this guide. Industrial safety shall be ensured by compliance with the applicable provisions of the Factories Act, 1948 and the Atomic Energy (Factories) Rules, 1996.

The guide has been prepared by AERB staff. It has been reviewed by experts and the Advisory Committee on Preparation of Code and Guides and on Governmental Organisation for Nuclear and Radiation Facilities (ACCGORN).

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



(S. S. Bajaj)
Chairman, AERB

DEFINITIONS

Acceptable Limits

Limits acceptable to the regulatory body for accident condition or potential exposure.

Accelerator

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

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 the Becquerel (Bq).

Afterloading Applicator

A device applied to the patient into which radioactive sources are introduced either manually or by a remotely operated system.

Applicant

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

Approval

A type of consent issued by the regulatory body to a proposal.

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.

Authorisation

A type of regulatory consent issued by the regulatory body for all sources, practices and uses involving radioactive materials and radiation generating equipment (see also 'Consent').

Becquerel

See 'Activity'

Betatron

An electron accelerator in which electrons are accelerated in an increasing magnetic field maintaining a stable orbit of electrons.

Commissioning

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

Competent Authority

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

Computed Tomography

Reconstructive tomography in which image recording and processing are effected by a computing system.

Consent

It is 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.

Consentee

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

Construction

The process of manufacturing, testing and assembling the components of a nuclear or radiation facility, the erection of civil works and structures, the installation of components and equipment and the performance of associated tests.

Contamination

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

Cyclotron

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

Decommissioning

The process by which a nuclear or radiation facility is finally taken out of operation, in

a manner that provides adequate protection to the health and safety of the workers, the public and the environment.

Decontamination

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

Disposal

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

Dose

A measure of the radiation absorbed by a target. The quantities termed absorbed dose, organ dose, equivalent dose, effective dose, committed equivalent dose or committed effective dose are used, depending on the context. The modifying terms are used when they are not necessary for defining the quantity of interest.

Dosimeter

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

Dosimetry

Measurements and/or calculations performed in connection with the determination of radiation dose and/or dose distributions in the irradiated volume.

Employer

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

Enclosed Installation

In case of industrial radiography any installation in which radiography operations are carried out in an enclosure which has walls providing adequate radiation protection to persons working outside the enclosure, and which prevents unauthorised entry of persons into the enclosure during radiography operations. Such installations may include open top installations also.

Ethical Review Committee

A committee of independent, qualified persons to advise on the conditions of exposure and the dose constraints to be observed for individuals exposed for biomedical research when there is no direct benefit to the exposed individual.

Fluoroscopy

The technique of imaging by using a fluorescent screen.

Handle

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

Industrial Gamma Radiography Exposure Device (IGRED)

An assembly of components necessary to make radiographic exposures and which includes the source housing, mechanism for securing the source assembly, exposure mechanism, that includes source drive associated system, positioning devices and guide tubes.

Industrial radiography

Non-destructive testing of materials employing ionising radiation.

Ionisation

Formation of ions by the division of molecules or by the addition or removal of electrons from atoms or molecules.

Irradiation

Exposure to ionising radiation.

Irradiators

A facility that houses a particle accelerator, X-ray machine, or large radioactive sources for imparting high radiation doses to materials.

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.

Limit

The value of a parameter or attribute (which is variable) used in certain specific activities or circumstances that must not be exceeded.

Luminescence

Phenomenon in which certain substances, when excited, emit light of wavelength characteristic of the substance.

Microtron

A cyclic accelerator in which electrons are guided by a constant magnetic field in circular orbits of increasing radii, tangential to each other and accelerated at the beginning of each orbit, by traversing an electric field produced by a radio frequency generator.

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.

Nuclear Medicine

The speciality that utilises radio-pharmaceuticals to investigate disorders of anatomy, physiology and patho-physiology, for diagnosis and/or treatment of diseases.

Package

The packaging with its radioactive contents as prescribed for transport.

Personnel Monitoring

Determination or estimation of the dose received by a person from external and internal radiation.

Practice

Any human activity that introduces additional sources of exposure or exposure pathways or extends exposure to additional people or modifies the network of exposure pathways from existing sources, so as to increase the exposure or the likelihood of exposure of people, or the number of people exposed.

Prescibed Limits

Limits established or accepted by the regulatory body.

Protective Barrier or Shielding (Radiation)

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

Protective Device

Device used for the purpose of radiological protection.

Quality Assurance

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

Radiation

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

Radiation Facility

Any installation/equipment or a practice involving use of radiation-generating units or radioisotopes in the field of research, industry, medicine and agriculture.

Radioactive Waste

Material, whatever its physical form, remaining from practices or interventions and for which no further use is foreseen. It can be (a) that contains or is contaminated with

radioactive substances and has an activity or activity concentration higher than the level for clearance from regulatory requirements, and (b) exposure to which is not excluded from regulatory control .

Radioactive Waste Management Facility

Facility specifically designed to handle, treat, condition, temporarily store or permanently dispose of radioactive waste.

Radioactivity

The phenomenon whereby atoms undergo spontaneous random disintegration, usually accompanied by the emission of radiation.

Radiography (Medical)

Technique for obtaining, recording and optionally processing, directly or after transfer, information contained in an X-ray pattern at an image receptor area.

Radiography Source

A source sealed in one or more capsules, or an X-ray tube, or an electron accelerator or a neutron source used for industrial radiography.

Radiography Technician/Radiography Technologist/Radiographer

A worker, who performs radiography operations employing radiography sources and possesses a valid qualification, duly recognised by the competent authority for the specific purpose.

Radiological Safety Officer (or Radiation Safety Officer)

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

Radiotherapy/Radiation Therapy

Medical treatment by ionising radiation.

Registration

A type of regulatory consent issued by the regulatory body for all sources, practices and uses involving radioactive materials and radiation generating equipment.

Regulatory Body

See ‘Atomic Energy Regulatory Board’

Safety Assessment

Review of the aspects of design and operation of a source, which are relevant to the protection of persons or the safety of the source, including the analysis of the provisions for safety and protection established in the design and operation of the source and the analysis of risks associated with normal conditions and accident situations.

Safety Site-in-charge

A person who has the qualifications and training prescribed for Level 2 radiological safety officer and who is appointed by the 'consentee' as the person supervising industrial radiography operations at an authorised radiography site with approval of the competent authority.

Sealed Source

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

Source

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

Source Changer

A device for transferring radiography sources from or to exposure device, and suitable for transport and storage of the source.

Source Housing

Shielding provided in any device containing a sealed source, in order to:

(i) define the useful beam; and

(ii) limit the radiation level outside of the useful beam to maximum permissible leakage levels, as specified by the competent authority.

Synchrotron

Particle accelerator in which charged particles travel in circular orbits of constant radius guided by an increasing magnetic field and accelerated by traversing a number of times an electric field produced by a high frequency generator in synchronism with the orbital motion.

Teletherapy

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

Tomography

Radiography of one or more sections/layers within an object.

Treatment Planning (Radiotherapy)

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

Treatment Simulation

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

Type Approval

Approval, issued by the competent authority, based on evaluation of the device to ensure that it conforms to safety standards.

Type A package

A Package designed to withstand normal conditions of transport without loss or dispersal of its contents or loss of shielding integrity. The radioactive material may be transported in a Type A package, either in special form radioactive material or other form, with the provision that the activity shall not exceed the applicable limits prescribed in the relevant code on 'Transport of Radioactive Materials'.

Type B(U) package

A package designed to contain an activity in excess of A_1, if special form radioactive material, or in excess of A_2 if not special form radioactive material, that is designed to withstand normal and accidental conditions of transport specified in the relevant code on 'Transport of Radioactive Materials'.

Unusual Occurrence

Any occurrence which has the potential to impair or impairs the plant safety, radiological safety, industrial safety and/or environmental safety.

SPECIAL DEFINITIONS
(Specific for the Present Guide)

Consumer Product

A manufactured product or item containing radioactive substance, which is exempted from regulatory control.

Field Radiography

Radiography operations carried out on shop floors, erection sites or other such areas with provisions for adequate radiological safety for the radiography personnel and others including members of the public.

Person

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

Worker

Any person who works, whether full-time, part-time or temporarily, for an employer and who has recognised rights and duties in relation to occupational radiation protection. (A self-employed person is regarded as having the duties of both an employer and a worker).

X-ray Equipment

Equipment consisting of combination of an X-ray generator, X-ray tube and associated equipment.

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APPENDIX-1

(Refer section 2.2)

INDUSTRIAL SAFETY

In the department of atomic energy (DAE) units AERB is responsible for enforcement of the Factories Act, 1948 and the Atomic Energy (Factories) Rules, 1996. Competent persons and safety officers are required to be appointed to carry out duties as mentioned in the above statutes.

For fire safety both manpower and fire fighting equipment are required to be provided as per AERB safety standard for 'Fire Protection Systems of Nuclear Facilities' [AERB/NF/SS/FPS (Rev. 1)]. All fire fighting equipment should be inspected and tested periodically as stipulated in the standard.

Pressure vessels and vacuum systems should be periodically inspected and tested as specified in the Atomic Energy (Factories) Rules, 1996 and should carry necessary certification from a competent person. Handling and storage of gas cylinders should be as per gas cylinder rules. All hoists, lifts and lifting tackles should be subjected to periodic inspection and testing and should be certified by a competent person. All moving machinery should be provided with protective guard. Periodic calibration of monitoring instruments and preventive maintenance of all the machinery and equipment should be done.

Noise in the work areas should be monitored and appropriate remedial measures/personal protective equipment (PPE) should be used. Appropriate lighting should be provided in the working areas and illumination should be measured. For noise and illumination, requirement as specified in the Atomic Energy (Factories) Rules, 1996 should be adhered to.

First aid provision should be available in the facility along with appropriate staff trained in first aid. Pre-employment medical examination and periodic medical examination should be carried out and the periodicity should be as specified in the Atomic Energy (Factories) Rules, 1996.

Pipelines should be colour coded as per Indian standard: 2379-1963 and Indian Standard: 5-1978. Electrical conduit panels should be colour coded as per Indian Standard: 375-1951 and Indian Standard: 5-1978. All construction should conform to National Building Code of bureau of indian standards (BIS) and relevant AERB documents. All ladders should be maintained as per the requirements mentioned in the Atomic Energy (Factories) Rules, 1996.

Material safety data sheet should be available for all hazardous chemicals handling and necessary personal protective equipment conforming to relevant Indian Standards should be provided to the workers exposed to hazards. Hand tools and portable power

tools should conform to the relevant BIS standards and should be used as per the requirements specified in the Atomic Energy (Factories) Rules, 1996.

Work environment and the neighbourhood should be monitored for physical, chemical and biological agents and see that the limits specified by the Acts and Competent Authority are not exceeded at any time.

(APPENDICES - 2A-2F PERTAIN TO GRAPF FACILITY)

APPENDIX-2A

(Refer section 3.2.1.2)

FORMAT OF SITE ASSESSMENT REPORT FOR GAMMA RADIATION PROCESSING FACILITY (GRAPF)

Geological and Geotechnical Investigations

1. Site investigations for Gamma Irradiators are necessary to determine the geotechnical characteristics of the site that affect the design, performance and safety of the irradiators. The investigations should produce the information needed to define the overall site geology to a degree that is necessary for an understanding of the subsurface conditions in order to ensure stability against natural hazards like earthquake, flood etc.

2. Site investigations should also provide information needed to define ground water conditions as well as the geotechnical parameters needed for analysis and design of foundations. These include parameters to evaluate the subsurface characteristics for safe engineering of irradiators, such as bearing capacity of foundation material, lateral earth pressure, the stability of cuts and slopes in rock, the effects of earthquake induced motions transmitted through underlying deposits on the response of soils and structure (including the potential for inducing liquefaction in soils) and also those needed to estimate the expected settlement of the structure.

3. Requirements of geotechnical investigations depend on the site specific conditions. However, the following investigations are the minimum, which should be carried out for the evaluation of parameters required for safe design:

   (a) Field Work

      (i) Drilling of bore holes, excavation of trial pits

      (ii) Collection of disturbed/undisturbed soil and water samples

      (iii) Standard penetration tests

      (iv) Plate load tests

      (v) Electrical resistivity tests

      (vi) Permeability tests

   (b) Laboratory Tests on Soil Samples

      (i) Grain size analysis (coarse and fine)

(ii) Consistency limit test

(iii) Specific gravity of soil

(iv) Proctor density test

(v) Permeability test

(vi) Consolidation test

(vii) Modulus of elasticity and poisons ratio

(viii) Unconfined/confined compression test

(ix) Direct shear test (consolidated drained)

(x) Chemical tests on soil

(c) Laboratory Tests on Rock Samples

(i) Petrographic study

(ii) Porosity

(iii) Unconfined/confined compression test

(iv) Modulus of elasticity and poisons ratio

(d) Test on Ground Water Samples

(i) Chemical analysis of ground water sample

4. Following requisites should be met in connection with geotechnical investigations:

(i) Prior to commencement of geotechnical investigation, a comprehensive plan of the work should be chalked out. Geological status of the site should be examined based on available information. Additional investigation may be required if site specific conditions warranted so for the safety of the plant.

(ii) Minimum depth of bore holes should be three times the larger dimension of the footing.

(iii) Number of bore holes should be such that subsurface profile of the plant area can be drawn with reasonable certainty in any direction. At least four data points should be available, in any direction, for plotting of sub surface profile.

(iv) Geological mapping of the foundation pit should be carried out after completion of excavation.

(v) Appropriate rectification/stabilisation measures shall be adopted if it is found necessary after excavation.

4.1 Reports on Geotechnical Investigation

The geotechnical report should contain the following details:

(i) Geological status of the site based on available information
(ii) Details of bore logs and trial pit logs
(iii) Permeability test results
(iv) Ground water observations
(v) Results of soil and rock tests
(vi) Chemical test results of water
(vii) Subsurface profiles
(viii) Electrical resistivity logging
(ix) Petrographic study results
(x) Evaluation of foundation design parameters

APPENDIX-2B

(Refer section 3.2.1.3)

FORMAT OF THE PRELIMINARY SAFETY ANALYSIS REPORT FOR GAMMA RADIATION PROCESSING FACILITY (GRAPF)

[PSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer)]

A. INTRODUCTORY INFORMATION

1. Name and address of institution (with e-mail and fax) :
2. Name and address of Gamma radiation processing plant (GRAPF) (with e-mail and fax) :
3. Name and address of the designer(s) of GRAPF (with e-mail and fax) :
4. Name and address of the manufacturer of GRAPF (with e-mail and fax) :
5. Category of GRAPF :
6. Name of radioactive source :
7. Maximum design strength of source : ———— PBq (——— kCi)
8. Address of the supplier of the source (with e-mail and fax) :
9. Purpose of GRAPF :

B. TECHNICAL DESCRIPTION OF THE GAMMA RADIATION PROCESSING FACILITY (GRAPF)

1. Brief description of the facility
2. Design details : (design principles, defence in depth concept, redundancy. independence and diversity in the design, built-in-safety features provided in the design, statement declaring compliance with the AERB Safety Standard

titled 'Land-Based Stationary Gamma Irradiators' [AERB/RF-IRRAD/SS-6 (Rev.1); 2007].

3. Site of installation of GRAPF: Geotechnical and geological information, field investigations, water table, weather, soil profile, laboratory investigations, allowable bearing pressure/safe bearing capacity, chemical analyses of water and soil

Site lay out, documentary evidence of the ownership of the site, regulatory Consent issued by AERB for site approval

- Structural details - type and depth of foundation, seismic requirements and precautions against flooding
- Buildings and residential complexes, occupancy, etc. within 50 m radius of the source location; give layout and height of the adjacent tallest building in the vicinity of 100 m)
- Access roads to the facility: road strength and width to carry transport flasks (culvert/bridge, if any, on the way - specify)
- Any additional information

Biological shield

- Sketch giving details of shielding wall surrounding the source, wall thickness, labyrinth access, openings, voids, reinforcements, embedment etc. in the biological shield.
- Shield material, density, quality assurance during construction
- Maximum & minimum shield thickness, roof thickness
- Dose rate profiles anticipated at various locations: (Maximum and minimum values). Indicate them on a sketch of the facility - to be stationed for work or otherwise.
- Maximum dose rate anticipated

Locations : (Indicate also in a sketch)

4. Safety Systems/Interlocks

4.1 Water Pool

- Detailed sketch or drawing of water pool for source storage showing dimensions, water proofing, lining details, penetrations, piping, fittings, embedment, locations of level measuring devices, inlet-outlet water piping,
- Water control dimensions, volume, maximum, minimum water levels, normal level and abnormal levels.

- Overhead water storage tank details, provision of emergency water discharge into pool, provision of overflow/ drainage of water from the pool to any municipal sewerage lines.
- Municipal water supply quality - TSD, TSS, hardness and conductivity
- Rate of water supply in emergency
- Quantity of water maintained in pool, conductivity maximum/ minimum, method of assuring water quality
- Method of assuring water levels
- Leakage from pool - prevention and assessment
- Normal evaporation water losses from pool (with and without ventilation) related to humidity and temperature
- System to prevent water flooding in the cell
- Method of cleaning water pool
- Pool grill cover strength - prevention of accidental fall into the pool - during normal times, during source loading operations
- Pool bottom surface plan - loading conditions, anchoring of source rack, provision for transport container, intermediate source storage, if any.
- Corrosion - intermetallic/galvanic, specification of metals coming in contact with pool water prevention thereof.
- Maximum water height above source rack during normal operation and expected radiation profiles on the pool surface, both at normal and abnormal water levels.
- Underwater lights, location, voltage, use, prevention of shocks and electrocution.
- Prevention of accidental fall of person and material into the pool
- Prevention of syphoning action in pool
- Prevention of accidental entry into the cell when the water level in the pool is low and when the source is exposed or in storage position.
- DM water plant capacity and type (anion, cation, mixed bed etc.)

4.2 Source Drive System

- Details of mechanical arrangement (include drawing) source raise/ lower loop. Anchoring and supports of source rack, source locking in the rack, prevention of accidental fall of sources.
- Maximum/minimum hydraulic pressure, cylinder type and their specifications
- Gravity/accidental fall of rack into the pool

- Source getting stuck in the exposed position - possibilities of remedial action
- Tension adjustment (and monitoring) in the ropes
- Source movement control - limits/ overshoot
- Protection to source rack from product/carrier/conveyor interference
- Accidental fall of carrier, product, product box into the pool - protection thereof
- Material of construction of - source rack, wires, fittings, etc.

4.3 Source Raise Conditions

- Information should include - protection against human access to the cell when the source is in raised position, mechanical, electrical, hydraulic, radiation interlocks, trespass control through product entry door.
- Interference to interlocks and source safety and protection against exposure to radiation
- Power failure and protection against accidental entry
- Cautions, display, alarm against entry into the cell

Source operation disable situation:

Describe point by point conditions under which the source cannot be raised from safe storage provisions. Emergency termination of source raise operations

Automatic source lowering situations:

Describe point by point situations under which the exposed source will move to storage position. Methods to achieve fail safe situation and monitoring thereof

Preconditions to raise source:

List the preconditions to be satisfied before the source can raised

4.4 Ventilation System

- Volume of cell including and excluding labyrinth, ventilation rate provided, anticipated minimum air changes in the cell
- Location and routing of ventilated ducts, fans, duct size, etc. (give sketch)
- Methods of monitoring ventilation and action on ventilation failure
- Location of ventilation exhaust and the height above the cell roof. Prevention of water flooding through ventilation ducts from roof (sketch)

- Ozone concentration (maximum) anticipated in the cell with ventilation on and off. Time duration in minutes for safe concentration of ozone in the cell (0.1ppm) after the exhaust is switched off.
- Prevention of entry to the cell when unsafe limit of ozone concentration exists
- Details of interlocks to retract the source to safe storage position in case of ventilation failure
- Provision for standby ventilation exhaust fans, if any
- Electric power failure rate. The number of days the source is likely to remain in the pool without exhaust and ventilation.

4.5 Fire Detection System

- Detection methods of excessive temperature rise, smoke, fire, and interlock if any with the source movement. Type of detectors used and their sensitivity, location of detectors.
- Validity certification for detectors
- Direction escape route for fire - fire fighting system, fire hydrants, extinguishers, dry risers, etc.

4.6 Control System General

- Give control system description in brief
- Voltage and currents employed, emergency power standby power, battery backup if any,
- Control logic and flow of command
- Interlock systems for fail-safe operation

4.7 Audio-visual Alarms/Anunciators

- Describe the list of audio-visual alarms provided, their location, purpose and effectiveness - against exposure to radiation, fire, smoke, toxic gases, etc.

4.8 Power Failure and Auxiliary Power

- Provisions made when power failure occurs, status of safety systems and source position indicators

4.9 Access Control

- Provisions made at personnel entry door and product entry door

5. Design Basis Accident Analysis and Safety Provisions

Abnormal events mentioned below shall be analysed and methods for achieving safety under these events shall be described.

(a) Accidental exposures

(b) Breaking of source hoist cable

(c) Fraying of source hoist cable in side the cell roof tube

(d) Source frame stuck in rest position due to

  (i) jamming of source raise wire rope in roof tube assembly

  (ii) jamming of source frame on guide wire ropes

(e) Failure of mooring of guide wire ropes of source frame

(f) Failure of PAD interlocks

(g) Fire in the irradiation cell

(h) Failure of ventilation system

(i) Damage to the sources

(j) Contamination of pool water

(k) Leakage of water from pool

(l) Earthquake at the irradiator site

(m) Flooding of irradiator cell with water

(n) Breakage of pool lining

(o) Fall of person in the water pool

(p) Product carrier interfering with source frame; dislodging of source in carriers and coming out of shield with it.

The designer/manufacturer shall carry out such safety analysis to demonstrate means provided to prevent and handle above situations safely .

6. Radiation Source Details

(i)	Address of supplier	:	
(ii)	Type and nature of radioactive source	:	
(iii)	Chemical form	:	
(iv)	Physical form	:	
(v)	Source pencil (ISU) assembly drawing and identification	:	length, diameter, welding method etc.

7. Provisions including Adequate Financial Arrangement for Safe Disposal of Spent/Disused Sources

8. Decommissioning of GRAPF

- Procedure to be followed when decision is made to close down the facility permanently.

APPPENDIX-2C

(Refer section 3.2.1.4)

FORMAT FOR THE ACCEPTANCE TEST REPORT TO VERIFY FUNCTIONAL PERFORMANCE OF SAFETY SYSTEMS/INTERLOCKS FOR GRAPF

(All the safety systems/sensors/signals/interlocks should be tested at least 15-20 times, with source rack in RAISED and DOWN position. Records in the format prescribed herewith shall be maintained separately each time)

1. SAFETY SYSTEMS/INTERLOCKS

S. No.	Safety system/ Interlock	Test conducted	Expected response of control system	Observed response of control system
1.	Pressure plate	Pressed or removed	1. Emergency alarm should sound, message to be displayed on the monitor and a hard copy to be obtained 2. Source, if exposed should lower and the conveyor should stop, if ON. 3. Search should get cancelled 4. Search can not be started or conducted if the emergency persists	
2.	Trip wire	Pulled or removed	1. Emergency alarm should sound, message to be displayed on the monitor and a hard copy to be obtained 2. Source, if exposed should lower and the conveyor should stop, if ON. 3. Search should get cancelled 4. Search can not be started or conducted if the emergency persists	
3.	Emergency push buttons at different locations (to be tested separately)	Pressed	1. Emergency alarm should sound, message to be displayed on the monitor and a hard copy to be obtained 2. Source, if exposed should lower and the conveyor should stop, if ON. 3. Search should get cancelled 4. Search can not be started or conducted, if the emergency persists	

1. SAFETY SYSTEMS/INTERLOCKS (CONTD.)

S. No.	Safety system/ Interlock	Test conducted	Expected response of control system	Observed response of control system
4.	Service keyes at different locations(to be tested separately)	Operated to select maintenance position	1. Emergency alarm should sound, message to be displayed on the monitor and a hard copy to be obtained 2. Source, if exposed should lower and the conveyor should stop, if ON. 3. Search should get cancelled 4. Search can not be started or conducted if the emergency persists	
5.	Source raise wire rope tension	Simulated by actuating the limit switches which sense the rope stretch and break condition	1. Emergency alarm should sound, message to be displayed on the monitor and a hard copy to be obtained 2. Source, if exposed should lower and the conveyor should stop, if ON. 3. Search should get cancelled 4. Search can not be started or conducted if the emergency persists	
6.	Cell exhaust air flow	Simulated the condition by stopping the exhaust fan	1. Emergency alarm should sound, message to be displayed on the monitor and a hard copy to be obtained 2. Source, if exposed should lower and the conveyor should stop, if ON. 3. Search can not be started or conducted if the emergency persists	
7.	Hydraulic oil level low	Simulated by manually actuating the oil level switch	1. Message to be displayed on the monitor and a hard copy to be obtained 2. Emergency alarm should sound 3. Source if exposed should lower and the conveyor should stop, if ON. 4. Search can not be started or conducted if the emergency persists 5. Hydraulic motor should stop.	

1. SAFETY SYSTEMS/INTERLOCKS (CONTD.)

S. No.	Safety system/ Interlock	Test conducted	Expected response of control system	Observed response of control system
8.	Clutch operated	Conveyor overload condition created by simulation	1. Clutch should disengage stopping the conveyor 2. Source, if exposed should lower 3. Message to be displayed on the monitor and a hard copy to be obtained 4. Search can not be started or conducted if the emergency persists	
9.	A.C. Supply under voltage	Simulated by lowering the supply voltage using a variac or by any other means.	1. Emergency alarm should sound, message to be displayed on the monitor and a hard copy to be obtained 2. Source, if exposed should lower and the conveyor should stop, if ON. 3. Search can not be started or conducted if the emergency persists	
10.	A.C. Supply over voltage	Simulated by increasing the supply voltage using a variac or by any other means	1. Emergency alarm should sound, message to be displayed on the monitor and a hard copy to be obtained 2. Source, if exposed should lower and the conveyor should stop, if ON. 3. Search can not be started or conducted if the emergency persists	
11.	DC Supply under voltage	Simulated by switching off the DC voltage	1. Emergency alarm should sound, message to be displayed on the monitor and a hard copy to be obtained 2. Source, if exposed should lower and the conveyor should stop, if ON. 3. Search can not be started or conducted if the emergency persists	
12.	Pool water contaminated	Simulated by bringing a test radioactive source near the detector of the contamination monitor	1. Audio alarm and visual indication by contamination monitor 2. Emergency alarm should sound, message to be displayed on the monitor and a hard copy to be obtained	

1. SAFETY SYSTEMS/INTERLOCKS (CONTD.)

S. No.	Safety system/ Interlock	Test conducted	Expected response of control system	Observed response of control system
12. (Contd.)			3. Source, if exposed should lower and the conveyor should stop, if ON. 4. Search should get cancelled 5. Search can not be started or conducted if the emergency persists 6. DM water pump should stop to prevent circulation of contaminated water	
13	Motive power failure	Simulated by switching off the main power supply	1. Battery back up supply to PLC through UPS 2. Source position indicators and emergency to be displayed 3. Source, if exposed should lower by gravity and the conveyor should stop, if ON.	
14	PLC failure	Simulated by switching off PLC supply	1. Source, if exposed should lower by gravity and the conveyor should stop, if ON. 2. Prevents source raising operations	
15	Product box jammed	Simulated by jamming product boxes	1. Source, if exposed should lower and the conveyor should stop, if ON. 2. Prevents source raising operations	
16	Seismic detector	Simulated by creating excess vibrations	1. Source, if exposed should lower and the conveyor should stop, if ON 2. Prevents source raising operations	

Tests Conducted by

(i) Name _____
Designation _____

(ii) Name _____
Designation _____

Tests Approved by

Name _____
Designation _____

Name _____
Designation _____

(Facility-In-Charge/RSO/Operator
of Radiation Processing Facility)

2. AREA/ZONE MONITORS

S. No.	Area monitors	Test conducted	Expected response of control system	Observed response of radiation monitors
1.	Area monitor installed in control room: radiation interlock (Radiation present in the cell when the source is in shield)	Simulated by bringing a test radioactive source near the detector located inside the cell.	1. Audio alarm and visual indication by area monitor. 2. Radiation plunger should fall in the groove provided on latch bar so that door can not be opened 3. Emergency alarm should sound 4. Message to be displayed on the monitor and a hard copy to be obtained 5. Search should get cancelled 6. Search can not be started or conducted if the emergency persists	
2.	Area monitor installed in DM plant	Simulated by bringing a test radioactive source near the detector of the area monitor	1. Audio alarm and visual indication by area monitor 2. Emergency alarm should sound 3. Message to be displayed on the monitor and a hard copy to be obtained 4. Search should get cancelled 5. Search can not be started or conducted if the emergency persists 6. DM water pump should stop to prevent circulation of contaminated water	
3.	Area monitor installed at product exit door.	Simulated by bringing a test radioactive source near the detector of the area monitor	1. Audio alarm and visual indication by area monitor 2. Emergency alarm should sound 3. Message to be displayed on the monitor and a hard copy to be obtained 4. Source, if exposed should lower and the conveyor should stop, if ON. 5. Search should get cancelled 6. Search can not be started or conducted if the emergency persists	

Tests Conducted by

(i) Name _____
Designation _____

(ii) Name _____
Designation _____

Tests Approved by

Name _____
Designation _____

Name _____
Designation _____

(Facility-In-Charge/RSO/Operator
of Radiation Processing Facility)

3. EMERGENCY WATER LEVEL SENSOR

S. No.	Interlock	Test conducted	Expected response of control system	Observed response of control system
1.	Emergency float switch WL3	Release to simulate water level too low condition (in source raised condition)	1. Emergency alarm should sound, message to be displayed on the monitor and a hard copy to be obtained 2. Source, if exposed should lower and the conveyor should stop, if ON. 3. Emergency solenoid valve should open and should permit municipal water to flow into water pool till normal level is reached 4. Door lock solenoid should drop into latch bar and cell door cannot be opened 5. Search should get cancelled	
2. (Contd.)	Emergency float switch WL3	Release to simulate water level too low condition (in source lowered condition)	1. Emergency alarm should sound, message to be displayed on the monitor and a hard copy to be obtained. 2. Area Monitor installed in control room should give audio alarm and visual indication 3. Search completion procedure should be inhibited 4. Source cannot be raised	

3. EMERGENCY WATER LEVEL SENSOR (CONTD.)

S. No.	Interlock	Test conducted	Expected response of control system	Observed response of control system
2. (Con-td.)			5. Emergency solenoid valve should open and should permit municipal water to flow into water pool till normal level is reached 6. Door lock solenoid should drop into latch bar and cell door cannot be opened	

Tests Conducted by

(i) Name _____
Designation _____

(ii) Name _____
Designation _____

Tests Approved by

Name _____
Designation _____

Name _____
Designation _____

(Facility-In-Charge/RSO/Operator of Radiation Processing Facility)

4. HEAT DETECTOR AND FIRE FIGHTING SYSTEM

S. No.	Interlock	Test conducted	Expected response of control system	Observed response of control system
1.	Heat detector	Create the high temperature condition by using a hot air blower	1. Message to be displayed on the monitor and a hard copy to be obtained 2. Emergency alarm and fire in cell alarm should sound 3. Source, if exposed should lower and the conveyor should stop, if ON. 4. Search should get cancelled 5. Search can not be started or conducted if the emergency persists	

4. HEAT DETECTOR AND FIRE FIGHTING SYSTEM (CONTD.)

S. No.	Interlock	Test conducted	Expected response of control system	Observed response of control system
1. (Contd.)			6. Exhaust fan should stop to prevent air circulation 7. Control system to give message for operating fire fighting system	
2.	Smoke detector	Create smoke by appropriate means	1. Message to be displayed on the monitor and a hard copy to be obtained 2. Emergency alarm and fire in cell alarm should sound 3. Source, if exposed should lower and the conveyor should stop, if ON. 4. Search should get cancelled 5. Search can not be started or conducted if the emergency persists 6. Exhaust fan should stop to prevent air circulation 7. Control system to give message for operating fighting system	

Tests Conducted by

(i) Name _____
Designation _____

(ii) Name _____
Designation _____

Tests Approved by

Name _____
Designation _____

Name _____
Designation _____

(Facility-In-Charge/RSO/Operator of Radiation Processing Facility)

5 (i) SEARCH OPERATION - 1
(Hydraulic pump is ON and search not performed)

S. No.	Description/ Interlock	Test conducted	Expected response of control system	Observed response of control system
1.	Source raise PB (Mode of box transfer-auto)	Pressed	Source should not come up	
2.	Source raise PB (Mode of box transfer-manual)	Pressed	Source should not come up	

Tests Conducted by

(i) Name _____
Designation _____

(ii) Name _____
Designation _____

Tests Approved by

Name _____
Designation _____

Name _____
Designation _____

(Facility-In-Charge/RSO/Operator
of Radiation Processing Facility)

5 (ii) SEARCH OPERATION - 2
(Improper Search Sequence)

S. No.	Interlock	Test conducted	Expected response of control system	Observed response of control system
1.	Search start Push Button (PB)	Pressed	1. Search start lamp to glow 2. Search alarm should sound 3. Message should be displayed on the monitor and a hard copy to be obtained	

5 (ii) SEARCH OPERATION - 2 (CONTD.)
(Improper Search Sequence)

S. No.	Discription/ interlock	Test conducted	Expected response of control system	Observed response of control system
2.	Search PB 1	Pressed	1. Search start lamp to glow 2. Search alarm should sound, message should be displayed on the monitor and a hard copy to be obtained	
3.	Search PB 3	Pressed instead of search PB2	1. Search procedure and search audio alarm should cancel. Search start lamp should become OFF. 2. Message should be displayed on the monitor and a hard copy to be obtained	
4.	Source raise PB	Pressed	1. Source should not come up. 2. Message should be displayed on the monitor and a hard copy to be obtained	

Note : The above operations should be performed with different combinations of search push buttons.

Tests Conducted by

(i) Name _____
Designation _____

(ii) Name _____
Designation _____

Tests Approved by

Name _____
Designation _____

Name _____
Designation _____

(Facility-In-Charge/RSO/Operator
of Radiation Processing Facility)

6. POOL WATER LEVEL INTERLOCK CHECKS***

S. No.	Condition	Water pump On / Off	Water Solenoid 1 Open / Close	Water Solenoid 2 Open / Close	Water Solenoid 3 Open / Close	Water Solenoid 4 Open / Close	Audio / Visual alarm status
1.	Pool water level 'Normal'						
2.	Pool water level below 150 mm (Float switch 1 dropped)						
3.	Pool water level below 300 mm (Float switch 2 dropped)						
4.	Pool water level below 450 mm (Emergency)(Float switch 1, 2 and 3 dropped)						
5.	DM water level in buffer tank below float level (Float switch dropped)						
6.	Pool water conductivity > Set value						

*** Indicate the operational status of water pump/solenoid under different conditions. In case of more than four solenoids, operational status of the same may be indicated.

Tests Conducted by

(i) Name _____
Designation _____

(ii) Name _____
Designation _____

Tests Approved by

Name _____
Designation _____

Name _____
Designation _____

(Facility-In-Charge/RSO/Operator of Radiation Processing Facility)

APPENDIX-2D

(Refer section 3.2.1.5)

FORMAT OF THE FINAL SAFETY ANALYSIS REPORT FOR GAMMA RADIATION PROCESSING FACILITY (GRAPF)

[FSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer) along with application for licence for commissioning operation of I.B.S. Gamma Radiation Processing Facility (GRAPF)]

A. GENERAL INFORMATION

1.	Name and address of institution (with e-mail and Fax)	:	
2.	Name and address of Gamma radiation processing plant (GRAPF) (with e-mail and Fax)	:	
3.	Name and address of the designer(s) of GRAPF (with e-mail and Fax)	:	
4.	Name and address of the manufacturer of GRAPF (with e-mail and Fax)	:	
5.	Category of GRAPF	:	
6.	Name of radioactive source	:	
7.	Maximum design strength of source	:	———— PBq (——— kCi)
8.	Address of the supplier of the source (with e-mail and Fax)	:	
9.	Purpose of GRAPF	:	

B. TECHNICAL DESCRIPTION OF THE GAMMA RADIATION PROCESSING FACILITY (GRAPF)

1. Brief Description of the Facility
2. Design details : (design principles, defence-in-depth concept, redundancy. independence and diversity in the design, built-in-safety features provided in

the design, statement declaring compliance with the AERB Safety Standard titled 'Land-Based Stationary Gamma Irradiators' [AERB/RF-IRRAD/SS-6 (Rev.1); 2007].

3. Site of installation of GRAPF : Geotechnical and geological information, field investigations, water table, weather, soil profile, laboratory investigations, allowable bearing pressure/safe bearing capacity, chemical analyses of water and soil

Site lay out, documentary evidence of the ownership of the site, regulatory Consent issued by AERB for site approval

- Structural details - type and depth of foundation, seismic requirements and precautions against flooding
- Buildings and residential complexes, occupancy, etc. within 50 m radius of the source location; give layout and height of the adjacent tallest building in the vicinity of 100 m)
- Access roads to the facility : road strength and width to carry transport flasks (culvert/bridge, if any, on the way - specify)
- Any additional information

Biological shield

- Sketch giving details of shielding wall surrounding the source, wall thickness, labyrinth access, openings, voids, reinforcements, embedment etc. in the biological shield
- Shield material, density, quality assurance during construction
- Maximum and minimum shield thickness, roof thickness
- Dose rate profiles anticipated at various locations : (Maximum and minimum values). Indicate them on a sketch of the facility - control room, roof, access doors, openings and where personnel are expected to be stationed for work or otherwise.
- Maximum dose rate anticipated

Locations : (Indicate also in a sketch)

4. Safety Systems/Interlocks

4.1 Water Pool

- Detailed sketch or drawing of water pool for source storage showing dimensions, water proofing, lining details, penetrations, piping, fittings, embedment, locations of level measuring devices, inlet-outlet water piping,
- Water control dimensions, volume, maximum, minimum water levels, normal level and abnormal levels.

- Overhead water storage tank details, provision of emergency water discharge into pool, provision of overflow/ drainage of water from the pool to any municipal sewerage lines.
- Municipal water supply quality - TSD, TSS, hardness and conductivity
- Rate of water supply in emergency
- Quantity of water maintained in pool, conductivity maximum/ minimum, method of assuring water quality
- Method of assuring water levels
- Leakage from pool - prevention and assessment
- Normal evaporation water losses from pool (with and without ventilation) related to humidity and temperature
- System to prevent water flooding in the cell
- Method of cleaning water pool
- Pool grill cover strength - prevention of accidental fall into the pool - during normal times, during source loading operations
- Pool bottom surface plan - loading conditions, anchoring of source rack, provision for transport container, intermediate source storage, if any.
- Corrosion - intermetallic/galvanic, specification of metals coming in contact with pool water prevention thereof.
- Maximum water height above source rack during normal operation and expected radiation profiles on the pool surface, both at normal and abnormal water levels.
- Underwater lights, location, voltage, use, prevention of shocks and electrocution.
- Prevention of syphoning action in pool
- Prevention of accidental entry into the cell when the water level in the pool is low and when the source is exposed or in storage position.
- DM water plant capacity and type (anion, cation, mixed bed etc.)

4.2 Source Drive System

- Details of mechanical arrangement (include drawing) source raise/ lower loop. Anchoring and supports of source rack, source locking in the rack, prevention of accidental fall of sources.
- Maximum/minimum hydraulic pressure, cylinder type and their specifications

- Gravity/accidental fall of rack into the pool
- Source getting stuck in the exposed position - possibilities of remedial action
- Tension adjustment (and monitoring) in the ropes
- Source movement control - limits/overshoot
- Protection to source rack from product/carrier/conveyor interference
- Accidental fall of carrier, product, product box into the pool - protection thereof
- Material of construction of - source rack, wires, fittings, etc.

4.3 Source Raise Conditions

- Information should include - protection against human access to the cell when the source is in raised position, mechanical, electrical, hydraulic, radiation interlocks, trespass control through product entry door.
- Interference to interlocks and source safety and protection against exposure to radiation
- Power failure and protection against accidental entry
- Cautions, display, alarm against entry into the cell

Source operation disable situation :

Describe point by point conditions under which the source cannot be raised from safe storage position. Emergency termination of source raise operations

Automatic source lowering situations :

Describe point by point situations under which the exposed source will move to storage position. Methods to achieve fail safe situation and monitoring thereof

Preconditions to raise source :

List the preconditions to be satisfied before the source can raised

4.4 Ventilation System

- Volume of cell including and excluding labyrinth, ventilation rate provided, anticipated minimum air changes in the cell
- Location and routing of ventilated ducts, fans, duct size, etc. (give sketch)
- Methods of monitoring ventilation and action on ventilation failure

- Location of ventilation exhaust and the height above the cell roof. Prevention of water flooding through ventilation ducts from roof (sketch)
- Ozone concentration (maximum) anticipated in the cell with ventilation on and off. Time duration in minutes for safe concentration of ozone in the cell (0.1ppm) after the exhaust is switched off.
- Prevention of entry to the cell when unsafe limit of ozone concentration exists
- Details of interlocks to retract the source to safe storage position in case of ventilation failure
- Provision for standby ventilation exhaust fans, if any
- Electric power failure rate. The number of days the source is likely to remain in the pool without exhaust and ventilation.

4.5 Fire Detection System

- Detection methods of excessive temperature rise, smoke, fire, and interlock if any with the source movement. Type of detectors used and their sensitivity, location of detectors.
- Validity certification for detectors
- Direction escape route for fire - fire fighting system, fire hydrants, extinguishers, dry risers, etc.

4.6 Control System General

- Give control system description in brief
- Voltage and currents employed, emergency power standby power, battery backup if any,
- Control logic and flow of command
- Interlock systems for fail-safe operation

4.7 Audio-visual Alarms/Anunciators

- Describe the list of audio-visual alarms provided, their location, purpose and effectiveness - against exposure to radiation, fire, smoke, toxic gases, etc.

4.8 Power Failure and Auxiliary Power

- Provisions made when power failure occurs, status of safety systems and source position indicators

4.9 Access Control

- Provisions made at personnel entry door and product entry door

5. Design Basis Accident Analysis

Abnormal events mentioned below shall be analysed and methods for achieving safety under these events shall be described.

(a) Accidental exposures

(b) Breaking of source hoist cable

(c) Fraying of source hoist cable in side the cell roof tube

(d) Source frame stuck in rest position due to

  (i) jamming of source raise wire rope in roof tube assembly

  (ii) jaming of source frame on guide wire ropes

(e) Failure of mooring of guide wire ropes of source frame

(f) Failure of PAD interlocks

(g) Fire in the irradiation cell

(h) Failure of ventilation system

(i) Damage to the sources

(j) Contamination of pool water

(k) Leakage of water from pool

(l) Earthquake at the irradiator site

(m) Flooding of irradiator cell with water

The designer/manufacturer shall carry out such safety analysis to demonstrate means provided to prevent and handle above situations safely.

6. Design Basis Accident Analysis and Safety Povisions

(a) Breaking of source raised wire rope

(b) Fraying of source raised wire ropes

(c) Source frame stuck in rest position due to,

  (i) jamming of source raise wire rope in roof tube assembly

  (ii) jaming of source frame on guide wire ropes

(d) Failure of personal entry door interlocks

(e) Fire in the cell

(f) Contamination of pool water

(g) Breakage of pool lining

(h) Flooding of the cell

(i) Fall of person in the water pool

(j) Product carrier interfering with source frame; dislodging of source in carriers and coming out of shield with it.

7. Acceptance Test Reports by Applicant

a.	Start-up sequence	:	Performance test
b.	Shut down sequence	:	Performance test
c.	Performance tests	:	Motors :
			Pumps :
d.	Performance of interlocks	:	Tripwire and other automatic source safe or fail safe systems
e.	High pressure lines	:	Test results - pressure gauge, valves, temperature cut off, etc.
f.	Electrical systems earthing	:	
g.	Leakage of pool water evaporation test (with switch off ventilation)	:	(10 days: mean value mm/day)
h.	Ventilation	:	Air changes :
i.	Dummy source load/ unload operations	:	

j. Source raise/lower operational reliability (50 operations) without failure or interference

k. System operations for one day without failure

m. Location and functions of all radiation monitors

n. Proof tests for hoists and handling equipment

8. Radiation Source Details

a.	Address of supplier	:	
b.	Type and nature of radioactive source	:	
c.	Chemical form	:	
d.	Physical form	:	
e.	Source encapsulation details	:	
f.	Source pencil (ISU) assembly drawing and identification	:	(length, diameter, welding method, etc.)
g.	Total number of ISU's	:	

h. Quantity of activity (total) per ISU : —— PBq (——— kCi)

i. Total activity : ——— PBq (—— kCi)

j. Performance certification (performance certificates as per (AERB/SS/3 (Rev. 1)/ISO 2919 (1980) with bend test requirements for L/D > 15) :

k. Source rack assembly details and location of the pencils in the rack (provide with sketch)

TABLE - 1

POSITION OF SOURCES IN SOURCE RACK AFTER SOURCE LOADING

S. No.	ISU identification number	Activity	Date	Position	Remarks
1					
2.					

9. Acceptance Test Reports after Source Loading Operations

(a) Dose rate profile measurement in the entire facility, strength of radiation source.

(b) Performance of radiation monitoring and control interlocks

(c) Performance of personnel monitors

(d) Dose concentration measurement with and without ventilation fan functioning

(e) Assurance and effectiveness of control functions and interlocks

Sketch of the facility and location of dose rate monitoring points and maximum/minimum dose rate levels should include :

(i) Name of persons carrying out the measurement

(ii) Instrument used in the radiation survey

(iii) Confidence limits of radiation level measurements

(iv) Background radiation levels in each location of measurement.

10. List of Critical Safety Components

The manufacturer of radiation processing plant shall provide to the operating organisation a complete list of components as per following classification:

Group A : Replaceable by manufacturer or with his explicit Consent

Group B : Replaceable to exact specifications

Group C : Replaceable without restriction

APPENDIX-2E

(Refer section 3.2.1.4)

RADIATION PROTECTION MANUAL OF GAMMA RADIATION PROCESSING FACILITY (GRAPF) (OPERATIONAL, MAINTENANCE, EMERGENCY ASPECTS)

A. ADMINISTRATION AND SAFETY ASSURANCE

(a) Administrative hierarchy/organisational set up

(b) Authorised personnel - Training and qualification of plant personnel, their knowledge in radiation safety, responsibilities of personnel, their availability in adequate number, Policies in case of long leave/absence of certified personnel

(c) Local safety committee - constitution, functions and responsibilities

(d) Procedures for reporting to the regulatory agency on unusual occurrences and periodic radiation safety status

(e) Procedures in case of change or repairs of safety system /interlocks, certification of log book entry by FIC/RSO

(f) Record of maintenance - source storage, maintenance schedule, radiation monitoring, calibration of survey meters, etc.

(g) Control and distribution of irradiator operating keys

(h) Industrial safety aspects - fire equipment, safety accessories etc.

(i) Facility security arrangements, fencing and personnel movement control etc.

(j) Removal and storage of contaminated material, if any.

(k) Medical assistance - First aid facility, location, periodic medical examination (once a year), medical facilities and treatment facilities for radiation incidents

B. MONITORING

(a) Radiation monitoring - Type of area monitors, sensitivity, survey meters, range,

		location, interlock alarm set levels (DM plant/Unloading bay, control room) and radiation survey meter
(b)	Contamination - monitoring	On line monitoring and sample measurement, method of collecting samples of pool water, accessible surfaces of source raise system)
(c)	Personnel monitoring -	Number of PM badges, procedure for their issuance, safe place for storage, etc.

C. OPERATIONAL PROCEDURES

(a) Sequential procedures for raising the source as per the design (with flow chart)

(b) Familiarisation and procedure for modifications

D. MAINTENANCE PROCEDURE FOR SAFETY SYSTEMS/INTERLOCKS

(a) Periodic maintenance - Daily/weekly/monthly/quarterly/yearly: items, procedures and schedules

(b) Procedure for maintenance of D.M. water supplies

(c) Maintenance and checking of alarm/warning devices

E. SOURCE REPLENISHMENT PROCEDURES

(i) Details of the agency responsible for source supply & source loading operation

(ii) Procedure for transporting the source flask from the source manufacturer to the facility

(iii) Procedure for unloading the source flask at the facility

(iv) Procedure for taking the source flask into & out of the irradiation cell

(v) Procedure for lifting the source flask down/up from the water pool

(vi) Technical speciation & test certificate of devices used for lifting the source flask (hoist etc.)

(vii) Procedure for transferring the sources from the flask to the source frame

(viii) List of source handling tools, equipment and safety accessories used for source loading operation

F. EMERGENCY PLANNING AND PROCEDURES

(a) Organisational structure and communication links

(b) Name, address, and telephone numbers of agencies to be contacted in case of emergency

(c) Emergency contact telephone/telex nos. and address of

- (i) Head of institution
- (ii) Facility-in-charge
- (iii) Radiological safety officer (RSO)
- (iv) Regulatory agency (AERB)
- (v) Fire officer (Local)
- (vi) Local fire station
- (vii) Local police
- (viii) Local medical hospital, Radiation therapy hospitals (Nearest)
- (ix) Radiation source supplier

(d) Type of emergencies envisaged - Prevention/handling of emergencies, investigation methods, etc. during major leaks of water, explosion or fire or smoke, radiation emergency, crisis management in case of emergency, earthquake, floods, other natural calamities.

APPENDIX-2F

(Refer section 3.2.1.5)

QUALITY ASSURANCE MANUAL (QAM) FOR GAMMA RADIATION PROCESSING FACILITY (GRAPF)

A. QUALITY ASSURANCE PROGRAM (QAP)

(i) An adequate quality assurance (QA) program, including appropriate quality control measures, shall be established for the design and manufacture, construction, operation and industrial safety of irradiators. Compliance with the ISO 9000 or IS 14000 series is desirable. Records of all QA procedures shall be maintained for the entire life of the irradiator.

(ii) Follow the quality assurance requirement specified in **Appendix-B** of AERB safety standard titled 'Land Based Stationary Gamma Irradiators' [AERB/RF-IRRAD/SS-6 (Rev.1); 2007].

B. QUALITY ASSURANCE IN DESIGN OF GRAPF

1. Quality Assurance Programme

The responsible organization shall develop and implement a QA programme, which describes the overall arrangements for the management, performance and assessment of the GRAPF. This programme should also provide the means to ensure that all work is suitably planned, correctly performed and properly assessed. Procedures should be defined by the responsible organization for control of design activities to ensure that the design of the GRAPF fulfils the specified requirements.

1.1 Grading

A graded approach based on the relative importance to radiological safety of each item, service or process shall be used.

1.1.1 The design activities, which could be graded, include:

(a) The level and detail of analysis of design

(b) The need for and level of design review and approval

(c) The degree of verification of design

(d) The controls applied to design change

(e) The detail of design records and their retention times

(f) The need for alternative calculations to be carried out

(g) The need to qualify or test the design output

(h) The need for qualification tests for design

1.2 Organisation

The responsible organisation shall identify the principal designer who has responsibility for specifying the design requirements and for approving the design output on its behalf.

1.3 Interfaces

Interface arrangements shall be agreed between organisations involved in design activities. Interface that should be addressed are for example:

(a) Interfaces between technical disciplines within the design organisation

(b) Principal designer with:

(i) Siting organisation

(ii) Construction organisation

(iii) Commissioning organisation

(iv) Operating organsiation

(v) Decommissioning organsiation

(vi) Regulatory body

1.4 Planning

Plans used in design should include the following where appropriate:

(a) Scope of work, including work carried out by other organisations

(b) Design methods

(c) Software requirements (software to be developed or software codes to be validated for use)

(d) Test requirements, including qualification tests, prototype, seismic, etc.

(e) Design review, verification and validation requirements

(f) Resource requirements

(g) Special training requirements

(h) Schedule of activities

(i) Points at which checks of the design process will take place and the frequency of such checks

(j) Inputs from safety, reliability, maintainability, human factors, standardisation and other disciplines.

1.5 Non-conformance Control and Corrective Actions

A system for the control of non-conformances and their corrective actions should be established.

1.6 Document Control and Records

Procedures for the preparation, review, approval, issue, modification and control of documents shall be established.

C. QUALITY ASSURANCE DURING CONSTRUCTION OF CIVIL ENGINEERING STRUCTURES OF GRAPF

1. Quality Assurance Programme

The responsible organisation shall develop and implement a QA programme, which describes the overall arrangements for the management, performance and assessment of civil engineering structures for gamma irradiators during construction. This programme should provide the means to ensure that all work is suitably planned, correctly performed and properly assessed in order to implement design intent in the construction.

1.1 Grading

Work procedures should be defined for control of construction activities at site and it should be reviewed and approved before use. A graded approach based on the relative importance to safety of each item, service or process shall be used. The construction activities, which could be graded, include:

(a) Qualification of special construction processes and the personnel to carry them out

(b) Detail and need for inspection plans

(c) Level of traceability

(d) Level of in process controls and need for hold points

(e) Records and archived samples

1.2 Organisation

The responsible organisation should formally appoint a person on its staff to be responsible for construction activities. The appointed person should have the necessary resources within the construction organisation to discharge the following responsibilities:

(i) Ensuring that construction and installation work is carried out in accordance with design specifications, drawings, procedures and instructions, including the implementation of specified QA requirements.

(ii) Ensuring that construction and installation work undertaken, including work by suppliers, is co-ordinated, conducted and completed in accordance with planned programmes of work.

(iii) Controlling access to the construction site.

1.3 Interfaces

Interface arrangements should be agreed between the construction organisation, suppliers and other organisational units performing the work. They should be defined in writing and should be included in procurement documents. Interfaces that should be addressed are:

(a) Construction organization with supplier

(b) Construction organization with operating organisation

(c) Suppliers with sub-suppliers

(d) Construction organisation with the principal designer

(e) Construction organisation with siting organization

(f) Interfaces between construction organisation and the regulatory body

1.4 Planning

All construction activities should be planned. The plan should define:

(a) The activities to be performed in manageable units

(b) The planned sequential order and duration of these activities

(c) The resource allocation for each activity

1.5 Non-conformance Control and Corrective Actions

The non-conformances that are required to be reported to the construction organisation should be identified. Suitable corrective action should also be recorded.

1.6 Document Control and Records

Procedures for the preparation, review, approval, issue, modification and control of documents should be established. The record system should be established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, storage, retrieval and disposal of construction records. Records should include all those, which record the as-built condition of structures, systems and components.

1.7 The civil engineering construction should be carried out following the relevant Indian standard codes/specifications. Quality of civil construction should satisfy the requirements of appropriate Indian standard codes/specifications and that of product specifications. Typical list of topics to be covered in QA programme for the civil engineering construction is given as below:

(a) Formwork, shuttering and pre-construction activities

(b) Concreting and curing

(c) Post concrete inspection

(d) Repair

(e) Fabrication and erection of embedded parts (EP)

(f) Fabrication and erection of structural steel

(g) Brick work

(h) Grounding network

(i) Painting for steel structure

(j) Finishing and repair control

(k) Painting of main plant structures/concretes faces

(l) List of procedures

(m) Miscellaneous items such as organisation chart of QA civil, flow chart showing production of good uniform concrete, schematic diagram on procedure of concrete mix design etc.

(n) Density of the concrete in construction of walls and roof of irradiation cell shall be maintained at least 2.5 g/cc and it shall be ensured that no voids or air gaps are present during concrete filling.

D. INDUSTRIAL SAFETY DURING CONSTRUCTION OF CIVIL ENGINEERING STRUCTURES

A policy reflecting industrial safety regulations should be established for all personnel, including suppliers and visitors. These should be in line with the prevailing factory rules. The policy should include arrangements for the effective planning, organisation, monitoring and review of the preventive and protective measures.

Management should provide all necessary support to the Contractor to ensure health and safety of the construction personnel.

(i) Job hazard analysis should be prepared before the start of construction.

(ii) Industrial safety at the construction site should be enforced by a safety officer.

(iii) All construction equipment should be tested prior to its use.

(iv) Construction personnel should be given orientation program on industrial safety.

(v) Accident statistics should be maintained at the construction site.

(vi) Appropriate arrangements for fire safety and first aid should be available.

E. QUALITY CONTROL - RESPONSIBILITY OF MANUFACTURER/ DESIGNER

(i) Equipment and Instrument quality and certification

(ii) Manufacturing material quality, tolerance of parts, fabrication specifications, inspection manufacturing and tests adopted, quality assurance procedures.

(iii) Quality of components used

(iv) Certification of wiring, electrical and mechanical safety

(v) Documentation of quality assurance and control procedures

(vi) Specifications of wire rope, source rack, hydraulic piping and pumps, sensors and their quality assurance

(APPENDICES 3B-I, 3B-II,3B-III,3C,3D-I & II, 3D-III,3E, 3F ARE FOR ACCELERATOR FACILITIES)

APPENDIX-3B-I

(Refer section 3.2.2.3)

FORMAT OF THE PRELIMINARY SAFETY ANALYSIS REPORT FOR INDUSTRIAL ACCELERATOR RADIATION PROCESSING FACILITY (IARPF)

[PSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer)]

1.	Name and address of the applicant	:	
2.	Details of supplier Name and address of the applicant/local supplier with PIN code (in block letters)	:	
3.	Details of system parameters	:	
	Model/type designation	:	
	Year and country of manufacture	:	
	Maximum voltage	-	MV
	Maximum beam current	-	mA
	Vacuum	-	Torr
	Maximum beam dimensions	-	mm
	Scan amplitude/scan angle	-	
	Operational life of the device (in hours)	:	
	Leakage radiation levels at a distance of one metre from the source when radiation beam is 'ON' (specify for maximum energy and mode)	:	….....mGy/h.....MV/ MeV/Photon/Electron
	Built-in safety features/operation procedures to prevent any radiologically unsafe malfunction of the equipment (Please attach relevant documents such as installation manual, operation/ servicing manual)	:	

Standards to which the accelerator comply :

Details of beam energy and current calibration facility :

4. Documentation Detail

Design Detail : Summary of accelerator design and general working principles, specifications and physical parameters of the system and user objectives.

Design manual of the accelerating device should include

(a) Drawing of the irradiation head showing the radiation shielding and materials of construction

(b) Drawings along with the functional description of safety related control systems and devices

(c) National standards to which the equipment conforms (English translation of the standard is to be provided)

(d) Test report on the performance of the accelerator demonstrating the compliance with the National Standard or IEC 601-1 and IEC 601-2-1

(e) Certificate from the competent authority of country of design/ manufacture to the effect that the equipment is approved for industrial use.

(f) Beam injection and transport system detailing their design, construction and testing.

Site characteristics : Location, occupancy in site area as well as surrounding population up to 30 meters radius, load bearing capacity of soil and rock, structural design criteria, foundation, meteorology, seismology etc.

Accelerator facility : Description of general layout, details of buildings, equipment, pressure vessels, vacuum system, beam injection and transport system, details of control console facility to view active and passive engineered controls etc.

Biological shield - Final sketch giving details of shielding wall surrounding the source, wall thickness, roof thickness, labyrinth access, openings, voids,

reinforcements, embedment etc. in the biological shield.

- Shield material, density, and quality assurance during construction
- Dose rate profiles anticipated at various locations: (maximum and minimum values). Indicate them on a sketch of the facility - control room, roof, access doors, openings and where personnel are expected to be stationed for work or otherwise.
- Maximum dose rate anticipated

. Lay out of the enclosure along with the location of the Accelerator device

(a) Shielding design detail and drawing of the accelerator enclosure, which includes

(i) Radiation shielding: concrete blocks, lead bricks, iron plates etc.

(ii) Barriers: fences, locked gates, doors etc.

(b) Area radiation monitors

(c) Ventilation facility details

(d) Access sensors or interlocks : magnetic and mechanical

(e) Search and rescue control

(f) Warning indicators (status lights, alarms, posted procedures)

(g) Inventory and labeling of control devices

5. Documentation Detail of Services

(a) Electrical power and power supply systems (including emergency power supply) major electrical equipment, illumination, lift, hoist, cranes etc.

(b) Air conditioning and ventilation system

(c) Cooling water supply system

(d) Compressed air system

(e) Insulating gas supply system

(f) Communication system

6. Safety Features including Hazard Evaluation

(a) Design safety of buildings and equipment

(b) Accelerator facility

(c) Electrical system and equipment

(i) Power and control cables-specifications

(ii) Cable ducting

(iii) Safety fencing of high voltage locations

(iv) Earthing

(v) Electromagnetic interference and suppression

(d) Air conditioning and ventilation

(e) Vacuum system

(f) Cooling water supply system

(g) Compressed air system

(h) Insulating gas supply system

(i) Communication system

(j) Control system

(k) Pressure vessels

(l) Production and removal of noxious gases

(m) Others, if any -

7. Radiation Safety

(a) Radiation safety policy

(b) Dose limits

(c) Planned exposure (operational hours/week)

(d) Planned special exposure

(e) Design features - shielding etc.

(f) Radiation monitoring and alarm system (including interlocks)

(g) Induced activity estimation - radiation levels due to induced activity, induced gaseous airborne activity (if applicable)

(h) Other radiation safety considerations - radioactive waste, postulation of radiation accident, analysis and action, administrative considerations (if applicable)

(i) Analysis of potential radiation exposure scenarios

8. Chemical Safety

List of chemicals used with quantities, their toxicity and hazards, safety considerations, analysis of potential release scenarios and preventive and

other action to be taken [e.g. ozone production and ozone depleting substance, flammable gases, liquids, oxygen deficiency hazard (SF6), biologically hazardous material, cryogenic fluids, etc.]

9. Fire Safety

Fire and explosion hazards, means of escape, access, fire detection and alarm system, fire fighting system - fire hydrants, dry risers, fire extinguishers etc.

10. Personnel Safety

Safety policy, organisation, functions of safety personnel, responsibilities, general safety rules, accident prevention program, safety equipment and procurement, safety inspection, housekeeping, accident reporting, investigation, preventive measures, training, medical facilities including first aid.

11. Normal and Emergency Operation Procedures of the Accelerating Device

12. Safety in Operation and Maintenance

(i) Startup procedure

(ii) Shutdown procedure

(iii) Emergency shutdown procedure

(iv) Search and secure

(v) Entry into beam hall during beam-on condition

(vi) Others (eg. gas handling procedure) please specify.

Emergency planning and procedures
(types of emergencies envisaged, preventive measures handling of emergencies, investigation etc.)

(i) During major leaks in the pressure vessel

(ii) During explosion and fire

(iii) During general fires

(iv) During beam loss/window foil puncture/target rupture etc.

(v) During radiation emergency such as overexposure/activation etc.

(vi) Crisis management in case of major emergency

13. Pre-operational Radiation Survey Report (background radiation in and vicinity of the enclosure)

14. Details of Quality Assurance Program during Design and Construction of the Facility

15. Details of Disposal Procedures and Provisions for Safe Disposal of Radioactive Waste, if applicable

16. Details Regarding the Decommissioning of the Facility

We certify that all the information provided by us is true and correct to the best of our knowledge and belief.

Place: Signature:

Date: Name:

Designation:

Documents to be attached

(i) Lay out of the enclosure along with the location of the Accelerator device

(ii) Shielding design details and drawing of the accelerator facility setup

(iii) Other supportive documents mentioned above.

APPENDIX-3B-II

(Refer section 3.3.1)

FORMAT OF THE PRELIMINARY SAFETY ANALYSIS REPORT FOR PARTICLE RESEARCH ACCELERATOR FACILITIES (PARF) < 10MeV

[PSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer)]

1.	Name and address of the applicant	:	
2.	Details of supplier Name and address of the applicant/local supplier with PIN code (in block letters)	:	
3.	Details of system parameters	:	
	Model/type designation	:	
	Year and country of manufacture	:	
	Maximum voltage	-	MV
	Maximum beam current	-	mA
	Vacuum	-	Torr
	Maximum beam dimensions	-	mm
	Scan amplitude/scan angle	-	
	Particles to be accelerated and purpose	:	
	Operational life of the device (in hours)	:	
	Leakage radiation levels at a distance of one metre from the source when radiation beam is 'ON' (specify for maximum energy and mode)	:	.....mGy/h.....MV/ MeV/Photon/Electron
	Built-in safety features/operation procedures to prevent any radiologically unsafe malfunction of the equipment (Please attach relevant documents such as installation manual, operation/servicing manual)	:	
	Standards to which the accelerator comply	:	

Details of beam energy and current calibration facility :

4. Documentation Detail

Design Detail : Summary of accelerator design and general working principles, specifications and physical parameters of the system and user objectives.

Design manual of the accelerating device which includes

(a) Drawing of the accelerator, beam transportlines and target showing the radiation shielding and materials of construction

(b) Drawings along with the functional description of safety related control systems and devices

(c) National standards to which the equipment conforms (English translation of the standard is to be provided)

(d) Test report on the performance of the accelerator demonstrating the compliance with the National Standard or IEC 601-1 and IEC 601-2-1

(e) Certificate from the competent authority of country of design/ manufacture to the effect that the equipment is approved for industrial use.

(f) Beam injection and transport system detailing their design, construction and testing.

Site characteristics : Location, occupancy in site area as well as surrounding population up to 1000 meters radius, load bearing capacity of soil and rock, structural design criteria, foundation, meteorology, seismology etc.

Accelerator facility : Description of general layout, details of buildings, equipment, pressure vessels, vacuum system, beam injection and transport system, details of control console facility to view active and passive engineered controls, Fail safe (any defect or component failure prevent accelerator operation) and operational independent mechanism etc.

Biological shield - Final sketch giving details of shielding wall surrounding the source, wall thickness, roof thickness, labyrinth access, openings, voids, reinforcements, embedment etc. in the biological shield.

- Shield material, density, and quality assurance during construction
- Dose rate profiles anticipated at various locations: (maximum and minimum values). Indicate them on a sketch of the facility - control room, roof, access doors, openings and where personnel are expected to be stationed for work or otherwise.
- Maximum dose rate anticipated

Lay out of the enclosure along with the location of the Accelerator device

(a) Shielding design detail and drawing of the accelerator enclosure, which includes :

(i) Radiation shielding: concrete blocks, lead bricks, iron plates etc.

(ii) Barriers: fences, locked gates, doors etc.

(b) Area radiation monitors

(c) Ventilation facility details

(d) Access sensors or interlocks : magnetic and mechanical

(e) 'Crash' or 'scram' buttons either mounted on walls or at doors and gates

(f) Search and rescue control

(g) Warning indicators (status lights, alarms, posted procedures)

(h) Inventory and labeling of control devices

5. Documentation Detail of Services

(a) Electrical power and power supply systems (including emergency power supply) major electrical equipment, illumination, lift, hoist, cranes etc.

(b) Air conditioning and ventilation system

(c) Cooling water supply system

(d) Compressed air system

(e) Insulating gas supply system

(f) Communication system

(g) Injector gas handling system-system description, characteristics of the gas (properties, specifications, purification etc.)

(h) Laboratory, workshops, stores etc.

(i) Other services - please specify

(j) Control of various subsystems, description, operation etc.

Summary list of potential hazards and safety measures to be taken

(a) During precommissioning trials of all systems and subsystems

(b) During commissioning

(c) During operation and maintenance

6. Safety Features including Hazard Evaluation

(a) Design safety of buildings and equipment

(b) Accelerator facility

(c) Electrical system and equipment

(i) Power and control cables-specifications

(ii) Cable ducting

(iii) Safety fencing of high voltage locations

(iv) Earthing

(v) Electromagnetic interference and suppression

(d) Air conditioning and ventilation

(e) Vacuum system

(f) Cooling water supply system

(g) Compressed air system

(h) Insulating gas supply system

(i) Communication system

(j) Control system

(k) Production and removal of noxious gases

(l) Pressure vessels

(m) Others, (if any)

7. Radiation Safety

(a) Radiation safety policy

(b) Dose limits

(c) Planned exposure (operational hours/week)

(d) Planned special exposure

(e) Design features - shielding etc.

(f) Radiation monitoring and alarm system (including interlocks)

(g) Induced activity estimation - radiation levels due to induced activity, induced gaseous airborne activity (if applicable)

(h) Other radiation safety considerations - radioactive waste, postulation of radiation accident, analysis and action, administrative considerations (if applicable)

(f) Analysis of potential radiation exposure scenarios

8. Chemical Safety

List of chemicals used with quantities, their toxicity and hazards, safety considerations, analysis of potential release scenarios and preventive and other action to be taken [e.g. ozone production and ozone depleting substance, flammable gases, liquids, oxygen deficiency hazard (SF6), biologically hazardous material, cryogenic fluids, etc.]

9. Fire Safety

Fire and explosion hazards, means of escape, access, fire detection and alarm system, fire fighting system- fire hydrants, dry risers, fire extinguishers etc.

10. Personnel Safety

Safety policy, organisation, functions of safety personnel, responsibilities, general safety rules, accident prevention program, safety equipment and procurement, safety inspection, housekeeping, accident reporting, investigation, preventive measures, training, medical facilities including first aid.

11. Normal and emergency operation procedures of the accelerating device

12. Safety in Operation and Maintenance

(i) Startup procedure

(ii) Shutdown procedure

(iii) Emergency shutdown procedure

(iv) Search and secure

(v) Entry into beam hall during beam - ON condition

(vi) Others (eg. gas handling procedure) please specify.

Emergency planning and procedures

(types of emergencies envisaged, preventive measures handling of emergencies, investigation etc.)

(i) During major leaks in the pressure vessel

(ii) During explosion and fire

(iii) During general fires

(iv) During beam loss/ window foil puncture/target rupture etc.

(v) During radiation emergency such as overexposure/activation etc.

(vi) Crisis management in case of major emergency

13. Pre-operational Radiation Survey Report (background radiation in and vicinity of the enclosure)

14. Details of Quality Assurance Program during Design and Construction of the Facility

15. Details of Disposal Procedures (if applicable)

(a) Storage/Shielding or activated materials for reuse or disposal

(b) Storing facility for radioactive waste and disposal procedure (waste is segregated into appropriate containers, inventory cards with radioactivity symbol)

(c) Activity in cooling water

16. Details Regarding the Decommissioning of the Facility (if applicable)

We certify that all the information provided by us is true and correct to the best of our knowledge and belief.

Place: Signature:

Date: Name:

Designation:

Documents to be attached

(i) Lay out of the enclosure along with the location of the accelerator device

(ii) Shielding design details and drawing of the accelerator facility setup

(iii) Other supportive documents mentioned in the application above.

APPENDIX-3B-III

(Refer section 3.7.8 .2)

FORMAT OF THE PRELIMINARY SAFETY ANALYSIS REPORT FOR INDUSTRIAL ACCELERATOR FACILITY (IAF) FOR NDT

[PSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer)]

1.	Name and address of the applicant	:	
2.	Details of supplier Name and address of the applicant/local supplier with PIN code (in block letters)	:	
3.	Details of system parameters	:	
	Model/type designation	:	
	Year and country of manufacture	:	
	Maximum voltage	-	MV
	Maximum beam current	-	mA
	Vacuum	-	Torr
	Maximum beam dimensions	-	mm
	Scan amplitude/scan angle	-	
	Operational life of the device (in hours)	:	
	Leakage radiation levels at a distance of one metre from the source when radiation beam is 'ON' (specify for maximum energy and mode)	:	….....mGy/h.....MV/ MeV/Photon/Electron
	Built-in safety features/operation procedures to prevent any radiologically unsafe malfunction of the equipment (Please attach relevant documents such as installation manual, operation/servicing manual)	:	
	Standards to which the accelerator comply	:	
	Details of beam energy and current calibration facility	:	

4. Documentation Detail

Design Detail : Summary of accelerator design and general working principles, specifications and physical parameters of the system and user objectives.

Design manual of the accelerating device which includes

(a) Drawing of the irradiation head showing the radiation shielding and materials of construction

(b) Drawings along with the functional description of safety related control systems and devices

(c) National standards to which the equipment conforms (English translation of the standard is to be provided)

(d) Test report on the performance of the accelerator demonstrating the compliance with the National Standard or IEC 601-1 and IEC 601-2-1

(e) Certificate from the competent authority of country of design/ manufacture to the effect that the equipment is approved for industrial use

(f) Beam injection and transport system detailing their design, construction and testing

Site characteristics : Location, occupancy in site area as well as surrounding population up to 30 meters radius, load bearing capacity of soil and rock, structural design criteria, foundation, meteorology, seismology etc.

Accelerator facility : Description of general layout, details of buildings, equipment, pressure vessels, vacuum system, beam injection and transport system, details of control console facility to view active and passive engineered controls etc.

Biological shield
- Final sketch giving details of shielding wall surrounding the source, wall thickness, roof thickness, labyrinth access, openings, voids, reinforcements, embedment etc. in the biological shield.
- Shield material, density, and quality assurance during construction
- Dose rate profiles anticipated at various locations: (Maximum and minimum values). Indicate them

on a sketch of the facility - control room, roof, access doors, openings and where personnel are expected to be stationed for work or otherwise.

- Maximum dose rate anticipated

Lay out of the enclosure along with the location of the accelerator device with

(a) Shielding design detail and drawing of the accelerator enclosure, which includes:

(i) Radiation shielding: concrete blocks, lead bricks, iron plates etc.

(ii) Barriers: fences, locked gates, doors etc.

(b) Area radiation monitors (Radiation hazard control setup details)

(c) Ventilation facility details

(d) Access sensors or interlocks: magnetic and mechanical

(e) 'Crash' or 'scram' buttons either mounted on walls or at doors and gates

(f) Search and rescue control

(g) Warning indicators (Status lights, alarms, posted procedures)

(h) Inventory and labeling of control devices

5. Documentation Detail of Services

(a) Electrical power and power supply systems (including emergency power supply) major electrical equipment, illumination, lift, hoist, cranes etc.

(b) Air conditioning and ventilation system

(c) Cooling water supply system

(d) Compressed air system

(e) Insulating gas supply system

6. Radiation Safety

(a) Radiation safety policy

(b) Dose limits

(c) Planned exposure (operational hours/week)

(d) Planned special exposure

7. Details of Quality Assurance Program during Design and Construction of the Facility

8. Normal and Emergency Operation Procedures of the Accelerating Device

9. Details Regarding the Decommissioning of the Facility (if applicable)

We certify that all the information provided by us is true and correct to the best of our knowledge and belief.

Place: Signature:

Date: Name:

Designation:

Documents to be attached

(i) Lay out of the enclosure along with the location of the Accelerator device

(ii) Shielding design details and drawing of the accelerator facility setup

(iii) Other supportive documents mentioned in above

APPENDIX-3C

(Refer section 3.2.2.4 for IARPF and PARF<10 MeV)
(Refer section 3.7.8.3 for IAF-NDT)

FORMAT FOR ACCEPTANCE TEST REPORT (ATR) FOR ACCELERATOR FACILITIES
[IARPF, IAF-NDT AND PARF<10MeV]

(All the safety systems/ sensors/ signals/ interlocks should be tested atleast 15-20 times, with accelerator ON and OFF condition and consolidated report in the format prescribed herewith shall be submitted)

1. General

Name and address of the operating institution :

Telephone No. :
Fax :

Facility-in-charge :
Radiological safety officer :

AERB approval details and reference :
Date of expiry : _____
Type of Facility : Radiation processing/ Research (<10MeV)/NDT :

2. Accelerator Specifications

Maximum voltage (MV)	
Maximum beam current (mA)	
Particles accelerated	
Vacuum (Torr)	
Maximum beam dimensions (mm)	
Scan amplitude/Scan angle	

3. Performance of Beam Calibration Devices

	Type of calibration	**Expected response of control system**	**Observed response of the control system**
Energy calibration			
Current calibration			

4. Performance of Safety System/Interlocks

Safety System/ Interlock with location	Test conducted	Expected response of control system	Observed response of the control system

5. Radiation Survey of the Facility during the Beam ON Condition at Maximum Parameters

Location	Nature of occupancy	Radiation level	Detector used

6. Performance of Installed On-line Radiation Monitors and Contamination Monitor

Installed location	Detector type	Make & model	Range	Date of calibration	Alarm level	Functional performance

7. Performance of Warning Indicators

Location	Type of warning indicator(s)	Posted procedures	Functional performance

8. Performance of Various Monitors and Associated Systems

Type of monitor	Functional performance
Ozone monitor	
Cryogenic leak monitor	
Instruments to monitor prompt high energy radiation	
Pulsed beam monitor	
RF monitor	

9. Availability of In-house Facilities (details may be furnished in separate pages)

Type of facility	**Available/Not available/ Not applicable**
Decontamination facility	
Personal dosimetry rack facility	
Storage of radioactive material	
Monitor for coolant system	
Monitoring of coolant filter	
Radioactive waste management facility	
Dosimetry faciity	
Ventilation system	
Others, if any	

10. Availabiliy of the Records

Type of record	**Available/ Not available/ Not applicable**
Record of training and experience of persons working in the accelerator facility	
Search and secure procedure	
Controlled access procedure	
Operating procedures	
Periodic radiation survey of facility	
Periodic contamination surveys	
Periodic air sampling	
Personnel monitoring records	
Unusual occurrences	

We hereby certify that the above information is correct to the best of our knowledgeand belief.

Place:

Date:

Signature:

Name:

Designation:

Name and Designation
of Facility-in-charge:

Signature:

APPENDIX-3D-I & II

(Refer section 3.2.2.5)

FORMAT OF THE FINAL SAFETY ANALYSIS REPORT FOR IARPF
(This format can also be used for PARF with beam energy <10 MeV)

[FSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer)]

A. ORGANISATION AND ADMINISTRATION :

(i) Name and Address of Institution :

(ii) Telephone No. :

(iii) Fax No. :

(iv) Purpose of the Plant (Industrial Application) :

(v) Design Approval of the Device obtained from AERB

Model :
Technical Specification : Maximum energy _____
Maximum current _____
Particles Accelerated : _____
Ref. No. :
Date of issue :
Valid up to :

(vi) Site, Layout and Construction Approval of the facility obtained from AERB

Ref. No. :
Date of issue :
Valid up to :

B. SAFETY PERSONNEL

(i) Head of Institution :

(ii) Facility-in-charge :

(iii) Radiological Safety Officer :
AERB Approval ref. :
Date of issue :
Valid up to :

DETAILS OF DOCUMENTS TO BE SUBMITTED

Required documents
Technical description of accelerator design and working procedure with drawings
Precommissioning test reports with results
Shielding design and of installation survey (along with drawings and layout)
Electrical circuit diagram and other interlocks of the accelerating device (inbuilt safety features)
Electrical circuit diagram and other interlocks of the accelerator vault
Provisions and procedures for particle beam energy and beam current calibration and periodic checks
Quality assurance manual (operation)
Arrangements for personal and environmental monitoring system
Periodic surveys of radioactive contamination if applicable
Radiation safety manual
Availability of local safety committee and their safety evaluation report
Details deviations from approved beam line components, accelerator vessel, layout, etc.
Decommissioning procedures of the accelerator facility (if applicable)

We certify that all the information provided by us is true and correct to the best of our knowledge and belief.

Place: Signature:

Date: Name:

Designation:

Documents to be attached : as mentioned above

APPENDIX-3D-III

(Refer section 3.7.8.3)

FORMAT OF THE FINAL SAFETY ANALYSIS REPORT FOR INDUSTRIAL ACCELERATOR FACILITY (IAF) FOR NDT

[FSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer)]

A. ORGANISATION AND ADMINISTRATION :

(i)	Name and Address of Institution	:	
(ii)	Telephone No..	:	
(iii)	Fax No.	:	
(iv)	Head of Institution	:	
(v)	Facility-in-charge	:	
(vi)	Purpose of the Plant (Industrial Application)	:	
(vii)	Site Layout and Construction Approval obtained from AERB		
	Ref. No.	:	
	Date of issue	:	
	Valid up to	:	
(viii)	Design Approval of the Device obtained from AERB		
	Model	:	
	Technical Specification	:	Maximum energy_____ Maximum current _____
	Particles Accelerated	:	_____
	Ref. No.	:	
	Date of issue	:	
	Valid up to	:	

B. SAFETY PERSONNEL

(i)	Radiological Safety Officer	:	
	AERB Approval ref.	:	
	Date of issue	:	
	Valid up to	:	

DETAILS OF DOCUMENTS TO BE SUBMITTED

Required documents
Summary of accelerator design and general working principles with drawings
Precommissioning test reports with results
Shielding design and of installation survey (along with drawings and layout)
Safety assessment reports
Facility operational and interlocks procedures
Calibration and daily checks (beam calibration/monitors)
Changes in operation, equipment, occupancy etc.
Arrangements for personal and environmental monitoring system
Periodic surveys of radioactive contamination if applicable
Radiation safety manual
Emergency scenarios and its response procedures
Organisational setup with responsibilities
Availability of local safety committee and their safety evaluation report
Details deviations from approved beam line components, accelerator vessel, layout etc.
Decommissioning procedures of the accelerator facility (if applicable)

We certify that all the information provided by us is true and correct to the best of our knowledge and belief.

Place: Signature:

Date: Name:

Designation:

Documents to be attached : as mentioned above

APPENDIX-3E

(Refer section 3.2.2.5 for IARPF and PARF<10 MeV)
(Refer section 3.7.8.3 for IAF-NDT)

FORMAT FOR RADIATION PROTECTION MANUAL FOR ALL ACCELERATOR FACILITIES [IARPF, IAF-NDT AND PARF <10MeV]

(OPERATION, MAINTENANCE, EMERGENCY ASPECTS)

A. ADMINISTRATION AND SAFETY ASSURANCE

(a) Administrative hierarchy/organisational set up

(b) Authorised personnel - Training and qualification of facility personnel, their knowledge in radiation safety, responsibilities of each of personnel, their availability in adequate number, policies in case of long leave/absence of certified personnel

(c) Local safety committee: constitution, functions and responsibilities

(d) Procedures for reporting to the regulatory agency on unusual occurrences and periodic radiation safety status

(e) Procedures in case of change or repairs of H.V. system, safety system/ interlocks, certification of log book entry by RSO

(f) Record of maintenance - maintenance schedule, radiation monitoring, and calibration of survey meters, etc.

(g) Industrial safety aspects - fire equipment, safety accessories etc.

(h) Facility security arrangements, fencing and personnel movement control etc.

(i) Removal and storage of contaminated material, if any.

(j) Medical assistance - First aid facility, location, periodic medical examination (once a year), medical facilities and treatment facilities for radiation incidents

B. MONITORING

(a) Radiation monitoring - Type of area monitors, sensitivity range, location, interlock alarm set levels

(b) Contamination monitoring - On line monitoring and sample measurement, method of collecting samples

(c) Personnel monitoring - Number of PM badges, procedure for their issuance, safe place for storage, etc.

C. OPERATION PROCEDURES

'Beam ON' procedures be established, documented and displayed in the console area

D. MAINTENANCE PROCEDURE FOR SAFETY SYSTEMS/INTER-LOCKS

(a) Periodic maintenance - Daily/weekly/monthly/quarterly/yearly (Items, procedures and schedules)

(b) Procedure for maintenance of cooling water used for cooling target beam line components, etc

(c) Procedure for maintenance of air cooling mechanism maintenance and checking of alarm/warning devices

E. EMERGENCY PLANNING AND PROCEDURES

(a) Organisational structure and communication links

(b) Name, address and telephone numbers of agencies to be contacted in case of emergency

(c) Emergency contact telephone/ telex nos. and address of

(i) Head of Institution

(ii) Facility-in-charge

(iii) Radiological safety officer (RSO)

(iv) Regulatory agency (AERB)

(v) Fire safety officer (Local)

(vi) Local fire station

(vii) Local police station

(viii) Local medical hospital, radiation therapy hospitals (nearest)

(d) Type of emergencies envisaged - Prevention/handling of emergencies, investigation methods, etc. during explosion or fire or smoke, radiation emergency, crisis management in case of emergency, earthquake, floods, other natural calamities.

APPENDIX-3F

(Refer sections 3.2.2.3 for IARPF.and PARF<10 MeV)
(Refer section 3.7.8.2 and 3.7.8.3 for IAF NDT)

QUALITY ASSURANCE MANUAL (QAM) FOR ACCELERATOR FACILITIES [IARPF, IAF-NDT, PARF<10MeV]

A. QUALITY ASSURANCE PROGRAM (QAP)

An adequate quality assurance (QA) program, including appropriate quality control measures, shall be established for the design and manufacture, construction and operation of accelerator. Compliance with the ISO 9000 or IS 14000 series is desirable. Records of all QA procedures shall be maintained for the entire life of the accelerator.

B. QUALITY ASSURANCE IN DESIGN:

1.1 Quality Assurance Programme

The responsible organisation shall develop and implement a QA programme, which describes the overall arrangements for the management, performance and assessment of the accelerator. This programme should also provide the means to ensure that all work is suitably planned, correctly performed and properly assessed. Procedures should be defined by the responsible organisation for control of design activities to ensure that the design of the accelerator fulfils specified requirements.

1.2 Grading

A graded approach based on the relative importance to radiological safety of each item, service or process shall be used.

1.2.1 The design activities, which could be graded, include:

(a) The level and detail of analysis of design

(b) The need for and level of design review and approval

(c) The degree of verification of design

(d) The controls applied to design change

(e) The detail of design records and their retention times

(f) The need for alternative calculations to be carried out

(g) The need to qualify or test the design output

(h) The need for qualification tests for design

1.3 Organisation

The responsible organisation shall identify the principal designer who has responsibility for specifying the design requirements and for approving the design output on its behalf.

1.4 Interfaces

Interface arrangements shall be agreed between organisations involved in design activities. Interface that should be addressed are for example:

(a) Interfaces between technical disciplines within the design organisation

(b) Principal designer with:

(i) Siting organisation

(ii) Construction organisation

(iii) Commissioning organisation

(iv) Operating organsiation

(v) Decommissioning organsiation

(vi) Regulatory body

1.5 Planning

Plans used in design should include the following where appropriate:

(a) Scope of work, including work carried out by other organisations

(b) Design methods

(c) Software requirements (software to be developed or software codes to be validated for use)

(d) Test requirements, including qualification tests, prototype, seismic, etc.

(e) Design review, verification and validation requirements

(f) Resource requirements

(g) Special training requirements

(h) Schedule of activities

(i) Points at which checks of the design process will take place and the frequency of such checks

(j) Inputs from safety, reliability, maintainability, human factors, standardisation and other disciplines.

1.6 Non-conformance Control and Corrective Actions

A system for the control of non-conformances and their corrective actions should be established.

1.7 Document Control and Records

Procedures for the preparation, review, approval, issue, modification and control of documents shall be established.

C. QUALITY ASSURANCE DURING CONSTRUCTION OF CIVIL ENGINEERING STRUCTURES OF ACCELERATOR

1.1 Quality Assurance Programme

The responsible organisation shall develop and implement a QA programme, which describes the overall arrangements for the management, performance and assessment of civil engineering structures for industrial processing accelerators during construction. This programme should provide the means to ensure that all work is suitably planned, correctly performed and properly assessed in order to implement design intent in the construction.

1.2 Grading

Work procedures should be defined for control of construction activities at site and it should be reviewed and approved before use. A graded approach based on the relative importance to safety of each item, service or process shall be used. The construction activities, which could be graded, include:

(a) Qualification of special construction processes and the personnel to carry them out

(b) Detail and need for inspection plans

(c) Level of traceability

(d) Level of in process controls and need for hold points

(e) Records and archived samples

1.3 Organisation

The responsible organisation should formally appoint a person on its staff to be responsible for construction activities. The appointed person should have the necessary resources within the construction organisation to discharge the following responsibilities:

(i) Ensuring that construction and installation work is carried out in accordance with design specifications, drawings, procedures and instructions, including the implementation of specified QA requirements.

(ii) Ensuring that construction and installation work undertaken, including work by suppliers, is co-ordinated, conducted and completed in accordance with planned programmes of work.

(iii) Controlling access to the construction site.

1.4 Interfaces

Interface arrangements should be agreed between the construction organisation, suppliers and other organisational units performing the work. They should be defined in writing and should be included in procurement documents. Interfaces that should be addressed are:

(a) Construction organisation with supplier

(b) Construction organisation with operating organisation

(c) Suppliers with sub-suppliers

(d) Construction organisation with the principal designer

(e) Construction organisation with siting organisation

(f) Interfaces between construction organisation and the AERB

1.5 Planning

All construction activities should be planned. The plan should define:

(a) The activities to be performed in manageable units

(b) The planned sequential order and duration of these activities

(c) The resource allocation for each activity

1.6 Non-conformance Control and Corrective Actions

The non-conformances that are required to be reported to the construction organisation should be identified. Suitable corrective action should also be recorded.

1.7 Document Control and Records

Procedures for the preparation, review, approval, issue, modification and control of documents should be established. The record system should be established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, storage, retrieval and disposal of construction records. Records should include all those, which record the as-built condition of structures, systems and components.

1.8 The civil engineering construction should be carried out following the relevant Indian standard codes/specifications. Quality of civil construction should satisfy the requirements of appropriate Indian standard codes/specifications

and that of product specifications. Typical list of topics to be covered in QA programme for the civil engineering construction is given as below:

(a) Formwork, shuttering and pre-construction activities

(b) Concreting and curing

(c) Post concrete inspection

(d) Repair

(e) Fabrication and erection of embeded parts (EP)

(f) Fabrication and erection of structural steel

(g) Brick work

(h) Grounding network

(i) Painting for steel structure

(j) Finishing and repair control

(k) Painting of main plant structures/concretes faces

(l) List of procedures

(m) Miscellaneous items such as organisation chart of QA civil, flow chart showing production of good uniform concrete, schematic diagram on procedure of concrete mix design etc.

(n) Density of the concrete in construction of walls and roof of irradiation cell/accelerator/beam hall shall be maintained at least 2.5 g/cc and it shall be ensured that no voids or air gaps are present during concrete filling.

(APPENDICES 4A, 4B-4D, 4C, 4F ARE FOR ACCELERATOR FACILITIES>10 MeV)

APPENDIX-4A

(Refer section 3.3.2)

FORMAT FOR SITE EVALUATION REPORT FOR PARTICLE ACCELERATOR RESEARCH FACILITY (PARF>10MeV)

1. Description of the Facility
   - (a) Specifications of the machine with maximum power
   - (b) Safety features
   - (c) End use of the facility.
2. Details of Proposed Site (a radius of 2 km around the site) Covering the Following Aspects:
   - (a) Location, area map, topography, terrain, rock, soil, rivers, water bodies, ocean in the vicinity
   - (b) A layout diagram of the proposed site, indicating all the units and the distances between them inside the boundary and the vicinity of the site in all directions
   - (c) Geological characteristics of the site-floods, storms, rain
   - (d) Soil survey report with reference to load bearing of the structure, elemental analysis of soil including lithium activation of the sub soil and ground water wherever applicable
   - (e) Meteorological data of the site
   - (f) Seismic data (seismic zone) of the site
   - (g) Meteorological data on wind speed, wind direction, temperature, rainfall, water logging, flood levels and other factors which might affect the safety aspects in the operation of the accelerator
   - (h) Availability of adequate water supply for cooling under all conditions including fire fighting
   - (i) Reliability and quality of electrical power available to the accelerator facility
   - (j) Population distribution (demography).
3. Justification for and Evaluation of the Particular Site for Locating the Facility

4. Hazard Assessment

   (a) Identification of hazards

   (b) Probable effects on workers, public and the environment, from normal operation and off-normal operations, accidental conditions and situation arising out of natural or disruptive factors

   (c) Means of mitigation of these hazards

   (d) Expected radioactive waste generation in solid, liquid and gaseous forms; their handling, effluent treatment and disposal method

   (e) Radiological impact assessment studies.

5. Facilities Available Near the Site, to Deal with Emergency Situations

6. Details of any existing or planned auxiliary facilities handling radioactive materials/radiation/industrial toxicants within the site or located nearby.

7. Other Supporting Documents, if any.

APPENDIX-4B, 4D

(Refer section 3.3.3, 3.3.4, 3.3.5)

FORMAT FOR (PRELIMINARY/FINAL) SAFETY ANALYSIS REPORT FOR PARF (>10MeV)

The purpose of Safety Analysis Report (SAR) is to ensure that the measures taken to minimise the consequences of hazards present in the proposed activity, or to mitigate their consequences, are sufficient to make the risks of the proposed activity acceptable. It should contain the following:

1. Introduction

   This Chapter should provide a basic understanding of the facility function and the protection features to the public, workers (health and safety), and the environment.

2. Executive Summary

   The summary should provide an overview of the results and conclusions of the analysis. The summary should address the results of Chapter 4 and Chapter 5 of the SAR.

3. Site, Facility and Operations Description

   (a) This section should describe the accelerator site location and provide specific data for characterising the site.

   (b) This section should also describe the accelerator by providing design criteria and as-built characteristics for the accelerator, for its supporting systems, and for components with safety-related functions.

   (c) For new facilities and those to undergo major modifications, a fire hazards analysis is to be included.

   (d) How the facility fits into the contractor's organisation, is to be described.

   (e) The experiments which will use the accelerator should be described, including those design criteria and characteristics of the experimental equipment, systems and components, having safety-related functions.

   (f) An operation/process description of the accelerator facility should be provided. Both potential accident and normal operation conditions for the machine and the experimental program should be appropriately detailed.

   (g) The design process and SAR should consider the worker safety conditions.

(h) Details of ventilation system for removal of noxious gases generated should be provided.

4. Safety Analysis

(a) This section should document the accident analysis, including any systematic methodology (i.e. failure mode and effects analysis, fault trees, etc.) used for the identification and mitigation of potential hazards.

(b) This section should discuss the methods used at the accelerator facility to control and mitigate the potential hazards.

(c) Analysis of design basis or postulated emergency conditions, including those due to natural or disruptive factors. Demonstration of adequacy of protective measures provided in the design.

(d) The residual risk to the facility, workers, the public, and the environment should be discussed.

5. Accelerator Safety Envelope

This section should provide the accelerator safety envelope (ASE) that will establish and define the limits of operation for the facility/operation.

6. Quality Assurance

This section should describe the quality assurance (QA) program to be applied to the accelerator facility (Give broad guidelines. In addition QA manual should be made separately as per **Appendix 4F** of AERB safety guide AERB/RF/SG/G-3)

7. Decommissioning and Decontamination Plan

A description of structural and internal features which would facilitate decommissioning and decontamination of the accelerator complex should be provided in this section. Waste management of radiological and hazardous material generation from the decommissioning and decontamination operation should be discussed. Provisions including adequate financial arrangement for safe disposal of spent/disused sources should be made.

8. References/Glossary/Abbreviations

In short, the FSAR (SAD) shall contain the following:

(a) A description of (or a reference to) the facility's function, location, and management organisation, as well as details of major facility components and their operation.

(b) Hazards from both normal operation and credible accidents in the facility and associated onsite and offsite impacts to workers, the public, and the environment.

(c) Sufficient descriptive information and analytical results pertaining to specific hazards and risks identified during the safety analysis process, and to provide an understanding of the risks presented by the proposed operations.

(d) A detailed description of engineered controls (e.g. interlocks and physical barriers) and administrative controls (e.g. training) implemented to eliminate, control, or mitigate risks associated with the operation.

(e) The set of physical and administrative bounding conditions for safe operations, based on the safety analysis documented in the SAR. These bounding conditions are known as the accelerator safety envelope (ASE). Any activity violating the ASE shall be terminated and immediately notified to AERB.

APPENDIX-4C

(Refer section 3.3.4)

FORMAT FOR THE ACCEPTANCE TEST REPORT (ATR) FOR PARTICLE ACCELERATOR RESEARCH FACILITIES (PARF >10MeV)

S. No.	Safety system	Observations/ Remarks	Signature with name and designation for accepting the performance
1.	Door Interlock - Power cutoff after opening - Signal in control room - Manual resetting		
2.	Scram Switches - Power cut-off after pressing the scram switch - Signal in control room - Manual resetting		
3.	Area Radiation Monitors Interlock - Power cut-off after radiation field increases more than specified - Signal in the control room - Local sound alarm - Calibration of monitors		
4.	Vacuum Failure - Identification of loss of vacuum - Functioning of gate valve - Response time		
5.	LCW Cooling System - Functioning of sensor for temperature, flow etc. - Indication in the control room - Tripping of plant system		

APPENDIX-4C (CONTD.)

(Refer section 3.3.4)

FORMAT FOR THE ACCEPTANCE TEST REPORT (ATR) FOR PARTICLE ACCELERATOR RESEARCH FACILITIES (PARF >10MeV)

S. No.	Safety system	Observations/ Remarks	Signature with name and designation for accepting the performance
6.	Public Address System (PAS) - Functioning of mike - Functioning of speakers at all locations		
7.	Fire Detection System - Power supply to fire detection system - Detection of fire - Alarm local and in control room - Resetting of alarm		
8.	Beam Shutter Response - Functioning - Response time		
9.	Beam Loss Monitor - Functioning of interlock with bending magnet - Signal in control room		
10.	Other safety systems [Add as applicable]		

APPENDIX-4F

(Refer section 3.3.2 to 3.3.4)

QUALITY ASSURANCE (QA) MANUAL FOR PARTICLE ACCELERATOR RESEARCH FACILITY [PARF] (BEAM ENERGY >10MeV)

A. QUALITY ASSURANCE PROGRAMME DURING CONSTRUCTION OF PARF>10 MeV

The Licensee shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of structures/ systems/components related to civil, mechanical, electrical and instrumentation aspects of PARF during design and construction. This programme should specify means to ensure that all work is suitably planned, correctly performed and properly assessed in order to implement design intent in the construction.

The QA manual (QAM) should be prepared addressing the following aspects:

A.1 INTRODUCTION

This section should include applicability and scope of the QAM.

A. 2 MANAGEMENT FUNCTIONS

This section should specify the management's Policy Statement and Organisation plan. Organisational plan should be documented addressing the following aspects:

(a) Organisational structure

(b) Functional responsibility

(c) Levels of authority

(d) Lines of internal and external communication.

It should also address requirements related to competent manpower for construction activities of the facility. The functional responsibilities of all the personnel distinguishing task including their assigned administrative powers should be identified and documented.

The Licensee should formally identify a person to be responsible for implementation of QA programme during construction activities. Responsibilities of key personnel in the organisation should be defined in writing. The person appointed should have the necessary resources to discharge the following responsibilities:

(a) Ensuring that construction and installation work is carried out in accordance with design specifications, drawings, procedures and instructions, including the implementation of specified QA requirements.

(b) Ensuring that construction and installation work undertaken, including work by manufacturers/suppliers, is coordinated, conducted and completed in accordance with planned programmes.

(c) Controlling access to the construction site.

Appropriate controls reflecting safety regulations shall be established for all personnel, including suppliers and visitors. These shall be in line with applicable statutes and shall include arrangements for effective planning, organisation, monitoring and review of the preventive and protective measures. Management shall provide all necessary support to the contractor to ensure health and safety of the construction personnel and quality assurance requirements of construction.

A. 2.1 Grading

A graded approach based on the relative importance to safety of each item, service or process should be adopted. Activities, which should be graded during construction include:

(a) Qualification of special construction processes and the personnel to carry them out

(b) Details and need for inspection plans

(c) Level of traceability of construction material and related records

(d) Level of in-process controls and need for hold points

(e) Complexity involved in equipment handling/ erection and post-erection preservation

A.2.2 Interfaces

Licensee should ensure that interface arrangements shall be agreed among the construction agencies, suppliers and other organisational units performing the work. These should be defined in writing and be included in relevant documents. Appropriate references of the same should be made in the QA programme. Handover/ transfer responsibilities after completion of construction/ installation to operating organisation.

A.3. PERFORMANCE FUNCTIONS

A.3.1 Document Control

Procedures for the preparation, review, approval, issue, modification and control of documents should be established. The record system should be

established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, storage, retrieval and disposal of construction records. Document control system should also include records of as-built condition of structures, systems and components.

A. 3.2 Procurement Control

Measures shall be established and documented to ensure that relevant standards/specifications and other requirements necessary to assure adequate quality are included or referenced for procurement of items and services required during construction of PARF.

Procurement requirements for assuring quality shall be covered by a procurement document. The document shall include items such as scope of work, technical requirements, and test, inspection and acceptance requirements.

Procedures for the preparation, review, approval, issue, modification and control of documents pertaining to activities affecting construction should be established. Document release and distribution system shall be established utilising up-to-date distribution lists. Individuals responsible for issue of documents shall be identified.

A.3.3 Supplier Evaluation and Selection

Supplier evaluation shall be carried out to assess the capability to provide items and services in accordance with the requirements of procurement document(s). The supplier evaluation includes as appropriate:

(a) evaluation of current technical capability, availability of expertise and resources,

(b) analysis of product samples, and

(c) review of historical quality performance data.

A.4 PROCESS CONTROL

Documented procedures should be established for all construction related activities of the PARF such as receiving and storing components, civil construction, equipment erection, cleaning/flushing, inspection, testing, modification etc. Provision should be made for verification, review and audit of activities affecting quality of construction.

Site construction activities should be planned and documented in adequate detail and approved by designated persons/agencies. The plan shall define:

(a) The planned sequential order and duration of activities

(b) The resource allocation for each activity

(c) Work planning and supervision

(d) Implementation of safety requirement during construction including fire safety and first aid

Preventive maintenance and preservation of items in stores or installed should be carried out in accordance with manufacturers' recommendations and good engineering practices, and documented.

A.5 VERIFICATION FUNCTIONS

A.5.1 Verification Programme

A comprehensive documented verification programme to be prepared to assure conformance of construction of the PARF as per the relevant codes and standards. Verification programme should comprise external (third party) as well as internal verification at specified stages/periodicity.

A.5.2 Inspection and Test Controls

A plan for inspection and testing of the materials/components used for construction, should be established. These should include identification of characteristics to be checked, type of check, acceptance norms etc. These should specifically include:

(a) Inspection of soil rocks, earthworks and foundation piles

(b) Testing of concrete

(c) Inspection of civil and steel structures

A.5.3 Audit

Provisions need to be prescribed detailing the establishment and implementation of a comprehensive system of planned and documented audits to verify the implementation and effectiveness of the various elements of the quality assurance programme. It should address the audit performance, audit personnel, audit plan and audit timing etc. The requirement for QA audit and extent of its application should be based on the safety significance of the system.

A.6 CORRECTIVE FUNCTIONS

A.6.1 Non-conformity Control and Corrective Actions

A system for the control of non-conformances and their corrective actions should be established. Non-conformances, deviations or inadequacies affecting quality should be identified and controlled. The persons responsible for review and disposition of non-conformances should be identified. The programme should provide that appropriate action be taken to ensure that

conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective or incorrect material, equipment and any other non-conformances are identified, corrected and recurrences are prevented.

A.7 RECORDS

Records should be prepared and maintained to provide objective evidence of quality to meet the requirements of applicable codes, standards and specifications to include details such as:

(a) Certificates of each component from the supplier/manufacturer; and the test and inspection records

(b) Non-conformance reports, corrective/preventive actions carried out

(c) Certificates about raw material such as cement, sand, iron, steel used during constructions

(d) Records of the test results, acceptance criteria and as-built condition of structures.

(e) Design reports and drawings

(f) Safety analysis reports

The record system shall be established which includes the arrangements and responsibilities for the categorization, receipt, indexing, preservation/storage, retrieval, inspection and disposal of records after expiry of the specified retention period of non-permanent records.

B. QUALITY ASSURANCE DURING COMMISSIONING AND OPERATION OF PARF (>10MeV)

Licensee shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of the PARF. This programme shall also provide means to ensure that all work is suitably planned, correctly performed and properly assessed. Procedures shall be defined by the Employer to ensure that the commissioning and operation of PARF fulfils specified requirements.

The QAM should be prepared in following format addressing the different aspects of the facility.

B.1. INTRODUCTION

This section should include Applicability and Scope of the QAM.

B. 2. MANAGEMENT FUNCTIONS

This section should specify the management's policy statement and organisation plan. Organisational plan should be documented addressing the following aspects:

(a) Organisational structure

(b) Functional responsibility

(c) Levels of authority

(d) Lines of internal and external communication.

It should also address requirements related to availability of competent manpower for commissioning and operation of the facility. The functional responsibilities of all the personnel distinguishing task including their assigned administrative powers should be identified and documented. The necessary resources required by these personnel to discharge the following responsibilities need to be identified:

(a) Commissioning and operation of the facility is carried out in accordance with approved procedures, design specifications, designers' instructions.

(b) Controlling access to the operating facility.

Procedures need to be documented for formal reviews of QA programme by management as often as necessary or any changes in the regulatory requirements that may have been introduced after the previous approval of QA programmes. Identification and control of compliance with applicable codes, standards, specification and practices; acceptance criteria (qualitative and/or quantitative as appropriate) for determining satisfactory completion of the commissioning and operation activity should be described in the QAM.

B.2.1 Interfaces

The interface arrangements should be agreed with the licensee and various agencies involved (namely design, construction, commissioning, operation, decommissioning, AERB and statutory agencies as applicable). Handover/ transfer responsibilities after completion of construction/ installation to operating organisation.

B.3 PERFORMANCE FUNCTIONS

B.3.1 Document Control

(a) Procedures for the preparation, review, approval, issue, modification and control of documents pertaining to activities affecting commissioning and operation should be established.

(b) Document release and distribution system shall be established utilising up-to-date distribution lists. Individuals responsible for issue of documents shall be identified.

(c) Documents important for commissioning and operation include, among others, final safety analysis report (FSAR), acceptance test

report (ATR), and radiation protection manual (RPM), commissioning reports and technical specifications for operation.

(d) Procedures for making interface with various components and systems should be prepared. Verification and validation of software used for operational control should be done by the independent agencies.

B.3.2 Process Control

B.3.2.1 Commissioning Control

Procedures should be established to ensure that appropriate tests are performed during commissioning to demonstrate that design intent and, regulatory and other statutory requirements are met. Satisfactory demonstration of functional capability of safety systems is a prerequisite for considering the PARF to be suitable for the operating phase.

Measures shall be established to ensure that all commissioning activities including beam extraction, transport and dumping are planned, controlled and implemented in accordance with approved documents such as procedures, instructions and checklists, and results documented.

Commissioning activities shall commence only after due completion of respective construction activities supported by certified documents. Inspection and surveillance shall be performed by the facility and documented to verify compliance with specification requirements.

Measures shall be established to identify, review, resolve and document all non-conformances and design changes.

A system for audit of commissioning, follow-up and record of corrective actions shall be established.

B.3.2.2 Operation Control

Documented procedure shall be established for safe operation of the PARF in accordance with the design intent and specified operational limits.

Provisions should be included to ensure interface among agencies for operation, maintenance, technical services, plant management, design, inspection, testing, verification and audit.

Provision shall exist for regular verification of operation activities related to safety. Preventive and maintenance schedule should be prepared for all safety systems as per the applicable codes.

Inspection and testing/surveillance during operation of safety equipment as well as subsequent to maintenance, modification or procedural changes should be performed to specified requirements and documented.

Trained and authorised operator should be available for operation of PARF.

Measures should be established to

(i) identify emergency situations and to develop and implement procedures for coping with emergencies; and

(ii) to hold emergency exercises at specified intervals to identify inadequacies, if any.

B.4 VERIFICATION FUNCTIONS

B.4.1 Verification Programme

A comprehensive documented verification programme should be prepared and verification conducted accordingly to assure conformance of commissioning and operation of the PARF as per the relevant specified codes and procedures. Verification programme should comprise external as well as internal verification

B.4.2 Inspection and Test Controls

Measures should be established to ensure that testing and measuring devices used in determining conformance to acceptance criteria are of proper range, type, accuracy and precision.

Testing and measuring devices should be controlled, calibrated and adjusted at specified intervals, or before use, to maintain accuracy within necessary limits.

Controls shall be established to ensure proper handling, storage and use of calibrated instruments.

B.4.3 Audit

Provisions need to be prescribed detailing the establishment and implementation of a comprehensive system of planned and documented audits to verify the implementation and effectiveness of the various elements of the quality assurance programme. It should address the audit performance, audit personnel, audit plan and audit timing etc. The requirement for QA audit and extent of its application should be based on the safety significance of the system.

B. 5 CORRECTIVE FUNCTIONS

B.5.1 Non-conformity Control and Corrective Actions

A system for the control of non-conformances and their corrective actions should be established. Non-conformances, deviations or inadequacies affecting quality should be identified and controlled. The persons responsible

for review and disposition of non-conformances should be identified. The programme should provide appropriate actions to be taken to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective or incorrect material, equipment and any other non-conformance are identified and corrected.

Preventive actions should also be identified based on the review of non-conformances.

B.6 RECORDS

Records should be prepared and maintained to provide objective evidence of quality to meet the requirements of applicable codes, standards and specifications.

Records should include:

(a) results of reviews, inspections, tests and audits,

(b) operation logs,

(c) non-conformance reports, repairs carried out,

(d) training, qualifications and certification of personnel,

(e) information pertaining to 'as built' condition of items in the plant,

(f) copies of design drawings, PSAR, FSAR, RPM, QAM, licence/ consents/certificates, etc.,

(g) radiation dose records, emergency exercises and maintenance records.

The record system shall be established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, preservation/storage, retrieval, inspection and disposal of records after expiry of the specified retention period of non-permanent records.

(APPENDICES 5B,5D, 5E, 5F REFER TO MEDICAL CYCLOTRON FACILITY)

APPENDIX-5B

(Refer section 3.4.1.3)

FORMAT OF THE PRELIMINARY SAFETY ANALYSIS REPORT (PSAR) FOR MEDICAL CYCLOTRON FACILITIES

[PSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer) along with the application for the layout and construction approval of Medical Cyclotron Facility]

INTRODUCTORY INFORMATION

1.	Name and address of the applicant	:	
	Institution profile	:	
	Purpose and scope of the project	:	
2.	Details of Supplier	:	
	Name and address of the applicant/local supplier with PIN code (in block letters)	:	
3.	Details of System Parameters		
	Model/Type designation of the medical cyclotron	:	
	Year and country of manufacture	:	
	Type of the medical cyclotron (shielded/non self- shielded)	:	
	Maximum beam energy	:	MeV
	Maximum beam current	:	μA
	Number of targets	:	
	Operational life of the device (in hours)	:	
	Radiation levels at a distance of one metre from the cyclotron under beam 'ON' condition (specify for maximum energy and mode) (Please attach dose contours around the cyclotron and cyclotron vault)	:	

Leakage radiation and other parameters .... :

Built-in safety features/operation procedures to prevent any radiologically unsafe malfunction of the equipment (Please attach relevant documents such as installation manual, operation/ servicing manual) :

Specify the standards to which the medical cyclotron comply :

Details of beam energy and current calibration facility :

4. Number of Synthesis and Dispensing Units :

5. Design Manual of the Medical Cyclotron which includes

(a) Drawing and functional description of the accelerating chamber and target systems along with radiation shielding

(b) Drawings along with the functional description of safety related control systems and devices

(c) National standards to which the equipment conforms (English translation of the Standard is to be provided)

(d) Test report on performance of the medical cyclotron demonstrating the compliance with the National standard

(e) Certificate from the competent authority of country of design/ manufacture to the effect that the equipment is approved for isotope production use

6. Layout of the Medical Cyclotron Vault and Associated Facilities, Indicating the following details

(a) Radiation shielding details : Concrete blocks, earth beams (barrier or insulation), lead bricks, iron plates etc.

(b) Barriers : Fences, locked gates, doors etc.

(c) Facility specific : Control console facility to view active and passive engineered controls

(d) Area radiation monitors

(e) Ventilation facility

(f) Caution and alert system

(g) Access sensors or interlocks : Electrical, magnetic and mechanical

(h) 'Crash' or 'Scram' buttons either mounted on walls or at doors and gates

(i) Search and rescue control

(j) Warning indicators (status lights, alarms, posted procedures)

7. Details of Documents with Details (to be submitted)

Design detail	:	Summary of medical cyclotron design and general working principles, specifications and physical parameters of the system and user objectives.
Site characteristics	:	Location, occupancy in site area as well as surrounding population up to 30 meters radius, geology, load bearing capacity of soil and rock, structural design criteria, foundation, meteorology, seismology, water table, flood level, plinth level (with respect to nearest accessible road), AERB site approval reference, etc.
Medical cyclotron	:	Description of general layout, details of buildings, pressure vessels, vacuum system, radio frequency system, magnetic field, beam injection, acceleration, transport and target system including their design, construction and testing and quality assurance manual for the equipment.
Synthesis and dispensing units	:	Name and address of the Manufacturer and supplier, make and model of the synthesis and dispensing unit, maximum activity to be handled, material and thickness of shielding.
Biological shield	-	Final sketch giving details of shielding wall surrounding the source, wall thickness, labyrinth access, openings, voids, reinforcements, embedment etc. in the biological shield. Method of shielding calculation and the dose limits followed
	-	Shield material, density, and quality control measures followed during shield construction
	-	Maximum and minimum shield thickness, roof thickness
	-	Drawings and layout of the device location installed

- Dose rate profiles anticipated at various locations: (maximum and minimum values). Indicate them on a sketch of the facility - control room, roof, access doors, openings and where personnel are expected to be stationed for work or otherwise.
- Radiation shielding evaluation including sky shine
- Maximum dose rate anticipated

  Locations: (Indicate also in a sketch)

8. Documentation Details of Auxiliary Services

   (a) Electrical power and power supply systems (including emergency power supply), major electrical equipment, illumination, lift, hoist, cranes etc.

   (b) Air conditioning and ventilation system (including treatment of noxious gases produced, if any)

   (c) Cooling water supply system

   (d) Compressed air system

   (e) Communication system

   (f) Target gas handling system - system description, characteristics of the gas (properties, specifications, purification etc.)

   (g) Laboratory, workshops, stores, etc.

   (h) Other services- please specify.

   (i) Controls of various subsystems, description, operation etc.

9. List of Potential Hazards and Safety Measures to be taken

   (a) During precommissioning trials of all systems and subsystems

   (b) During commissioning

   (c) During operation and maintenance

10. Safety Features Including Hazard Evaluation

    (a) Design safety of buildings and equipment

    (b) Structural design: Seismic and wind load parameter details

    (c) Accelerator facility

    (d) Electrical system and equipment

        (i) Power and control cables-specifications

        (ii) Cable ducting

(iii) Safety fencing of high voltage locations

(iv) Earthing

(v) Electromagnetic interference and suppression

(e) Air conditioning and ventilation

(f) Vacuum system

(g) Cooling water supply system

(h) Compressed air system

(i) Dry nitrogen supply system

(j) Communication system

(k) Control system

(l) Fail safe (any defect or component failure, which prevents the cyclotron operation) and operational independent

(m) Inventory and labeling of control devices

(n) Others, please specify.

11. Radiation Safety

(a) Radiation safety policy

(b) Dose equivalent limits

(c) Planned exposure (operational hours/week)

(d) Planned special exposure

(e) Design features - shielding etc.

(f) Radiation monitoring and alarm system (including interlocks)

(g) Induced activity estimation - radiation levels due to induced activity, induced gaseous airborne activity (if applicable)

(h) Radiation sensitive components installed inside the facility and their durability

(i) Induced activity in cooling water

(j) Other radiation safety considerations - radioactive waste, postulation of radiation accident (target rupture, loss of shielding integrity), analysis and action, administrative considerations (if applicable)

(k) Analysis of potential radiation exposure scenarios

12. Chemical Safety

List of chemicals used with quantities, their toxicity and hazards, safety considerations, analysis of potential release scenarios and preventive and

other action to be taken (e.g. Ozone production and ozone depleting substance, flammable gases, liquids, oxygen deficiency hazard (SF6), biologically hazardous material, cryogenic fluids, etc.)

13. Fire Safety

Fire and explosion hazards, means of escape, access, fire detection and alarm system, fire fighting system-fire hydrants, dry risers, fire extinguishers etc.

14. Personnel Safety

Safety policy, organisation, functions of safety personnel, responsibilities, general safety rules, accident prevention program, safety equipment and procurement, safety inspection, housekeeping, accident reporting, investigation, preventive measures, training, medical facilities including first aid.

15. Safety in Operation and Maintenance

(i) Startup procedure

(ii) Shutdown procedure

(iii) Emergency shutdown procedure

(iv) Search and secure

(v) Procedure for entry into cyclotron vault

(vi) Others (eg. gas handling procedure), please specify

16. Emergency Planning and Procedures
(types of emergencies envisaged, preventive measures, handling of emergencies, investigation etc.)

(i) During major leaks, foil rupture, contamination, target rupture, loss of shielding integrity

(ii) During explosion and fire

(iii) During general fires

(iv) During emergency in tanks and equipment etc.

(v) During radiation emergency

(vi) Crisis management in case of major emergency

17. Pre-operational Radiation Survey Report (background radiation in and vicinity of the medical cyclotron facility)

18. Quality Assurance Manual for Construction of the Facility (as per format given in item A of **Appendix-6A** of AERB/RF/SG/G-3)

19. Details of waste disposal pocedures and provisions including adequate financial arrangement for safe disposal of spent/ disused sources.

20. Details of storage facility for activated components and procedure (identifying long half life radioisotopes)

21. Details to be furnished regarding the decommissioning of the facility.

We certify that all the information provided by us is true and correct to the best of our knowledge and belief.

Place: Signature:

Date: Name:

Designation:

APPENDIX-5D

(Refer section 3.4.1.4)

FORMAT OF THE FINAL SAFETY ANALYSIS REPORT (FSAR) FOR MEDICAL CYCLOTRON FACILITIES

[FSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer) along with the application for the commissioning and operation of Medical Cyclotron Facility]

A. INTRODUCTORY INFORMATION

1. Name and address of the applicant :

   Head of Institution :

2. Institution profile :

3. Purpose and scope of the project :

4. Details of Supplier :

   Name and address of the applicant/local supplier with PIN code (in block letters) :

5. Details of AERB Site Approval

   Ref. No. :
   Date of issue :
   Valid up to :

6. Details of AERB Layout and Construction Approval

   Ref. No. :
   Date of issue :
   Valid up to :

7. Detail of System Parameters :

   Model/Type designation of the medical cyclotron :
   Year and country of manufacture :
   Type of the medical cyclotron (shielded/non shielded) :
   Maximum beam energy - : MeV
   Maximum beam current - : μA
   Number of targets - :

Operational life of the device (in hours) :

Radiation levels at a distance of one metre from the cyclotron under beam 'ON' condition (specify for maximum energy and mode) (Please attach dose contours around the cyclotron and cyclotron vault) :

Leakage radiation and other parameters .... :

Built-in safety features/operation procedures to prevent any radiologically unsafe malfunction of the equipment (Please attach relevant documents such as installation manual, operation/servicing manual) :

Specify the standards to which the medical cyclotron comply :

Details of beam energy and current calibration facility :

Number of synthesis and dispensing units :

8. Design Manual of the Medical Cyclotron which includes

   (a) Drawing and functional description of the accelerating chamber and target systems along with radiation shielding

   (b) Drawings along with the functional description of safety related control systems and devices

   (c) National standards to which the equipment conforms (English translation of the Standard is to be provided)

   (d) Test report on performance of the medical cyclotron demonstrating the compliance with the National standard

   (e) Certificate from the competent authority of country of design/ manufacture to the effect that the equipment is approved for isotope production use

9. Layout of the Medical Cyclotron Vault and Associated Facilities, indicating the following details

   (a) Radiation shielding details : concrete blocks, earth beams (barrier or insulation), lead bricks, iron plates etc.

   (b) Barriers: fences, locked gates, doors etc.

(c) Facility specific : Control console facility to view active and passive engineered controls

(d) Area radiation monitors

(e) Ventilation facility

(f) Caution and alert system

(g) Access sensors or interlocks: Electrical, magnetic and mechanical

(h) 'Crash' or 'Scram' buttons either mounted on walls or at doors and gates

(i) Search and rescue control

(j) Warning indicators (status lights, alarms, posted procedures)

10. Details of Documents with Details (to be submitted)

Design detail	:	Summary of medical cyclotron design and general working principles, specifications and physical parameters of the system and user objectives.
Site characteristics	:	Location, occupancy in site area as well as surrounding population up to 30 meters radius, geology, load bearing capacity of soil and rock, structural design criteria, foundation, meteorology, seismology, Water table, flood level, plinth level (with respect to nearest accessible road), AERB site approval reference, etc.
Medical cyclotron	:	Description of general layout, details of buildings, pressure vessels, vacuum system, Radio frequency system, Magnetic field, beam injection, acceleration, transport and target system including their design, construction and testing and quality assurance manual for the equipment.
Synthesis and dispensing units	:	Name and address of the manufacturer and supplier, make and model of the synthesis and dispensing unit, maximum activity to be handled, material and thickness of shielding.
Biological shield	-	Final sketch giving details of shielding wall surrounding the source, wall thickness, labyrinth access, openings, voids, reinforcements, embedment etc. in the biological shield. Method of shielding calculation and the dose limits followed

- Shield material, density, and quality control measures followed during shield construction
- Maximum and minimum shield thickness, roof thickness
- Drawings and layout of the device location installed
- Dose rate profiles anticipated at various locations: (Maximum and minimum values). Indicate them on a sketch of the facility - control room, roof, access doors, openings and where personnel are expected to be stationed for work or otherwise.
- Radiation shielding evaluation including sky shine
- Maximum dose rate anticipated

  Locations : (indicate also in a sketch)

11. Documentation Details of Auxiliary Services

    (a) Electrical power and power supply systems (including emergency power supply), major electrical equipment, illumination, lift, hoist, cranes etc.

    (b) Air conditioning and ventilation system (including treatment of noxious gases produced, if any)

    (c) Cooling water supply system

    (d) Compressed air system

    (e) Communication system

    (f) Target gas handling system - system description, characteristics of the gas (properties, specifications, purification etc.)

    (g) Laboratory, workshops, stores, etc.

    (h) Other services (please specify)

    (i) Controls of various subsystems, description, operation etc.

12. List of Potential Hazards and Safety Measures to be Taken

    (a) During precommissioning trials of all systems and subsystems

    (b) During commissioning

    (c) During operation and maintenance

13. Safety Features Including Hazard Evaluation

    (a) Design safety of buildings and equipment

(b) Structural design: Seismic and wind load parameter details

(c) Accelerator facility

(d) Electrical system and equipment

  (i) Power and control cables-specifications

  (ii) Cable ducting

  (iii) Safety fencing of high voltage locations

  (iv) Earthing

  (v) Electromagnetic interference and suppression

(e) Air conditioning and ventilation

(f) Vacuum system

(g) Cooling water supply system

(h) Compressed air system

(i) Dry nitrogen supply system

(j) Communication system

(k) Control system

(l) Fail safe (any defect or component failure, which prevents the cyclotron operation) and operational independent

(m) Inventory and labeling of control devices

(n) Others, Please specify.

14. Radiation Safety

(a) Radiation safety policy

(b) Dose equivalent limits

(c) Planned exposure (operational hours/week)

(d) Planned special exposure

(e) Design features - shielding etc.

(f) Radiation monitoring and alarm system (including interlocks)

(g) Induced activity estimation - radiation levels due to induced activity, induced gaseous airborne activity (if applicable)

(h) Radiation sensitive components installed inside the facility and their durability

(i) Induced activity in cooling water

(j) Other radiation safety considerations - radioactive waste, postulation of radiation accident (target rupture, loss of shielding integrity), analysis and action, administrative considerations (if applicable)

(k) Analysis of potential radiation exposure scenarios

15. Chemical Safety

List of chemicals used with quantities, their toxicity and hazards, safety considerations, analysis of potential release scenarios and preventive and other action to be taken [e.g. ozone production and ozone depleting substance, flammable gases, liquids, oxygen deficiency hazard (SF6), biologically hazardous material, cryogenic fluids, etc.]

16. Fire Safety

Fire and explosion hazards, means of escape, access, fire detection and alarm system, fire fighting system- fire hydrants, dry risers, fire extinguishers etc.

17. Personnel Safety

Safety policy, organisation, functions of safety personnel, responsibilities, general safety rules, accident prevention program, safety equipment and procurement, safety inspection, housekeeping, accident reporting, investigation, preventive measures, training, medical facilities including first aid.

18. Safety in Operation and Maintenance

(i) Startup procedure

(ii) Shutdown procedure

(iii) Emergency shutdown procedure

(iv) Search and secure

(v) Procedure for entry into cyclotron vault

(vi) Others (eg. gas handling procedure), please specify.

19. Emergency Planning and Procedures
(types of emergencies envisaged, preventive measures, handling of emergencies, investigation etc.)

(i) During major leaks, foil rupture, contamination, target rupture, loss of shielding integrity

(ii) During explosion and fire

(iii) During general fires

(iv) During emergency in tanks and equipment etc.

(v) During radiation emergency

(vi) Crisis management in case of major emergency

20. Pre-operational radiation survey report (background radiation in and vicinity of the medical cyclotron facility)

21. Quality assurance manual for construction of the facility (as per format given in item A of **Appendix 6A** of AERB/RF/SG/G-3)

22. Details of waste disposal pocedures and provisions including adequate financial arrangement for safe disposal of spent/ disused sources.

23. Details of storage facility for activated components and procedure (identifying long half life radioisotopes)

24. Details to be furnished regarding the decommissioning of the facility.

B. OPERATING AND SAFETY PERSONNEL

(i) Cyclotron operator :

(ii) Radiopharmacist :

(iii) Radiological safety officer :

AERB Approval Ref. :

Date of issue :

Valid up to :

DETAILS OF DOCUMENTS TO BE SUBMITTED

Required documents
Technical description of medical cyclotron design and working procedure with drawings
Electrical circuit diagram and other interlocks of the medical cyclotron device (inbuilt safety features)
Electrical circuit diagram and other interlocks of the medical cyclotron vault
Calibration and periodic checks
Provisions and procedures for (particle beam energy, beam current)
Quality assurance manual (operation)
Arrangements for personal and environmental monitoring system
Periodic surveys of radioactive contamination if applicable
Availability of local safety committee and their safety evaluation report
Details of deviations from approved medical cyclotron components, medical cyclotron vault, shielding design, etc.
Decommissioning procedures of the medical cyclotron facility

We certify that all the information provided by us is true and correct to the best of our knowledge and belief.

Place:

Date:

Signature:

Name:

Designation:

Encl : Documents attached as per the above requirement

APPENDIX-5E

(Refer section 3.4.1.4)

RADIATION PROTECTION MANUAL FOR MEDICAL CYCLOTRON FACILITY

(OPERATION, MAINTENANCE, EMERGENCY ASPECTS)

A. ADMINISTRATION AND SAFETY ASSURANCE

(a) Administrative hierarchy/organisational set up

(b) Authorised personnel - Training and qualification of facility personnel, their knowledge in radiation safety, responsibilities of each of personnel, their availability in adequate number, policies in case of long leave/ absence of certified personnel

(c) Local safety committee: constitution, functions and responsibilities

(d) Procedures for reporting to the regulatory agency on unusual occurrences and periodic radiation safety status

(e) Procedures in case of change or repairs of H.V. system, safety system/ interlocks, certification of log book entry by RSO

(f) Records of maintenance - maintenance schedule, radiation monitoring, and calibration of survey meters, etc.

(g) Industrial safety aspects - fire equipment, safety accessories etc.

(h) Facility security arrangements, fencing and personnel movement control etc.

(i) Removal and storage of contaminated material, if any.

(j) Medical assistance - first aid facility, location, periodic medical examination (once a year), medical facilities and treatment facilities for radiation incidents

B. MONITORING

(a) Radiation monitoring - Type of area monitors, sensitivity range, location, interlock alarm set levels

(b) Contamination monitoring - On line monitoring and sample measurement, method of collecting samples

(c) Personnel monitoring - Number of PM badges, procedure for their issuance, safe place for storage, etc.

C. OPERATION PROCEDURES

'Beam ON' procedures be established, documented and displayed in the console area

D. MAINTENANCE PROCEDURE FOR SAFETY SYSTEMS/ INTERLOCKS

(a) Periodic maintenance - Daily/weekly/monthly/quarterly/ yearly (items, procedures and schedules)

(b) Procedure for maintenance of cooing water used for cooling target beam line components, etc

(c) Procedure for maintenance of air cooling mechanism, maintenance and checking of alarm/ warning devices

E. EMERGENCY PLANNING AND PROCEDURES

(a) Organisational structure and communication links

(b) Name, address and telephone numbers of agencies to be contacted in case of emergency

(c) Emergency contact telephone/ telex nos. and address of

(i) Head of Institution

(ii) Facility-in-charge

(iii) Radiological safety officer (RSO)

(iv) Regulatory agency (AERB)

(v) Fire safety officer (Local)

(vi) Local fire station

(vii) Local police station

(viii) Local medical hospital, radiation therapy hospitals (nearest)

(d) Type of emergencies envisaged - Prevention/handling of emergencies, investigation methods, etc. during major leaks of water, explosion or fire or smoke, radiation emergency, crisis management in case of emergency, earthquake, floods, other natural calamities.

APPENDIX-5F

(Refer section 3.4.1.3, 3.4.1.4)

QUALITY ASSURANCE MANUAL (QAM) FOR MEDICAL CYCLOTRON FACILITIES

A. QUALITY ASSURANCE PROGRAMME DURING CONSTRUCTION OF MEDICAL CYCLOTRON FACILITIES

The Employer/Licensee shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of structures/systems/components related to civil, mechanical, electrical and instrumentation aspects of medical cyclotron facilities during construction. This programme should specify the means to ensure that all work is suitably planned, correctly performed and properly assessed in order to implement design intent in the construction.

The QA manual (QAM) should be prepared addressing the following aspects:

A.1 INTRODUCTION

This section should include applicability and scope of the QAM.

A.2 MANAGEMENT FUNCTIONS

This section should specify the management's policy statement and organisational plan. Organisational plan should be documented addressing the following aspects:

(a) Organisational structure

(b) Functional responsibility

(c) Levels of authority

(d) Lines of internal and external communication.

It should also address requirements related to competent manpower for construction activities of the facility. The functional responsibilities of all the personnel distinguishing task including their assigned administrative powers should be identified and documented.

The Licensee should formally identify a person to be responsible for implementation of QA programme during construction activities. Responsibilities of key personnel in the organisation should be defined in writing. The person appointed should have the necessary resources to discharge the following responsibilities:

(a) Ensuring that construction and installation work is carried out in accordance with design specifications, drawings, procedures and instructions, including the implementation of specified QA requirements.

(b) Ensuring that construction and installation work undertaken, including work by manufacturers/suppliers, is coordinated, conducted and completed in accordance with planned programmes.

(c) Controlling access to the construction site.

Appropriate controls reflecting safety regulations shall be established for all personnel, including suppliers and visitors. These shall be in line with applicable statutes and shall include arrangements for effective planning, organisation, monitoring and review of the preventive and protective measures. Management shall provide all necessary support to the contractor to ensure health and safety of the construction personnel and quality assurance requirements of construction.

A.2.1 Grading

A graded approach based on the relative importance to safety of each item, service or process should be adopted. Activities, which should be graded during construction include:

(a) Qualification of special construction processes and the personnel to carry them out

(b) Details and need for inspection plans

(c) Level of traceability of construction material and related records

(d) Level of in-process controls and need for hold points

(e) Complexity involved in equipment handling/erection and post-erection preservation.

A.2.2 Interfaces

Employer/Licensee should ensure that interface arrangements shall be agreed among the construction agencies, suppliers and other organisational units performing the work. These should be defined in writing and be included in relevant documents. Appropriate references of the same should be made in the QA programme. Handover/transfer responsibilities after completion of construction/installation to operating organisation.

A.3. PERFORMANCE FUNCTIONS

A.3.1 Document Control

Procedures for the preparation, review, approval, issue, modification and

control of documents should be established. The record system should be established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, storage, retrieval and disposal of construction records. Document control system should also include records of as-built condition of structures, systems and components.

A.3.2 Procurement Control

Measures shall be established and documented to ensure that relevant standards/specifications and other requirements necessary to assure adequate quality are included or referenced for procurement of items and services required during construction of medical cyclotron facilities.

Procurement requirements for assuring quality shall be covered by a procurement document. The document shall include items such as scope of work, technical requirements, and test, inspection and acceptance requirements.

Procedures for the preparation, review, approval, issue, modification and control of documents pertaining to activities affecting construction should be established. Document release and distribution system shall be established utilising up-to-date distribution lists. Individuals responsible for issue of documents shall be identified. Records important for construction include PSAR, civil structure design documents etc.

A.3.3 Supplier Evaluation and Selection

Supplier evaluation shall be carried out to assess the capability to provide items and services in accordance with the requirements of procurement document(s). The supplier evaluation includes as appropriate:

(a) evaluation of current technical capability, availability of expertise and resources,

(b) analysis of product samples, and

(c) review of historical quality performance data.

A.4 PROCESS CONTROL

Documented procedures should be established for all construction related activities of the medical cyclotron facilites such as receiving and storing components, civil construction, equipment erection, cleaning/flushing, inspection, testing, modification etc. Provision should be made for verification, review and audit of activities affecting quality of construction.

Site construction activities should be planned and documented in adequate detail and approved by designated persons/agencies. The plan shall define:

(a) The planned sequential order and duration of activities

(b) The resource allocation for each activity

(c) Work planning and supervision

(d) Implementation of safety requirement during construction including fire safety and first aid

Preventive maintenance and preservation of items in stores or installed should be carried out in accordance with manufacturers' recommendations and good engineering practices, and documented.

A.5 VERIFICATION FUNCTIONS

A.5.1 Verification Programme

A comprehensive documented verification programme to be prepared to assure conformance of construction of the medical cyclotron facilities as per the relevant codes and standards. Verification programme should comprise external (third party) as well as internal verification at specified stages/ periodicity.

A.5.2 Inspection and Test Controls

A plan for inspection and testing of the materials/components used for construction, should be established. These should include identification of characteristics to be checked, type of check, acceptance norms etc. These should specifically include identification of characteristics to be checked, type of check, acceptance norms etc. Provisions to test construction equipment, calibration of testing and measuring instruments etc. prior to their use need to be established.

A.5.3 Audit

Provisions need to be prescribed detailing the establishment and implementation of a comprehensive system of planned and documented audits to verify the implementation and effectiveness of the various elements of the quality assurance programme. It should address the audit performance, audit personnel, audit plan and audit timing etc. The requirement for QA audit and extent of its application should be based on the safety significance of the system.

A.6. CORRECTIVE FUNCTIONS

A.6.1 Non-conformity Control and Corrective actions

A system for the control of non-conformances and their corrective actions should be established. Non-conformances, deviations or inadequacies affecting quality should be identified and controlled. The persons responsible

for review and disposition of non-conformances should be identified. The programme should provide that appropriate action be taken to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective or incorrect material, equipment and any other non-conformances are identified, corrected and recurrences are prevented.

A.7. RECORDS

Records should be prepared and maintained to provide objective evidence of quality to meet the requirements of applicable codes, standards and specifications to include details such as:

(a) Certificates of each component from the supplier/manufacturer; and the test and inspection records

(b) Non-conformance reports, corrective/preventive actions carried out

(c) Certificates about raw material such as cement, sand, iron, steel used during constructions

(d) Records of the test results, acceptance criteria and as-built condition of structures.

(e) Design reports and drawings

(f) Safety analysis reports

The record system shall be established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, preservation/storage, retrieval, inspection and disposal of records after expiry of the specified retention period of non-permanent records.

B. QUALITY ASSURANCE DURING COMMISSIONING AND OPERATION OF MEDICAL CYCLOTRON

Employer/Licensee shall develop and implement a QA programme which describes the overall arrangements for the management, performance and assessment of the medical cyclotron facilites. This programme shall also provide means to ensure that all work is suitably planned, correctly performed and properly assessed. Procedures shall be defined by the Employer to ensure that the commissioning and operation of medical cyclotron facilites fulfils specified requirements.

The QAM should be prepared in following format addressing the different aspects of the facility.

B.1. INTRODUCTION

This section should include Applicability and Scope of the QAM.

B.2. MANAGEMENT FUNCTIONS

This section should specify the management's policy statement and organisation plan. Organisational plan should be documented addressing the following aspects:

(a) Organisational structure

(b) Functional responsibility

(c) Levels of authority

(d) Lines of internal and external communication.

It should also address requirements related to availability of competent manpower for commissioning and operation of the facility. The functional responsibilities of all the personnel distinguishing task including their assigned administrative powers should be identified and documented. The necessary resources required by these personnel to discharge the following responsibilities need to be identified:

(a) Commissioning and operation of the facility is carried out in accordance with approved procedures, design specifications, designers' instructions.

(b) Controlling access to the operating facility.

Procedures need to be documented for formal reviews of QA programme by management as often as necessary or any changes in the regulatory requirements that may have been introduced after the previous approval of QA programmes. Identification and control of compliance with applicable codes, standards, specification and practices; acceptance criteria (qualitative and/or quantitative as appropriate) for determining satisfactory completion of the commissioning and operation activity should be described in the QAM.

B.2.1 Interfaces

The interface arrangements should be agreed with the licensee and various agencies involved (namely design, construction, commissioning, operation, decommissioning, AERB and statutory agencies as applicable). Handover/ transfer responsibilities after completion of construction/ installation to operating organisation.

B.3 PERFORMANCE FUNCTIONS

B.3.1 Document Control

(a) Procedures for the preparation, review, approval, issue, modification and control of documents pertaining to activities affecting commissioning and operation should be established.

(b) Document release and distribution system shall be established utilising up-to-date distribution lists. Individuals responsible for issue of documents shall be identified.

(c) Documents important for commissioning and operation include among others, final safety analysis report (FSAR), acceptance test report (ATR), and radiation protection manual (RPM), commissioning reports and technical specifications for operation.

(d) Procedures for making interface with various components and systems should be prepared. Verification and validation of software used for operational control should be done by the independent agencies.

B.3.2 Process Control

B.3.2.1 Commissioning Control

Procedures should be established to ensure that appropriate tests are performed during commissioning to demonstrate that design intent and, regulatory and other statutory requirements are met. Satisfactory demonstration of functional capability of safety systems is a prerequisite for considering the medical cyclotron facilites to be suitable for the operating phase.

Measures shall be established to ensure that all commissioning activities including beam extraction, transport and dumping are planned, controlled and implemented in accordance with approved documents such as procedures, instructions and checklists, and results documented.

Commissioning activities shall commence only after due completion of respective construction activities supported by certified documents. Inspection and surveillance shall be performed by the facility and documented to verify compliance with specification requirements.

Measures shall be established to identify, review, resolve and document all non-conformances and design changes.

A system for audit of commissioning, follow-up and record of corrective actions shall be established.

B.3.2.2 Operation Control

Documented procedure shall be established for safe operation of the medical cyclotron facilites in accordance with the design intent and specified operational limits.

Provisions should be included to ensure interface among agencies for operation, maintenance, technical services, plant management, design, inspection, testing, verification and audit.

Provision shall exist for regular verification of operation activities related to safety. Preventive and maintenance schedule should be prepared for all safety systems as per the applicable codes.

Inspection and testing/surveillance during operation of safety equipment as well as subsequent to maintenance, modification or procedural changes should be performed to specified requirements and documented.

B.4 VERIFICATION FUNCTIONS

B.4.1 Verification Programme

A comprehensive documented verification programme should be prepared and verification conducted accordingly to assure conformance of commissioning and operation of the medical cyclotron facilites as per the relevant specified codes and procedures. Verification programme should comprise external as well as internal verification

B.4.2 Inspection and Test Controls

Measures should be established to ensure that testing and measuring devices (e.g. radiation survey meters, area monitors, tools, gauges and other devices) used in determining conformance to acceptance criteria are of proper range, type, accuracy and precision.

Testing and measuring devices should be controlled, calibrated and adjusted at specified intervals, or before use, to maintain accuracy within necessary limits.

Controls shall be established to ensure proper handling, storage and use of calibrated instruments.

B.4.3 Audit

Provisions need to be prescribed detailing the establishment and implementation of a comprehensive system of planned and documented audits to verify the implementation and effectiveness of the various elements of the quality assurance programme. It should address the audit performance, audit personnel, audit plan and audit timing etc. The requirement for QA audit and extent of its application should be based on the safety significance of the system.

B.5 CORRECTIVE FUNCTIONS

B.5.1 Non-conformity Control and Corrective Actions

A system for the control of non-conformances and their corrective actions should be established. Non-conformances, deviations or inadequacies affecting quality should be identified and controlled. The persons responsible

for review and disposition of non-conformances should be identified. The programme should provide appropriate actions to be taken to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective or incorrect material, equipment and any other non-conformance are identified and corrected.

Preventive actions should also be identified based on the review of non-conformances.

B.6 QA RECORDS

Records should be prepared and maintained to provide objective evidence of quality to meet the requirements of applicable codes, standards and specifications.

Records should include:

(a) results of reviews, inspections, tests and audits,

(b) operation logs,

(c) non-conformance reports, repairs carried out,

(d) training, qualifications and certification of personnel,

(e) information pertaining to 'as-built' condition of items in the plant,

(f) copies of design drawings, PSAR, FSAR, RPM, QAM, licence/ consents/certificates, etc.,

(g) radiation dose records, emergency exercises and maintenance records.

The record system shall be established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, preservation/storage, retrieval, inspection and disposal of records after expiry of the specified retention period of non-permanent records.

(APPENDICES 6A.6B,6D, 6E, 6F ARE FOR IFRT)

APPENDIX-6A

(Refer section 3.4.3.2)

FORMAT FOR SITE ASSESSMENT REPORT OF INTEGRATED FACILITY FOR RADIATION TECHNOLOGY (IFRT)

GEOLOGICAL AND GEOTECHNICAL INVESTIGATIONS

1. Site investigations for Integrated Facility for Radiation Technology are necessary to determine the geotechnical characteristics of the site that affect the design, performance and safety of the IFRT. The investigations should produce the information needed to define the overall site geology to a degree that is necessary for an understanding of the subsurface conditions in order to ensure stability against natural hazards like earthquake, flood etc.

2. Site investigations should also provide information needed to define ground water conditions as well as the geotechnical parameters needed for analysis and design of foundations. These include parameters to evaluate the subsurface characteristics for safe engineering of IFRT, such as bearing capacity of foundation material, lateral earth pressure, the stability of cuts and slopes in rock, the effects of earthquake induced motions transmitted through underlying deposits on the response of soils and structure (including the potential for inducing liquefaction in soils) and also those needed to estimate the expected settlement of the structure.

3. Requirements of geotechnical investigations depend on the site specific conditions. However, the following investigations are the minimum, which should be carried out for the evaluation of parameters required for safe design:

   (a) Field Work

      (i) Drilling of bore holes

      (ii) Collection of disturbed/undisturbed soil and water samples

      (iii) Standard penetration tests

      (iv) Plate load tests

      (v) Electrical receptivity tests

   (b) Laboratory Tests on Soil Samples

      (i) Grain size analysis (Coarse and fine)

      (ii) Consistency limit test

(iii) Specific gravity of soil

(iv) Proctor density test

(v) Permeability test

(vi) Consolidation test

(vii) Modulus of elasticity and poisons ratio

(viii) Unconfined/confined compression test

(ix) Direct shear test (consolidated drained)

(x) Chemical tests on soil

(c) Laboratory Tests on Rock Samples

(i) Petrographic study

(ii) Porosity

(iii) Unconfined/confined compression test

(iv) Modulus of elasticity and poisons ratio

(d) Test on Ground Water Samples

Chemical analysis of ground water sample

4. Following requisites should be met in connection with geotechnical investigations:

(i) Prior to commencement of geotechnical investigation, a comprehensive plan of the work should be chalked out. Geological status of the site should be examined based on available information. Additional investigation may be required if site specific conditions warranted so for the safety of the plant.

(ii) Minimum depth of boreholes should be three times the larger dimension of the footing.

(iii) Number of boreholes should be such that subsurface profile of the plant area can be drawn with reasonable certainty in any direction. At least four data points should be available, in any direction, for plotting of sub surface profile.

(iv) Geological mapping of the foundation pit should be carried out after completion of excavation.

(v) Appropriate rectification/stabilisation measures shall be adopted if it is found necessary after excavation.

4.1 Report on geotechnical investigation with the following details:

(i) Geological status of the site based on available information

(ii) Details of bore logs and trial pit logs

(iii) Permeability test results

(iv) Ground water observations

(v) Results of soil and rock tests

(vi) Chemical test results of water

(vii) Sub surface profiles

(viii) Electrical resistivity logging

(ix) Petrographic study results

(x) Evaluation of foundation design parameters

APPENDIX-6B

(Refer section 3.4.3.3)

FORMAT OF THE PRELIMINARY SAFETY ANALYSIS REPORT FOR INTEGRATED FACILITY FOR RADIATION TECHNOLOGY (IFRT)

[PSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer)]

A. INTRODUCTORY INFORMATION

1(a)	Name of the utility/institution setting up the IFRT	:
	Mode of communication	:
	Telephone No.	:
	Fax. No.	:
	E-mail	:
(b)	Postal address of the utility/institution	:
2.	Name, designation and address of the applicant officially representing the utility/institution	:
3.	Name and address of the designer(s) of IFRT (with e-mail and fax)	:
4.	Name and address of the manufacturer of IFRT (with e-mail and fax)	:
5.	Project Details	:
	(a) Type of nuclear/radiation facility	:
	(b) Objective/purpose	:
	(c) Nature of the facility	:
6.	Design class of hot cell structure	:
7.	Type of radioactive sources to be handled	:
8.	The Maximum activity to be handled in the facility	: ———— PBq (——— kCi)
9.	State whether similar plant is operating elsewhere by applicant	:

B. TECHNICAL DESCRIPTION OF THE INTEGRATED FACILITY FOR RADIATION TECHNOLOGY (IFRT)

1. Brief Description of the Facility

2. Design details : Design philosophy, defence-in-depth concept, redundancy. independence and diversity in the design, built-in-safety features provided in the design.

3. Site of Installation of IFRT : Geotechnical and geological information, Field investigations, water table, weather, soil profile, laboratory investigations, allowable bearing pressure/safe bearing capacity, chemical analyses of water and soil, site lay out, documentary evidence of the ownership of the site, Regulatory Consent issued by AERB for site approval

   - Structural details - type and depth of foundation and precautions against flooding
   - Seismic considerations and IS Tec. doc. proposed to be followed for construction
   - Buildings and residential complexes, occupancy, etc. within 30m radius of the facility location; give layout and height of the adjacent tallest building in the vicinity of 100 m.
   - Access roads to the facility : road strength and width to carry transport flasks containing radioation sources (culvert/bridge, if any, on the way - specify)
   - Any additional information

4. Biological Shield

   - Sketch giving details of shielding wall surrounding the hot cell and its thickness, openings, voids, reinforcements, embedment etc. in the biological shield.
   - Sketch of low bay area design details
   - Shield material, density, quality assurance during construction
   - Maximum and minimum shield thickness, roof thickness

- Dose rate profiles anticipated at various locations: (maximum and minimum values). Indicate them on a sketch of the facility - control room, roof, access doors, openings and where personnel are expected to be stationed for work or otherwise.
- Maximum dose rate anticipated at various locations : (Indicate also in a sketch)
- Shielding thickness of lead glass window and its light transmission efficiency

5. Different Systems of the High Bay Area and Safety Systems/Interlocks

5.1 Hot cell

- Design details of Hot Cell with drawing providing all dimensions
- Details of SS lining inside wall of Hot cell and roof.

Source cask handling crane

- Technical specification of components of EOT cranes to be installed for source cask handling
- Details of mechanical arrangement (include drawing) of source handling cranes.
- No. and locations of the cranes
- Load carrying capacity of the crane, prevention of source cask from crane, Dimensions of wire used in crane.
- Safety provisions for operational controls and interlocking mechanism.

Master slave manipulator (MSM)

- Technical details of master-slave manipulator (MSM)
- Operating procedures of MSM
- Lifting capacity of MSM
- Installation and testing procedures

5.2 Water pool

- Detailed sketch or drawing of water pool for source storage showing dimensions, water proofing, lining details, penetrations, piping,

fittings, embedment, locations of level measuring devices, inlet-outlet water piping

- Water level monitoring system for maximum-minimum water levels, normal level and abnormal levels; Total volume of water.
- Buffer storage tank details, overhead water storage tank details, provision of emergency water discharge into pool, provision of overflow/ drainage of water from the pool to any municipal sewerage lines.
- Municipal water supply quality - TSD, TSS, hardness and conductivity
- Rate of water supply in emergency
- Quantity of water maintained in pool, conductivity maximum/minimum, method of assuring water quality, PH of water.
- Leakage from pool - prevention and assessment
- Normal evaporation water losses from pool with and without ventilation related to humidity and temperature
- System to prevent water flooding in the cell
- Method of cleaning water pool
- Pool grill cover strength - prevention of accidental fall into the pool - during routine operations like source container handling operations
- Pool bottom surface plan - loading conditions, provisions for transport container, intermediate source storage, if any.
- Corrosion- intermetallic/galvanic, specification of metals coming in contact with pool water prevention thereof.
- Maximum water height above sources when it is taken out from storage containers under water and expected radiation profiles on the pool surface, both at normal and abnormal water levels
- Underwater lights, location, voltage use, prevention of shocks and electrocution.

		- Prevention of accidental fall of person and material into the pool
		- Prevention of syphoning action in pool
		- Prevention of accidental entry into the room, when the water level in the pool is low and when the sources are in storage position.
		- DM water plant capacity and type (anion, cation, mixed bed etc.)
5.3	Ventilation	- Volume of hot cell, including and excluding high bay and low bay area
		- Ventilation rate provided, anticipated minimum air changes in the hot cell, high bay area, water pool, low bay area
		- Location and routing of ventilated ducts, fans, duct size, etc. (give sketch), air handling units, HEPA filters.
		- Methods of monitoring ventilation and action on ventilation failure
		- Location of ventilation exhaust and the height of stack above the hot cell roof. Prevention of water flooding through ventilation ducts from roof (sketch)
		- Ozone concentration (maximum) anticipated in the cell with ventilation ON and OFF. Time duration in minutes for safe concentration of ozone in the cell (0.1ppm) after the exhaust is switched off.
		- Prevention of entry to the hot cell when unsafe limit of ozone concentration exists
		- Details of safety interlock interlocks to retract in case of ventilation failure
		- Provisions for standby ventilation exhaust fans, if any
5.4	Access door	- Design details of access door with material used, thickness, its shielding adequacy
		- Information on safety interlocks provided to prevent human access to the hot cell when the radiation sources are handled.

- Interference to interlocks and source safety and protection against exposure to radiation or accidental entry.
- Cautions, visual display and audio alarm against entry into the cell

5.5 Low bay area
- Purpose of the area
- Design details of the area
- Access control to the this area

6. Radioactive Waste and DecontAmination:
- Different types of waste generated; provision and procedure made for the safe disposal of the same
- Details of decontamination procedures for hot cell, tools used in hot cell, flasks and floors, washbasins
- Collection and storage of solid waste, sump with stainless steel (SS) lining for collection of liquid waste
- Discharge methods of gaseous waste from hot cell, high bay area, filters used and monitoring methods of gaseous discharge to atmosphere.

7. Radiation Monitoring Instruments:
- Personnel monitoring, contamination monitoring and area monitoring equipment, personnel protective equipment
- Locations of area monitors, zone monitors and the preset values
- Interlocking mechanism of radiation area monitors with access into the Hot cell.
- Different types of radiation survey meters

8. Detailed Access Control Procedure and Operating Procedures in the Hot Cell :

9. Fire Detection System :
- Detection methods of excessive temperature rise, smoke, fire, and interlock if any in cell area, high bay and low bay area.

- Type of detectors used and their sensitivity, location of detectors.
- Validity certification for detectors
- Direction escape route for fire - fire fighting system, fire hydrants, extinguishers, dry risers, etc.

10. Control System :

- Give control system description in brief
- Voltage and currents employed, emergency power standby power, battery backup if any,
- Control logic and flow of command
- Interlock systems for fail-safe operation

11. Audio-visual Alarms/Anunciators :

- Describe the list of audio visual alarms provided, their location, purpose and effectiveness - against exposure to radiation, fire, smoke, toxic gases, radioactive gaseous waste discharge etc.

12. Electrical System and Emergency Power Supply :

- Provisions made when power failure occurs, ratings of normal and emergency power systems, status of systems like manipulators and cranes
- Emergency power supply caters to cell ventilation, access door, cell instruments, remote hoist, cell lights and emergency alarms

13. Design Basis Accident Analysis and Safety Provisions:

Abnormal events mentioned below shall be analysed and methods for achieving safety under these events shall be described.

(a) Release of radioactivity or accidental exposures in hot cell and water pool area

(b) Jamming of master-sleeve manipulators

(c) Failure of crane

(i) Failure of cranes brakes during handling of the flask cover inside cell

(ii) Breaking of wire rope of overhead crane

(d) Slug(s) is missing or rolled from the hot cell table

(e) Heavy contamination of hot cell, contamination of pool water pool

(f) High activity of gaseous waste discharge in air

(g) Failure of access door interlocks

(h) Fire in the IFRT

(i) Failure of ventilation system

(j) Failure of power supply

(k) Failure of PLC

(l) Earthquake at the IFRT site

(m) Flooding of hot cell with water

(n) Leakage of water from pool

(o) Breakage of pool lining

(p) Fall of person in the water pool

The designer/manufacturer shall carry out such analysis to demonstrate means provided to prevent and handle above situations safely.

14. Decommissioning of IFRT:

- Procedure to be followed when decision is made to close down the facility permanently.
- Provisions including adequate financial arrangement for safe disposal of spent/disused sources.

APPENDIX-6D

(Refer section 3.4.3.4)

FORMAT OF THE FINAL SAFETY ANALYSIS REPORT FOR INTEGRATED FACILITY FOR RADIATION TECHNOLOGY (IFRT)

[FSAR should be submitted to AERB in this format, duly signed by Head of the organisation (employer) along with the application for obtaining the licence for commissioning/operation of IFRT]

A. INTRODUCTORY INFORMATION

1(a)	Name of the utility/institution setting up the IFRT	:	
	Mode of communication	:	
	Telephone No.	:	
	Fax. No.	:	
	E-mail	:	
(b)	Postal address of the utility/ institution	:	
2.	Name, designation and address of the applicant officially representing the utility/institution	:	
3.	Name and address of the designer(s) of IFRT (with e-mail and fax)	:	
4.	Name and address of the manufacturer of IFRT (with e-mail and fax)	:	
5.	Project Details :		
	(a) Type of nuclear radiation facility	:	
	(b) Objective/purpose	:	
	(c) Nature of the facility	:	
6.	Design class of hot cell structure	:	
7.	Type of radioactive sources to be handled	:	
8.	The maximum activity to be handled in the facility	:	——— PBq (——— kCi)
9.	State whether similar plant is operating elsewhere by applicant	:	

B. TECHNICAL DESCRIPTION OF THE INTEGRATED FACILITY FOR RADIATION TECHNOLOGY (IFRT)

1. Brief description of the facility

2. Design details : Design philosophy, defence-in-depth concept, redundancy. independence and diversity in the design, built-in-safety features provided in the design.

3. Site of installation of IFRT: Geotechnical and geological information, Field investigations, water table, weather, soil profile, laboratory investigations, allowable bearing pressure/safe bearing capacity, chemical analyses of water and soil, site lay out, documentary evidence of the ownership of the site, Regulatory Consent issued by AERB for site approval

   - Structural details - type and depth of foundation and precautions against flooding
   - Seismic considerations and IS Tec. doc. 1893 (curent revision) proposed to be followed for construction
   - Buildings and residential complexes, occupancy, etc. within 30m radius of the facility location; give layout and height of the adjacent tallest building in the vicinity of 100m.
   - Access roads to the facility : road strength and width to carry transport flasks containing radioation sources (culvert/ bridge, if any, on the way - specify)
   - Any additional information

4. Biological shield of hot cell

   - Sketch giving details of shielding wall surrounding the hot cell and its thickness, openings, voids, reinforcements, embedment etc. in the biological shield.
   - Sketch of low bay area design details
   - Shield material, density, quality assurance during construction
   - Maximum and minimum shield thickness, roof thickness

- Dose rate profiles anticipated at various locations: (maximum and minimum values). Indicate them on a sketch of the facility - control room, roof, access doors, openings and where personnel are expected to be stationed for work or otherwise.
- Maximum dose rate anticipated at various locations : (Indicate also in a sketch)
- Shielding thickness of lead glass window and its light transmission efficiency

5. Different systems of the high bay area and safety systems/interlocks

5.1 Hot cell

- Design details of hot cell with drawing providing all dimensions
- Details of SS lining inside wall of Hot cell and roof.

Source cask handling crane

- Technical specification of components of EOT cranes to be installed for source cask handling
- Details of mechanical arrangement (include drawing) of source handling cranes.
- No. and locations of the cranes
- Load carrying capacity of the crane, prevention of accidental fall of source cask from crane, Dimensions of wire used in crane.
- Safety provisions for operational controls and interlocking mechanism.

Master slave manipulator (MSM)

- Technical details of master-slave manipulator (MSM)
- Operating procedures of MSM
- Lifting capacity of MSM
- Installation and testing procedures

5.2 Water pool

- Detailed sketch or drawing of water pool for source storage showing dimensions, water proofing, lining details, penetrations, piping,

fittings, embedment, locations of level measuring devices, inlet-outlet water piping

- Water level monitoring system for maximum-minimum water levels, normal level and abnormal levels; total volume of water.
- Buffer storage tank details, overhead water storage tank details, provision of emergency water discharge into pool, provision of overflow/drainage of water from the pool to any municipal sewerage lines.
- Municipal water supply quality - TSD, TSS, hardness and conductivity
- Rate of water supply in emergency
- Quantity of water maintained in pool, conductivity maximum/minimum, method of assuring water quality, PH of water.
- Leakage from pool - prevention and assessment
- Normal evaporation water losses from pool with and without ventilation related to humidity and temperature
- System to prevent water flooding in the cell
- Method of cleaning water pool
- Pool grill cover strength - prevention of accidental fall into the pool - during routine operations like source container handling operations
- Pool bottom surface plan - loading conditions, provisions for transport container, intermediate source storage, if any.
- Corrosion-intermetallic/galvanic, specification of metals coming in contact with pool water prevention thereof.
- Maximum water height above sources when it is taken out from storage containers under water and expected radiation profiles on the pool surface, both at normal and abnormal water levels
- Underwater lights, location, voltage use, prevention of shocks and electrocution.

		-	Prevention of accidental fall of person and material into the pool
		-	Prevention of syphoning action in pool
		-	Prevention of accidental entry into the room, when the water level in the pool is low and when the sources are in storage position.
		-	DM water plant capacity and type (anion, cation, mixed bed etc.)
5.3	Ventilation	-	Volume of hot cell, including and excluding high bay and low bay area
		-	Ventilation rate provided, anticipated minimum air changes in the hot cell, high bay area, water pool, low bay area
		-	Location and routing of ventilated ducts, fans, duct size, etc. (give sketch), air handling units, HEPA filters.
		-	Methods of monitoring ventilation and action on ventilation failure
		-	Location of ventilation exhaust and the height of stack above the hot cell roof. Prevention of water flooding through ventilation ducts from roof (sketch)
		-	Ozone concentration (maximum) anticipated in the cell with ventilation ON and OFF. Time duration in minutes for safe concentration of ozone in the cell (0.1ppm) after the exhaust is switched off.
		-	Prevention of entry to the hot cell when unsafe limit of ozone concentration exists
		-	Details of safety interlock interlocks to retract in case of ventilation failure
		-	Provisions for standby ventilation exhaust fans, if any
5.4	Access Door	-	Design details of access door with material used, thickness, its shielding adequacy
		-	Information on safety interlocks provided to prevent human access to the hot cell when the radiation sources are handled.

- Interference to interlocks and source safety and protection against exposure to radiation or accidental entry.
- Cautions, visual display and audio alarm against entry into the cell

5.5 Low Bay Area
- Purpose of the area
- Design details of the area
- Access control to the this area

6. Radioactive Waste and Decontamination:
- Different types of waste generated; provision and procedure made for the safe disposal of the same
- Details of decontamination procedures for hot cell, tools used in hot cell, flasks and floors, washbasins
- Collection and storage of solid waste, sump with stainless steel (SS) lining for collection of liquid waste
- Discharge methods of gaseous waste from hot cell, high bay area, filters used and monitoring methods of gaseous discharge to atmosphere.

7. Radiation Monitoring Instruments:
- Personnel monitoring, contamination monitoring and area monitoring equipment, personnel protective equipment
- Locations of area monitors, zone monitors and the preset values
- Interlocking mechanism of radiation area monitors with access into the Hot cell.
- Different types of radiation survey meters

8. Detailed Access Control Procedure and Operating Procedures in the Hot Cell :

9. Fire Detection System :
- Detection methods of excessive temperature rise, smoke, fire, and interlock if any in cell area, high bay and low bay area.

- Type of detectors used and their sensitivity, location of detectors.
- Validity certification for detectors
- Direction escape route for fire - fire fighting system, fire hydrants, extinguishers, dry risers, etc.

10. Control System :

- Give control system description in brief
- Voltage and currents employed, emergency power standby power, battery backup if any,
- Control logic and flow of command
- Interlock systems for fail-safe operation

11. Audio-visual Alarms/ Anunciators :

- Describe the list of audio visual alarms provided, their location, purpose and effectiveness - against exposure to radiation, fire, smoke, toxic gases, radioactive gaseous waste discharge etc.

12. Electrical System and Emergency Power Supply :

- Provisions made when power failure occurs, ratings of normal and emergency power systems, status of systems like manipulators and cranes
- Emergency power supply caters to cell ventilation, access door, cell instruments, remote hoist, cell lights and emergency alarms

13. Design Basis Accident Analysis and Safety Provisions:

Abnormal events mentioned below shall be analysed and methods for achieving safety under these events shall be described.

(a) Release of radioactivity or accidental exposures in hot cell and water pool area

(b) Jamming of Master-sleeve manipulators

(c) Failure of crane

(i) Failure of cranes brakes during handling of the flask cover inside cell

(ii) Breaking of wire rope of overhead crane

(d) Slug(s) is missing or rolled from the hot cell table

(e) Heavy contamination of hot cell, contamination of pool water pool

(f) High activity of gaseous waste discharge in air

(g) Failure of access door interlocks

(h) Fire in the IFRT

(i) Failure of ventilation system

(j) Failure of power supply

(k) Failure of PLC

(l) Earthquake at the IFRT site

(m) Flooding of hot cell with water

(n) Leakage of water from pool

(o) Breakage of pool lining

(p) Fall of person in the water pool

The designer/manufacturer shall carry out such analysis to demonstrate means provided to prevent and handle above situations safely.

14. Acceptance test reports after installation of safety systems:

(a) Dose rate profile measurement in the entire facility, strength of radiation source.

(b) Performance of radiation monitoring and control interlocks

(c) Performance of personnel monitors

(d) Dose concentration measurement with and without ventilation fan functioning

(e) Assurance and effectiveness of control functions and interlocks

Sketch of the facility and location of dose rate monitoring points and maximum/minimum dose rate levels should include :

(a) Name of persons carrying out the measurement

(b) Instrument used in the radiation survey

(c) Confidence limits of radiation level measurements

(d) Background radiation levels in each location of measurement

15. Decommissioning of IFRT:

Procedure to be followed when decision is made to close down the facility permanently.

Provisions including adequate financial arrangement for safe disposal of spent/ disused sources.

16. List of critical safety components:

The manufacturer of IFRT shall provide to the operating organisation a complete list of components as per following classification:

Group A : Replaceable by manufacturer or with his explicit Consent

Group B : Replaceable to exact specifications

Group C : Replaceable without restriction

APPENDIX-6E

(Refer section 3.4.3.4)

RADIATION PROTECTION MANUAL OF INTEGRATED FACILITY FOR RADIATION TECHNOLOGY (IFRT)

(OPERATION, MAINTENANCE AND EMERGENCY ASPECTS)

A. ADMINISTRATION AND SAFETY ASSURANCE

(a) Administrative hierarchy/organisational set up

(b) Authorised personnel - Training and qualification of facility personnel, their knowledge in radiation safety, responsibilities of each of personnel, their availability in adequate number, policies in case of long leave/absence of certified personnel

(c) Local safety committee : constitution, functions and responsibilities

(d) Procedures for reporting to the regulatory agency on unusual occurrences and periodic radiation safety status

(e) Procedures in case of change or repairs of H.V. system, safety system/ interlocks, certification of log book entry by RSO

(f) Records of maintenance - maintenance schedule, radiation monitoring, and calibration of survey meters, etc.

(g) Control and distribution of hot cell/facility keys

(h) Industrial safety aspects - fire equipment, safety accessories etc.

(i) Facility security arrangements, fencing and personnel movement control etc.

(j) Removal and storage of contaminated material, if any.

(k) Medical assistance - First aid facility, location, periodic medical examination (once a year), medical facilities and treatment facilities for radiation incidents

B. MONITORING

(a) Radiation monitoring - Type of area monitors, sensitivity range, location, interlock alarm set levels (DM plant/unloading bay, control room)

(b) Contamination monitoring - On line monitoring and sample measurement, method of collecting samples of pool water, accessible surfaces of source raise system

(c) Personnel monitoring - Number of PM badges, procedure for their issuance, safe place for storage, etc.

C. OPERATION PROCEDURES

(a) Master-slave manipulators

(b) External transfer drawer

(c) Cask handling cranes

D. MAINTENANCE PROCEDURE FOR SAFETY SYSTEMS/ INTERLOCKS

(a) Periodic Maintenance - Daily/weekly/monthly/quarterly/yearly (Items, procedures and schedules)

(b) Procedure for maintenance of D.M. water supplies

(c) Maintenance checking of alarm/ warning devices

E. EMERGENCY PLANNING AND PROCEDURES

(a) Organisational structure and communication links

(b) Name, address and telephone numbers of agencies to be contacted in case of emergency

(c) Emergency contact telephone/ telex nos. and address of

(i) Head of Institution

(ii) Facility-in-charge

(iii) Radiological safety officer (RSO)

(iv) Regulatory agency (AERB)

(v) Fire safety officer (Local)

(vi) Local fire station

(vii) Local police station

(viii) Local medical hospital, radiation therapy hospitals (nearest)

(d) Type of emergencies envisaged - Prevention/handling of emergencies, investigation methods, etc. during major leaks of water, explosion or fire or smoke, radiation emergency, crisis management in case of emergency, earthquake, floods, other natural calamities.

APPENDIX-6F

(Refer section. 3.4.3.4)

QUALITY ASSURANCE MANUAL (QAM) FOR INTEGRATD FACILITY FOR RADIATION TECHNOLOGY (IFRT)

A. QUALITY ASSURANCE PROGRAM (QAP)

An adequate quality assurance (QA) program, including appropriate quality control measures, shall be established for the design and manufacture, construction, operation and industrial safety of integrated facility for radiation technology (IFRT). Compliance with the ISO 9000 or IS 14000 series is desirable. Records of all QA procedures shall be maintained for the entire life of the IFRT.

B. QUALITY ASSURANCE IN DESIGN OF IFRT:

1.1 Quality Assurance Programme

The responsible organisation shall develop and implement a QA programme, which describes the overall arrangements for the management, performance and assessment of the IFRT. This programme should also provide the means to ensure that all work is suitably planned, correctly performed and properly assessed. Procedures should be defined by the responsible organisation for control of design activities to ensure that the design of the IFRT fulfils specified requirements.

1.2 Grading

A graded approach based on the relative importance to radiological safety of each item, service or process shall be used.

1.2.1 The design activities, which could be graded, include:

(a) The level and detail of analysis of design

(b) The need for and level of design review and approval

(c) The degree of verification of design

(d) The controls applied to design change

(e) The detail of design records and their retention times

(f) The need for alternative calculations to be carried out

(g) The need to qualify or test the design output

(h) The need for qualification tests for design

1.3 Organisation

The responsible organisation shall identify the principal designer who has responsibility for specifying the design requirements and for approving the design output on its behalf.

1.4 Interfaces

Interface arrangements shall be agreed between organisations involved in design activities. Interface that should be addressed are for example:

(a) Interfaces between technical disciplines within the design organisation

(b) Principal designer with:

  (i) Siting organisation

  (ii) Construction organisation

  (iii) Commissioning organisation

  (iv) Operating organsiation

  (v) Decommissioning organsiation

  (vi) Regulatory body

1.5 Planning

Plans used in design should include the following where appropriate:

(a) Scope of work, including work carried out by other organisations

(b) Design methods

(c) Software requirements (software to be developed or software codes to be validated for use)

(d) Test requirements, including qualification tests, prototype, seismic, etc.

(e) Design review, verification and validation requirements

(f) Resource requirements

(g) Special training requirements

(h) Schedule of activities

(i) Points at which checks of the design process will take place and the frequency of such checks

(j) Inputs from safety, reliability, maintainability, human factors, standardisation and other disciplines.

1.6 Non-conformance Control and Corrective Actions

A system for the control of non-conformances and their corrective actions should be established.

1.7 Document Control and Records

Procedures for the preparation, review, approval, issue, modification and control of documents shall be established.

C. QUALITY ASSURANCE DURING CONSTRUCTION OF CIVIL ENGINEERING STRUCTURES OF IFRT

1.1 Quality Assurance Programme

The responsible organisation shall develop and implement a QA programme, which describes the overall arrangements for the management, performance and assessment of civil engineering structures for IFRT during construction. This programme should provide the means to ensure that all work is suitably planned, correctly performed and properly assessed in order to implement design intent in the construction.

1.2 Grading

Work procedures should be defined for control of construction activities at site and it should be reviewed and approved before use. A graded approach based on the relative importance to safety of each item, service or process shall be used. The construction activities, which could be graded, include:

(a) Qualification of special construction processes and the personnel to carry them out

(b) Detail and need for inspection plans

(c) Level of traceability

(d) Level of in process controls and need for hold points

(e) Records and archived samples

1.3 Organisation

The responsible organisation should formally appoint a person on its staff to be responsible for construction activities. The appointed person should have the necessary resources within the construction organisation to discharge the following responsibilities:

(i) Ensuring that construction and installation work is carried out in accordance with design specifications, drawings, procedures and instructions, including the implementation of specified QA requirements.

(ii) Ensuring that construction and installation work undertaken, including work by suppliers, is co-ordinated, conducted and completed in accordance with planned programmes of work.

(iii) Controlling access to the construction site.

1.4 Interfaces

Interface arrangements should be agreed between the construction organisation, suppliers and other organisational units performing the work. They should be defined in writing and should be included in procurement documents. Interfaces that should be addressed are:

(a) Construction organisation with supplier

(b) Construction organisation with operating organisation

(c) Suppliers with sub-suppliers

(d) Construction organisation with the principal designer

(e) Construction organisation with siting organisation

(f) Interfaces between construction organisation and the regulatory body

1.5 Planning

All construction activities should be planned. The plan should define:

(a) The activities to be performed in manageable units

(b) The planned sequential order and duration of these activities

(c) The resource allocation for each activity

1.6 Non-conformance Control and Corrective Actions

The non-conformances that are required to be reported to the construction organisation should be identified. Suitable corrective action should also be recorded.

1.7 Document Control and Records

Procedures for the preparation, review, approval, issue, modification and control of documents should be established. The record system should be established which includes the arrangements and responsibilities for the categorisation, receipt, indexing, storage, retrieval and disposal of construction records. Records should include all those, which record the as-built condition of structures, systems and components.

1.8 The civil engineering construction should be carried out following the relevant Indian standard codes/specifications. Quality of civil construction should satisfy the requirements of appropriate Indian standard codes/specifications

and that of product specifications. Typical list of topics to be covered in QA programme for the civil engineering construction is given as below:

(a) Formwork, shuttering and pre-construction activities

(b) Concreting and curing

(c) Post concrete inspection

(d) Repair

(e) Fabrication and erection of embedded parts (EP)

(f) Fabrication and erection of structural steel

(g) Brick work

(h) Grounding network

(i) Painting for steel structure

(j) Finishing and repair control

(k) Painting of main plant structures/concretes faces

(l) List of procedures

(m) Miscellaneous items such as organisation chart of QA civil, flow chart showing production of good uniform concrete, schematic diagram on procedure of concrete mix design etc.

(n) Density of the concrete in construction of walls and roof of irradiation cell shall be maintained at least 2.5 g/cc and it shall be ensured that no voids or air gaps are present during concrete filling.

D. INDUSTRIAL SAFETY DURING CONSTRUCTION OF CIVIL ENGINEERING STRUCTURES FOR IFRT

A policy reflecting industrial safety regulations should be established for all personnel, including suppliers and visitors. These should be in line with the prevailing factory rules. The policy should include arrangements for the effective planning, organisation, monitoring and review of the preventive and protective measures.

1.1 Management should provide all necessary support to the Contractor to ensure health and safety of the construction personnel.

1.2 Job hazard analysis should be prepared before the start of construction.

1.3 Industrial safety at the construction site should be enforced by a safety officer.

1.4 All construction equipment should be tested prior to its use.

1.5 Construction personnel should be given orientation program on industrial safety.

1.6 Accident statistics should be maintained at the construction site.

1.7 Appropriate arrangements for fire safety and first aid should be available.

E. QUALITY CONTROL-RESPONIBILITY OF MANUFACTURER/ DESIGNER

1.1 Equipment and instrument quality and certification

1.2 Manufacturing material quality, tolerance of parts, fabrication specifications, inspection during manufacturing and tests and adopted quality assurance procedures.

1.3 Quality of components used

1.4 Certification of wiring, electrical, mechanical safety

1.5 Documentation of quality assurance and control procedures

1.6 Wire rope, source rack, hydraulic piping and pumps, specification, quality assurance

1.7 Sensors and their quality assurance

(THIS IS THE ONLY APPENDIX FOR RADIOTHERAPY FACILITY)

APPENDIX-7E

(Refer section 3. 5.1.5)
(Refer section 3.8.4)

RADIATION PROTECTION MANUAL OF RADIOTHERAPY FACILITY

(Applicable for Telegamma Accelerator and Brachytherapy Facilities)
(Operation, Maintenance and Emergency Aspects)

A. ADMINISTRATION AND SAFETY ASSURANCE

(a) Administrative hierarchy/organisational set up

(b) Authorised personnel - Training and qualification of facility personnel, their knowledge in radiation safety, responsibilities of each of personnel, their availability in adequate number, policies in case of long leave/ absence of certified personnel

(c) Local safety committee : constitution, functions and responsibilities

(d) Procedures for reporting to the regulatory agency on unusual occurrences and periodic radiation safety status

(e) Procedures in case of change or repairs of H.V. system (if applicable), safety system /interlocks, certification of log book entry by RSO

(f) Records of maintenance - maintenance schedule, radiation monitoring, and calibration of survey meters, etc.

(g) Control and distribution of radiotherapy rooms.

(h) Industrial safety aspects - fire equipment, safety accessories etc.

(i) Facility security arrangements, fencing and personnel movement control etc.

(j) Removal and storage of contaminated material, if any.

(k) Medical assistance - First aid facility, location, periodic medical examination (once a year), medical facilities and treatment facilities for radiation incidents

B. MONITORING

1. Radiation monitoring - Type of area monitors, sensitivity, range, location, alarm set levels for

		radiation zone monitors and radiation survey meters.
2.	Contamination monitoring -	Method of collecting samples and measurement of activity for contamination checks.
3.	Personnel monitoring -	Number of personnel monitoring badges, procedure for their issuance, safe place for storage, etc.

C. OPERATIONAL PROCEDURES

The procedures to be followed prior to treatment delivery such as daily quality assurance (QA) checks.

D. MAINTENANCE PROCEDURE FOR SAFETY SYSTEMS/ INTERLOCKS

Periodic maintenance - Daily/weekly/monthly/quarterly/yearly : items, procedures and schedules

Maintenance and checking of alarm/ warning devices

E. SOURCE LOADING/UNLOADING PROCEDURES FOR TELEGAMMA AND BRACHYTHERAPY

Procedure to be adopted for source replacement in the event of source decay or disused:

Procedure for source loading/unloading- responsible agency/agencies

Procedure of movement of source container for source load/unload and responsible personnel

Test report for source container handling and lifting system

F. EMERGENCY PLANNING AND PROCEDURES

(a) Organisational structure and communication links

(b) Name, address and telephone numbers of agencies to be contacted in case of emergency

(c) Emergency contact telephone/telex nos. and address of

(i) Head of institution

(ii) Facility-in-charge

(iii) Radiological safety officer (RSO)

(iv) Regulatory agency (AERB)

(v) Fire safety officer (Local)

(vi) Local fire station

(vii) Local police station

(viii) Local medical hospital, radiation therapy hospitals (nearest)

G. TYPE OF EMERGENCIES ENVISAGED

Prevention/handling of emergencies, investigation methods, etc. during treatment, explosion or fire or smoke, radiation emergency, crisis management in case of emergency, earthquake, floods, other natural calamities.

(APPENDIX 8C-I, 8C-II, 8C-III AND 8E ARE FOR DIAGNOSTIC FACILITIES)

APPENDIX-8C-I

(Refer section 3.6.3)

ACCEPTANCE/PERFORMANCE/QUALITY ASSURANCE TEST FOR COMPUTED TOMOGRAPHY (CT) SCANNER

PART I

INTRODUCTORY INFORMATION

1.1.	Name and address of the manufacturer	:	
1.2	Name and address of local agent/supplier	:	
1.3.	Name and address of the institution, where the scanner is tested	:	
1.4	Model name of the scanner	:	
1.5	Features of the scanner	:	Conventional/Spiral Single slice/Multiple slice
1.6	Tests conducted by	:	

Date:

Signature

Name

Designation

Company

APPENDIX-8C-I

(Refer section 3.6.3)

PART II

SPECIFICATIONS AND TECHNICAL DETAILS OF THE SCANNER

A. X-RAY GENERATOR

1.	Make and model	:	
2.	Operating potential (kVp)	:	
3.	Operating current (mA)	:	
4.	Mains requirement	:	
5.	Generator capacity (power)	:	
6.	Scan time per rotation	:	
7.	Scan time for full helical scan	:	
8.	Type of rectification	:	Full wave/ multi-pulse

B. X-RAY TUBE

1.	Make and model of the tube	:	
2.	Type of anode/material/angle	:	Rotating/stationary
3.	No. of focal spots	:	One/two
	Focal spot dimensions	:	
	Focus-1	———— mm	X ———— mm
	Focus-2	———— mm	X ———— mm

C. BEAM COLLIMATION SYSTEM

1.	Selectable slice thickness in mm/ slice acquisition mode	:	

2.	Pre-patient/post-patient collimator (collimator width)/(detector width)	:	
3.	Fan angle of scan beam	:	

D. GANTRY

1.	Type of the scan motion	:	Rotate-Rotate/ Stationary-Rotate
2.	Continuous rotation	:	available (Limits :)
		:	not available
3.	Rotation mechanism	:	slip ring/other
4.	Gantry aperture diameter	:	——————— cm
5.	Gantry tilt (maximum)		
	Gantry top towards couch	:	———————
	Gantry top away from the couch	:	———————
	Angular accuracy	:	±
6.	Light-field localiser type	:	Laser/focussed light beam
	Position of light field localizer	:	At scan plane/external to scan aperture
7.	Focus-isocentre distance	:	
8.	Focus-detector distance	:	
9.	Maximum field of view (FOV)	:	
10.	Bi-way patient communication system	:	

E. PATIENT SCANNING TABLE

1.	Maximum movements (Full out to full in scan table length):		——————— cm
	Minimum table incrementation available	:	——————— mm
	Indexing accuracy	:	± ——————— mm
	Minimum table height	:	± ——————— cm
	Maximum table height	:	± ——————— cm

2.	Location of table position indicators		
	Gantry	:	Yes/No
	Table	:	Yes/No
	Control console	:	Yes/No
	Scan image	:	Yes/No
3.	Table tilt	:	Possible/Not possible
	If possible		
	Head end up	:	_____
	Head end down	:	_____
	Angulation accuracy	:	_____

F. DETECTORS

1.	Type	:	Scintillator/photodiode
			Scintillator/PM tube
			Pressurised xenon chamber
			Other (specify)
	Type of scintillator	:	
2.	Number of detectors (total)	:	
	Number of reference detectors	:	
	Number of measuring detectors	:	
	Total No. of detector rows	:	
	Number of measuring channels	:	
3.	Recommended calibration frequency		
	Air calibration scans	:	
	Water calibration scans	:	
4.	Availability of imaging phantom	:	Yes/No

APPENDIX-8C-I

(Refer section 3.6.3)

PART-III

A. MECHANICAL TESTS

A.1 Alignment of Table to Gantry

Check the congruence between the gantry midline and table midline using plumb line.

Result (Gantry midline to table midline) :

Tolerance : ± 5 mm

A.2 Scan Localisation Light Accuracy (use film without screen)

Exposure parameters : kVp : mAs: Slice thickness (min) :

Result :

Alignment error : Internal laser light :———— mm

External laser light:———— mm

Tolerance : ± 2.0 mm

A.3 Gantry Tilt

Exposure parameters : kVp : mAs:

Result :

Actual gantry tilt :

Measured gantry tilt :

Tolerance : $\pm 3^0$

A.4 Table Position /Incrementation (same film can be used for tests A2, A3, and A4)

Initial table position (arbitrary) :

Load on couch :

Exposure parameters : kVp : mAs: Slice thickness :

Applied table incrementation :

Tolerance : ± 2.0 mm

Table position from reference position	**1 cm**	**2 cm**	**3 cm**	**4 cm**	**5 cm**
Expected					
Measured					

B. COLLIMATION TEST

B.1 Radiation Profile Width

Exposure parameters : kVp : mAs:

Result :

Applied slice thickness (mm)	Measured density profile width (FWHM)

Tolerance : ± 1.0 mm (without post patient collimator)

C. TESTS ON X-RAY GENERATOR

C.1 Measurement of Operating Potential

Set kV	mA station I	mA station II	mA station III	mA station IV

Tolerance : ± 2 kVp

C.2 Measurement of mA Linearity

Operating parameters : kVp : Slice thickness : Time:

mA settings	mAs	Output µGy	µGy/mAs (X)

Coefficient of linearity (COL) = $\frac{X_{max} - X_{min}}{X_{max} + X_{min}}$

Tolerance in COL : ± 0.1

C.3 Measurement of Timer Linearity

Operating parameters : kVp : Slice thickness : mA:

mA settings	mAs	Output µGy	µGy/mAs (X)

Coefficient of linearity (COL) = $\frac{X_{max} - X_{min}}{X_{max} + X_{min}}$

Tolerance in COL : ± 0.1

C.4 Output Consistency

Operating parameters : mAs : Slice thickness :

kVp	Output					Mean (X)	COV
	1	2	3	4	5		

Coefficient of Variation (COV) = $[\sum (X_i - X_{mean})^2/(n-1)]^{½} / X_{mean}$

Tolerance in COV : ± 0.05

D. CONTRAST RESOLUTION

D.1 Low Contrast Resolution

Use low contrast resolution test phantom.

Operating parameters : kVp : mAs : Slice thickness
Window width :

Result :

Low contrast resolution : ———— mm at ———— % contrast difference

Tolerance : 5.0 mm at 1% contrast difference (minimum)

2.5 mm at 0.5 % contrast difference (expected)

D.2 High Contrast Resolution

Use high contrast resolution test phantom.

Operating parameters : kVp : mAs : Slice thickness :

Window width : Use high resolution algorithm.

Result :

Size of the smallest resolvable bar/hole pattern : _____ mm

(_____ lp/cm)

Tolerance : At 10% contrast difference the size of the bar/hole pattern that could be resolvable should be 1.6 mm (≈ 3.12 lp/cm).

Expected high contrast resolution : 0.8 mm (≈ 6.25 lp/cm)

E. RADIATION DOSE TESTS

E.1 Measurement of Computed Tomography Dose Index (CTDI)

Use pencil ionisation chamber connected to a suitable electrometer or TLD, in conjunction with a head/body phantom. Measure the dose in the axial and peripheral cavities of the phantom for typical techniques.

Operating parameters : kVp : 80 / 100 / 140 mAs : 100

Slice thickness :

Result	**Head**	**Body**
Axial dose	: ———— mGy/mAs	———— mGy/mAs
Peripheral dose	: ———— mGy/mAs	———— mGy/mAs
	: ———— mGy/mAs	———— mGy/mAs
	: ———— mGy/mAs	———— mGy/mAs
	: ———— mGy/mAs	———— mGy/mAs
Peripheral dose (mean)	: ———— mGy/mAs	———— mGy/mAs
$CTDI_{c(central)}$	: ———— mGy/mAs	———— mGy/mAs
$CTDI_{p\ (mean)}$	: ———— mGy/mAs	———— mGy/mAs

Weighted CTDI ($CTDI_w$) = 1/3 $CTDI_c$ + 2/3 $CTDI_p$

$CTDI_w$: ———— mGy/mAs

Tolerance : ± 20% of the quoted value (expected)
± 40% of the quoted value (maximum)

F. RADIATION LEAKAGE LEVELS FROM X-RAY TUBE HOUSING AT 1 m FROM THE FOCUS

Operating Potential : kV, mAs: mA X seconds
(use maximum kV available in the machine for leakage measurement)

Radiation leakage level (mR/hour)			
Front (Cathode)	**Back (Anode)**	**Left**	**Right**

Maximum leakage = $\frac{\text{—— mA minutes X —— Maximum leakage mR/h}}{\text{60 X —— mA used for measurement}}$

Maximum radiation leakage from tube = ———————— mR in one hour

Result: Maximum radiation leakage at 1 meter from the focus for workload of 180 mAminutes in one hour is _____ mR.

Recommended upper limit:

Leakage radiation level at 1 meter from the focus should be ≤ 115 mR in one hour.

Date: Tested by: Signature

Name

Designation

Company

Signature of customer/user

(Seal of the institution)

APPENDIX-8C-II

(Refer section 3.6.3 and 3.13.2.5)

ACCEPTANCE/PERFORMANCE/QUALITY ASSURANCE TEST FOR DIAGNOSTIC X-RAY UNIT/CATH LAB

A. DETAILS OF THE DIAGNOSTIC X-RAY UNIT

1.	Name of the manufacturer	:	
2.	Name and address of the of the institution where the unit tested	:	
3.	Name(s) of person(s) testing the unit	:	
4.	Dates and duration of the tests	:	
5.	Model name	:	
6.	No. of X-ray tubes	:	One/two
7.	Maximum rating of the unit	:	
	(a) Potential (kV)	:	
	(b) Current (mA)	:	
	(c) Exposure time (seconds)	:	
8.	Name of the Manufacturer of the X-ray Tube	:	
9.	Type of Detector	:	Screen film/CR/Digital/IIT
10.	Total filtration	:	———————— mm of Al

Date:

Tested by:

Signature:

Name:

B. CONGRUENCE OF RADIATION & OPTICAL FIELD

Operating Parameters :

Distance : 100 cm, kV : 60 kV, mAs : 5 (mA = ————, s = ————)

(a) Shift in the edges of the radiation field

X = cm % of TFD (TFD: Table to focus distance)

X' = cm % of TFD

Y = cm % of TFD

Y' = cm % of TFD

Tolerance : 2 % of TFD

(b) Difference in the dimensions of the radiation and optical fields

X + X' = cm % of TFD

Y + Y' = cm % of TFD

Tolerance : 3 % of TFD

(c) Difference between sums of lengths and widths of optical and radiation fields

X + X' + Y + Y' = cm % of TFD

Tolerance : 4 % of TFD

1. CENTRAL BEAM ALIGNMENT

Observe the images of the two steel balls on the radiograph and evaluate tilt in the central beam.

Tilt in the central beam is _____

Tolerance : Tilt < 1.5^0

2. FOCAL SPOT SIZE

Distance : 60 cm, kV : 70, mAs : 40 - 50 (mA = 40-50, s = 1.6)

(non-screen film technique)

Large focal spot size : ———— mm X ———— mm (stated)

: ———— mm X ———— mm (measured)

Small focal spot size : ———— mm X ———— mm (stated)

: ———— mm X ———— mm (observed)

Tolerance :

1. + 0.5 f for f < 0.8 mm
2. + 0.4 f for 0.8 ≤ f ≤ 1.5 mm
3. + 0.3 f for f > 1.5 mm

3. TIMER CHECK

Set time	Observed time	% Error

Tolerance: ± 10 %

4. ACCELERATING VOLTAGE

Operating parameters : Distance : 40 - 50 cm

Applied kVp	Measured kVp
60 kV (40 mAs)	
70 kV (32 mAs)	
80 kV (25 mAs)	
90 kV (20 mAs)	
100 kV (20 mAs)	
kV max (15 mAs)	

Tolerance : ± 5 kV

5. LINEARITY OF mA LOADING STATION

Operating parameters : Distance : 100 cm, kV : 60, Time : 1.0 second

mA Range	Out put			Average	mR/mAs (X)
	1	2	3		
100					
200					
300					

Coefficient of linearity = $\frac{X_{max} - X_{min}}{X_{max} + X_{min}}$

Tolerance : COL < 0.1

6. LINEARITY OF TIMER

Operating parameters : Distance : 100 cm, kV : 50, mA : 200

Time	**Out put**			**Average**	**mR/mAs (X)**
	1	**2**	**3**		
0.5					
1.0					
1.5					

Coefficient of linearity = $\frac{X_{max} - X_{min}}{X_{max} + X_{min}}$

Tolerance : COL < 0.1

7. OUTPUT CONSISTANCY

Operating parameters : Distance : 100 cm

Applied kV	**mA**	**Output**					**Average (X)**
		1	**2**	**3**	**4**	**5**	
70							
80							
100							
120							

Coefficient of variation = $[\sum (X_i - X_{mean})^2/(n-1)]^{1/2} / X_{mean}$

COV =

———— for ———— kV

———— for ———— kV

———— for ———— kV

———— for ———— kV

———— for ———— kV

Tolerance : COV < 0.05

8. TOTAL FILTRATION

Operating parameters : Focus to detector distance : 100 cm

kV : 100, mAs : 20 (mA : 100, Time : 0.2 seconds)

Added filter (mm Al)	**Output**			**% Transmission**
	1	**2**	**Average**	
0				
1.0				
2.0				
3.0				
4.0				
5.0				
6.0				
Table top				

[Plot a graph between Al thickness added mm (X-axis) and % transmission (Y-axis); find HVT from graph]

Total filtration = ———————— mm of Al. (from table)

Tolerance : 1.5 mm Al for kV ≤ 70

2.0 mm Al for kV ≤ 100

mm Al for kV > 100

Aluminium equivalence of the table top is ———————— mm of Al at 100 kV.

Recommended upper limit : Al equivalence of table top ≤ 1.0 mm at 100 kV.

9. PERFORMANCE OF THE IMAGE INTENSIFIER (II)

(a) Details of the II tube:

1. Name and address of the manufacturer:

2. Make, model and format of the II tube:

3. Make and model of the X-ray tube used for testing the II tube:

(b) Low contrast sensitivity:

Diameter of the smallest size hole clearly seen on the monitor:————————

Recommended performance standard:

Hole of 1/8" diameter must be clearly seen.

(c) High contrast sensitivity

Bar strips of frequency ———— lp/mm resolved on the monitor.

Recommended performance standard:

Bar strips of 1.5 lp/mm must be resolved.

(d) Exposure rate at table top

——————— R/minute at ——————— kV(maximum) and

——————— mA (maximum)

Recommended upper limit:

Exposure rate at table top ≤ 5.7 R/minute at focus to table top distance —— cm.

[focus to table top distance shall not be less than 30 cm.]

10. TUBE HOUSING LEAKAGE

Operating parameters :

Applied voltage : ———— kV , mAs : ———— (———— mA, 1.5 Sec.)
(Maximum) (minimum)

Location (at 1.0 m from the focus)	**Exposure level (mR/h)**				
	Left	**Right**	**Front**	**Back**	**Top**
Tube					
Collimator					

Work load =

$$\text{Maximum leakage} = \frac{\text{180 mA minutes X — Maximum leakage mR/hr}}{\text{60 X — mA used for measurement}}$$

Maximum radiation leakage from tube = ————— mR in one hour

Result : Maximum radiation leakage at 1 meter from the focus for workload of 180 mAminutes in one hour is _____ mR.

Recommended upper limit : Leakage radiation level at 1 meter from the focus should be ≤ 115 mR in one hour.

TABLE-1 : EFFECTIVE FOCAL SPOT SIZE FOR A MAGNIFICATION OF 4/3

Smallest group resolved	lp/mm	Effective focal spot size (mm)
1	0.84	4.3
2	1.00	3.7
3	1.19	3.1
4	1.14	2.6
5	1.68	2.2
6	2.00	1.8
7	2.38	1.5
8	2.83	1.3
9	3.36	1.1
10	4.00	0.9
11	4.76	0.8
12	5.66	0.7

TABLE 2 : HVT AS A FUNCTION OF FILTRATION AND TUBE POTENTIAL (SINGLE PHASE GENERATORS)

Total filtration (mm Al)	Peak potential (kV)									
	30	40	50	60	70	80	90	100	110	120
0.5	0.36	0.47	0.58	0.67	0.76	0.84	0.92	1.00	1.08	1.16
1.0	0.55	0.78	0.95	1.08	1.21	1.33	1.46	1.58	1.70	1.82
1.5	0.78	1.04	1.25	1.42	1.59	1.75	1.90	2.08	2.25	2.42
2.0	0.92	1.22	1.49	1.70	1.90	2.10	2.28	2.48	2.70	2.90
2.5	1.02	1.38	1.69	1.95	2.16	2.37	2.58	2.82	3.06	3.30
3.0		1.49	1.87	2.16	2.40	2.62	2.86	3.12	3.38	3.65
3.5		1.58	2.00	2.34	2.60	2.86	3.12	3.40	3.68	3.95

TABLE 3 : HVT AS A FUNCTION OF FILTRATION AND TUBE POTENTIAL (THREE PHASE GENERATORS)

Total filtration (mm Al)	Peak potential (kV)								
	60	70	80	90	100	110	120	130	140
	Half value thickness (mm Al)								
2.5	2.2	2.4	2.7	3.1	3.3	3.6	4.0		
3.0	2.3	2.6	3.0	3.3	3.6	4.0	4.3	4.6	5.0
3.5	2.6	2.9	3.2	3.6	3.9	4.3	4.6		

APPENDIX-8C-III

(Refer section 3.13.2.5)

ACCEPTANCE/PERFORMANCE/QUALITY ASSURANCE TEST FOR MAMMOGRAPHY UNIT

1. DETAILS OF THE MAMMOGRAPHY UNIT TESTED

1.1	Name and address of the manufacturer	:	
1.2	Name and address of the of the institution where the unit tested	:	
1.3	Name(s) of person(s) testing the unit	:	
1.4	Dates and duration of the tests	:	
1.5	Type of model	:	Film-screen radiography/Digital
1.6	Maximum rating of the unit	:	
	(a) Operating potential (kV)	:	
	(b) Current (mA)	:	
	(c) Exposure time (s)	:	
1.7	Name of the manufacturer of the X-ray tube	:	
1.8	Total filtration (Material and thickness)	:	——————— mm (Al/Mo)

2. MECHANICAL CHARACTERISTICS

2.1	Locking facility adequacy For immobilizing the X-ray tube satisfactory	:	Yes/No
2.2	Accuracy of tube orientation Indication satisfactory	:	Yes/No
2.3	Movement of field limiting diaphragm satisfactory	:	Yes/No
2.4	Alignment of compression device satisfactory ?	:	Yes/No

2.5 Locking facility of the compression device satisfactory ? : Yes/No

3 DISPLAYS/INDICATORS

3.1 CONTROL PANEL

3.1.1 Power 'ON' display
Provided ? : Yes/No
Satisfactory ? : Yes/No

3.1.2 Tube current display
Provided ? : Yes/No
Satisfactory ? : Yes/No

3.1.3 Tube potential display
Provided ? : Yes/No
Satisfactory ? : Yes/No

3.1.4 Exposure time selection Satisfactory : Yes/No

Any other indicator (s) (Please specify) :

3.2 TUBE HOUSING

3.2.1 Material and thickness of inherent filtration indicated ? : Yes/No

3.2.2 Material and thickness of added filtration indicated ? : Yes/No

3.2.3 Total filtration indicated ? : Yes/No

3.2.4 Focal spot location indicated ? : Yes/No
Any other indication (s) (Please specify) :

4. RADIATION CHARACTERISTICS

4.1 Congruence of Radiation and Optical Fields

Focus to Film Distance : 60 cm.

Result : (a) Shift in the edges of the radiation field

X = _____ cm % of TFD

X' = _____ cm % of TFD

Y = _____ cm % of TFD

Y' = _____ cm % of TFD

Tolerance : 2% of TFD

(b) Difference in the dimensions of the radiation and optical fields

$|X| + |X'|$ =_____ cm % of TFD

$|Y| + |Y'|$ =_____ cm % of TFD

Tolerance : 3% of TFD

(c) Difference between sums of lengths and widths of optical and radiation field

$|X| + |X'| + |Y| + |Y'|$ =_____cm % of TFD

Tolerance : 4% of TFD

(d) Observe the images of the two steel balls on the radiograph. Refer Table 1 for evaluating tilt in the central beam

Result : The tilt in the central beam is _____^{o} (degree).

Tolerance : Tilt < 1.5 ^{o}

5. FOCAL SPOT SIZE:

Large focus : Stated _____ mm x _____ mm

: Measured _____ mm x _____ mm

Small focus : Stated _____ mm x _____ mm

: Measured _____ mm x _____ mm

Result :

Tolerence : (i) + 0.5 f for f < 0.8 mm

(ii) + 0.4 f for $0.8 \leq f \leq 1.5$ mm

(iii) + 0.3 f for f > 1.5 mm

Refer Table 1 for evaluating the focal spot size

6. ACCELERATING VOLTAGE

Result :

Set kVp	Measured kVp

Tolerance : ± 1 kV

7. TIMER CHECKING

Exposure parameters : _____ kV, _____ mA.

Time (seconds)	Exposure parameters mA kV	Time (seconds) Set Recorded	% Error
t < 0.2			
0.2 < t < 1.0			
0.5 < t < 1.0			
t > 1.0			

Tolerence : ± 10 %

8. TOTAL FILTRATION AND ALUMINIUM EQUIVALENCE OF THE COMPRESSION DEVICE

(i) Molybdenum target, Beryllium window

Added filter thickness =———— mm Molybdenum

Operating potential	mAs	Added filter (mm Al) compression device							HVT mm Al
28 kVp		0.0	0.1	0.2	0.3	0.4	0.5		

Result: The HVT of the unit is = _____ mm of Al for 28 kVp

Recommended Value : 0.3 mm Al ≤ HVL ≤0.37 mm Al at 28 kVp

(ii) Tungsten target, Glass/Beryllium window

Added filter thickness = ———— mm Molybdenum/Aluminium/ Rhodium

Operating potential	mAs	Added filter (mm Al)							HVT mm Al
49 kVp		0.0	0.1	0.20	0.50	1.00	1.5	2.0	

Result: The HVT of the unit is =_____ mm of Al for 49 kVp

Recommended value : 0.8 mm Al ≤ HVL ≤ 1.0mm Mo/Rh filter

1.1 mm Al≤ HVL ≤1.6 mm Al filter

Al equivalence of the compression device ≤ 0.1 mm of Al

≤ 2.0 mm of plexi glass

9. LINEARITY OF mA LOADING STATION

Operating Potential : kV : _____ ; Seconds : _____ ;

mA Range	mA	X, Instrument reading (mR)					Avg. ξ	mR/mAs M
		1	2	3	4	5		
50 < ι < 100								
100 < ι < 200								
200 < ι <400								
400 < ι < 800								

Result : Coefficient of linearity for mA loading stations are _____ and _____ for small focus and large focus, respectively.

Tolerance : Coefficient of linearity < 0.1

9.1 Linearity of Timer:

kVp : _____ ; mA _____ ;

Time (seconds)	s	X, Instrument reading (mR)					Avg. ξ	mR/mAs M
		1	2	3	4	5		
0.2 < ι < 0.4								
0.4 < ι < 0.6								
0.6 < ι < 0.8								
0.8 < ι < 1.5								

Result : Coefficient of linearity for timer of the unit is _____

Tolerance : Coefficient of linearity < 0.1

9.2 Output Consistence:

Operating potential	mAs	X, Instrument reading (mR)					Avg. ξ	mR/mAs M
		1	2	3	4	5		

Tolerance : Coefficient of variation < 0.05

9.3 Radiation Leakage Levels from X-ray Tube Housing at 1 metre from the Focus

Operating potential : _____ kV, mAs : _____ mA x _____seconds

Radiation leakage level (mR/h or mR)				
Cathode	Anode	Stand	Front	Top

Result : Maximum radiation leakage at 1 metre from the focus for work-load of 180 mA

minutes in one hour is _____ mR.

Recommended upper limit :

Leakage radiation level at 1 metre from the focus

≤ 115 mR in one hour.

9.4 Radiation Leakage Levels from the Diaphragm/Collimator at 1 metre from the Focus

Operating potential : _____ kV, mAs : _____ mA x _____seconds

Radiation leakage level (mR/h or mR)				
Cathode	Anode	Stand	Front	Top

Result : Maximum radiation leakage through diaphragm/collimator at 1 metre from the focus for work-load of 180 mA minutes in one hour is _____ mR.

Recommended Upper Limit:

Radiation level due to leakage through diaphragm/ collimator at 1 metre from the focus ≤ 115 mR in one hour.

9.5 Calibration of Compression Device:

9.6 Testing of Automatic Exposure Control Device:

Date:

Tested by:

Signature:

Name:

APPENDIX-8E

(Refer section 3.6.3)

RADIATION PROTECTION MANUAL

Radiation Protection Manual (RPM) for Diagnostic X-ray facilities including Computed Tomography(CT)/Interventional Radiology Istallations and Facilities Engaged in the Commercial Production of Radiation Generating Equipment.

A. Administrative Hierarchy/Organisational set up:

Authorised personnel:	Describe the organisational/management set up responsible for radiation safety. State the name, qualifications and training of Radiologist(s) and technicians and their work experiences in radiation field. State the name of the person nominated for Radiological afety Officer.

Procedures for reporting to the AERB for annual radiation safety status report.

B. Monitoring

Describe the policy for issuing personnel monitoring badges, their safe storage and record keeping of personnel monitoring history of radiation workers.

Describe the local working rules and internal investigative procedure for incidents or accidents.

Describe the procedure for monitoring of radiation working areas.

C. Operational Procedures

Describe the methodology for minimising repetition of diagnostic X-ray examinations.

Describe the provisions for medical research (if applicable to the facility) is subject to the consideration by an ethical review committee.

D. Maintenance Procedure for Safety Systems/Interlocks

Describe maintenance data of periodic equipment services, testing and maintenance and their record keeping.

Describe inventory of all the X-ray equipment in the institution (manufacturer's name, model name, AERB type approval No. of the installed units and their location in the premises).

Describe the CT/Interventional Radiology unit's Quality Assurance (QA) programme.

E. Emergency Planning and Procedures

Name, address and telephone numbers of individuals/agencies to be contacted in case of emergency

Emergency contact telephone/telex nos. and address of

(i) Head of the Institution

(ii) Head of the Radiology Department

(iii) Radiological Safety Officer (RSO)

(iv) Service Engineer

(v) Fire Officer(Local)

(vi) Local Fire Station

(vii) Regulatory Agency (AERB)

(THIS IS THE ONLY APPENDIX FOR INDUSTRIAL RADIOGRAPHY FACILITY)

APPENDIX-9E

(Refer section 3.7.5)

RADIATION PROTECTION MANUAL FOR INDUSTRIAL RADIOGRAPHY FACILITY

Radiation protection manual (RPM) is an operation manual prepared specific to the licensee's organisation stating all operations relating to work with radiation and identifying the tasks and the person(s) assigned to each task. The RPM ensures that the licensee indeed works safely with radiation and determines how exactly safety requirements will be fulfilled. The format of RPM is given bellow:

Contents of RPM

(a) Purpose and scope

(b) Organisational chart and responsibilities of persons

(c) Radiography source (gamma/X-ray) procurement

(d) Radiography source (gamma/X-ray) transport

(e) Radiography source (gamma) disposal

(f) Inventory of radiography equipment/radiation monitors

(g) Procedure for obtaining radiography site approval

(h) Standard operating procedure (SOP) for radiography work in respect of open field (site radiography) and enclosed installations.

(i) Safety and security of radiography sources and devices at radiography installations.

(j) Inspection and maintenance of radiography exposure devices (IGRED /industrial X-ray) and associated accessories

(k) Maintenance and calibration of radiation monitors

(l) Emergency response plans and preparedness

(m) Submission of safety status reports (IU-6) to AERB

(n) Procedure for documentation :

(i) log-book, (ii) dose records (iii) IU-6 form

(o) Information and Training on radiation safety.

Example for Site Radiography:

	Activity		Responsible identified Person(s)
1.	Identification of IGRED/X-ray, area monitors, radiography personnel, radiation protection accessories to be sent to radiography site.	:	
2.	Confirmation of safe and secure source storage room	:	
3.	Source movement permission from AERB	:	
4.	Shift of IGRED/X-ray machine with permission of AERB	:	
5.	Issuance of TLD badges to radiography personnel	:	
6.	Carrying IGRED/X-ray machine from source storage room to the location where radiography job to be carried out	:	
7.	Set of radiography job	:	
8.	Cordon the required area	:	
9.	Operation of IGRED/X-ray machine	:	
10.	Radiation monitoring around the cordon area	:	
11.	Retract of radiography source into the source housing	:	
12.	Properly lock of the IGRED after completion of job	:	
13.	Removal of cordon	:	
14.	Carrying of IGRED/X-ray machine to source storage room	:	
15.	Placement of IGRED in the source storage room	:	
16.	Return of TLD to RSO	:	
17.	Storage of TLD badges securely	:	
18.	Log-book entries	:	
19.	Emergency plan and preparedness	:	
20.	Site co-ordinator for safety and security	:	

APPENDIX-10

(Refer section 3.18.1)

LIST OF AERB CODES, STANDARDS AND GUIDES USED FOR RADIATION FACILITIES

Type of Approval/ Radiation facility	AERB/Code/Standard/ Guide No.	Title
Industrial gamma radiography exposure devices	AERB /RF-IR/ SS-1, Rev-1 (2007)	ATOMIC ENERGY REGULATORY BOARD, Safety Standard for the Design and Construction of Industrial Gamma Radiography Exposure Devices and Source Changers, AERB/RF-IR/SS-1, Rev-1 (2007).
Industrial ionising radiation gauging devices	AERB/SS-2, Rev. 1 (2001)	ATOMIC ENERGY REGULATORY BOARD, Standard Specifications for Radiological Safety in the Design and Construction of Industrial Ionising Radiation Gauging Devices, AERB/SS-2, Rev. 1 (2001).
Sealed sources	AERB/SS-3, Rev. 1 (2001)	ATOMIC ENERGY REGULATORY BOARD, Standard Specifications for Testing and Classification of Sealed Radioactive Sources, AERB/SS-3, Rev. 1 (2001).
Consumer products containing radioactive material	AERB/SS-4 (1990)	ATOMIC ENERGY REGULATORY BOARD, Standard Specification for Radiological Safety in the Design and Manufacture of Consumer Products Containing Radioactive Substances, AERB/SS-4 (1991).
X-ray analysis equipment	AERB/SS-5 (1992)	ATOMIC ENERGY REGULATORY BOARD, Standard Specifications for Radiological Safety in the Design and Manufacture of X-ray Analysis Equipment, AERB/SS-5 (1992).
Land-based gamma radiation processing plant other than gamma irradiation chambers	AERB/RF-IRRAD/SS-6, Rev.1 (2007)	ATOMIC ENERGY REGULATORY BOARD, Safety Standard for the Land-based Stationary Gamma Irradiators, AERB/RF-IRRAD/SS-6, Rev.1 (2007)

APPENDIX-10 (CONTD.)

(Refer section 3.18.1)

LIST OF AERB CODES, STANDARDS AND GUIDES USED FOR RADIATION FACILITIES

Type of Approval/ Radiation facility	AERB/Code/Standard/ Guide No.	Title
Land-based gamma radiation processing plant other than gamma irradiation chambers	AERB/SC/IRRAD (1993)	ATOMIC ENERGY REGULATORY BOARD, Safety Code on Operation and Maintenance of Land-based Stationary Gamma Irradiators. AERB/SC/IRRAD, (1993).
Radiation therapy	AERB/RF-MED/SC-1 (Rev. 1) (2011)	ATOMIC ENERGY REGULATORY BOARD, Safety Code for Radiation Therapy Sources Equipment and Installations, AERB/RF-MED/SC-1 (Rev. 1) (2011).
Transport of radioactive material	AERB/SC/TR-1 (1986)	ATOMIC ENERGY REGULATORY BOARD, Safety Code on Transport of Radioactive Materials, AERB/SC/TR-1 (1986).
Industrial radiography	AERB/SC/IR-1(2001)	ATOMIC ENERGY RGULATORY BOARD, Safety Code on Industrial Radiography, AERB/SC/IR-1(2001)
	AERB/SG/IN-1 (1986)	ATOMIC ENERGY RGULATORY BOARD, Safety Guide on Radiological Safety in Enclosed Radiography Installation, AERB/SG/IN-1, 1986.
	AERB/SG/IN-2 (1987)	ATOMIC ENERGY RGULATORY BOARD, Safety Guide on Radiological Safety in Open Field Industrial Radiography, AERB/SG/IN-2, 1987.
	AERB/SG/IN-3 (1989)	ATOMIC ENERGY RGULATORY BOARD, Safety Guide on Handling of Emergencies in Industrial Radiography, AERB/SG/IN-3, 1989.

APPENDIX-10 (CONTD.)

(Refer section 3.18.1)

LIST OF AERB CODES, STANDARDS AND GUIDES USED FOR RADIATION FACILITIES

Type of Approval/ Radiation facility	AERB/Code/Standard/ Guide No.	Title
Medical diagnostic X-ray equipment	AERB/RF-MED/SC-2 (Rev. 2) (2011)	ATOMIC ENERGY REGULATORY BOARD, Safety Code for Medical Diagnostic X-ray Equipment and Installations, AERB/SC/MED-2, Rev. 1 (2001).
Brachytherapy facilities	AERB/SC/MED-3 (1988)	ATOMIC ENERGY REGULATORY BOARD, Safety Code for Brachytherapy Sources, Equipment and Installations, AERB/SC/MED-3 (1988).
Nuclear medicine facilities	AERB/RF-MED/SC-2 (Rev. 2) (2011)	ATOMIC ENERGY REGULATORY BOARD, Safety Code on Nuclear Medicine Facilities AERB/RF-MED/SC-2 (Rev. 2) (2011).

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13. ATOMIC ENERGY REGULATORY BOARD, Safety Standard on 'Design and Construction of Industrial Ionising Radiation Gauging Devices', AERB Safety Standard No. AERB/SS/2, Mumbai, India (2001).

14. ATOMIC ENERGY REGULATORY BOARD, Safety Standard on 'Testing and Classification of Sealed Radioactive Sources', AERB Safety Standard No. AERB/SS/3 (Rev. 1), Mumbai, India (2001).

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WORKING GROUP

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	March 2, 3,	2009
	April 11, 12, 13,	2009
	May 7, 8, 13, 14, 15, 18, 19, 21, 22,	2009

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Dates of meeting:	January 23, 1998	February 10, 1998
	June 17, 1999	July 12, 1999
	October 5 & 6, 2000	October 17, 2000
	April 1, 2005	August 4, 2006
	September 25 & 26, 2006	October 5, 2006
	November 24, 2007	July 4, 2008
	August 7 & 8, 2008	November 28, 2008

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Shri G.V. Nadkarny	:	NPCIL (Former)
Shri A.K. Asrani	:	AERB (Former)
Shri T.N. Krishnamurthi	:	AERB (Former)
Late Dr. I.S. Sundara Rao	:	AERB (Former)
Shri N.K. Jhamb	:	AERB (Former)
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PROVISIONAL LIST OF CODES, GUIDES AND MANUALS FOR REGULATION OF NUCLEAR AND RADIATION FACILITIES

Safety Series No.	Titles
AERB/SC/G	Regulation of Nuclear and Radiation Facilities
AERB/NPP&RR/ SG/G-1	Consenting Process for Nuclear Power Plants and Research Reactors
AERB/NF/SG/G-2	Consenting Process for Nuclear Fuel Cycle Facilities and Related Industrial Facilities other than Nuclear Power Plants and Research Reactors
AERB/RF/SG/G-3	Consenting Process for Radiation Facilities
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AERB/SG/G-5	Role of AERB with respect to Emergency Response and Preparedness at Nuclear and Radiation Facilities
AERB/SG/G-6	Codes, Standards and Guides to be Prepared by the AERB for Nuclear and Radiation Facilities
AERB/SG/G-7	Regulatory Consents for Nuclear and Radiation Facilities: Contents and Formats
AERB/SG/G-8	Criteria for Regulation of Health and Safety of Nuclear Power Plant Personnel, the Public and the Environment
AERB/NPP&RR/ SM/G-1	Regulatory Inspection and Enforcement in Nuclear Power Plants and Research Reactors
AERB/NF/SM/G-2	Regulatory Inspection and Enforcement in Nuclear Fuel Cycle and Related Industrial Facilities other than Nuclear Power Plants and Research Reactors
AERB/RF/SM/G-3	Regulatory Inspection and Enforcement in Radiation Facilities

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