MANUAL NO. AERB/RF/SM/G-3



GOVERNMENT OF INDIA

AERB SAFETY MANUAL

REGULATORY INSPECTION AND ENFORCEMENT IN RADIATION FACILITIES



ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY MANUAL NO. AERB/RF/SM/G-3

REGULATORY INSPECTION AND ENFORCEMENT IN RADIATION FACILITIES

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The Chief Administrative Officer Atomic Energy Regulatory Board Niyamak Bhavan Anushaktinagar 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 codes, safety standards, 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 safety standards are formulated on the basis of nationally and internationally accepted safety criteria for design, construction and operation of specific equipment, structures, systems and components of nuclear and radiation facilities. Safety codes establish the objectives and set requirements that shall be fulfilled to provide adequate assurance for safety. Safety guides and guidelines 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. These 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 issuance of regulatory consent at every stage. AERB has also issued a safety guide on the 'Regulatory Inspection and Enforcement in Nuclear and Radiation Facilities' (AERB/SG/G-4), that provides guidance to the regulatory body on its role for regulatory inspection of nuclear and radiation facilities and enforcement actions. This safety manual details inspection programme, methodology of inspection and suggested types of enforcement actions. It is also intended to assist all the participating agencies in fulfilling the intent of the above safety code and guide.

Consistent with the accepted practice, 'shall' and 'should' are used in the manual to distinguish between a firm requirement and a desirable option respectively. Appendices are an integral part of the document, whereas Annexures and bibliography are included to provide further information on the subject that might be helpful to the user(s).

Non-radiological aspects such as industrial safety and environmental protection are not explicitly considered in this manual in respect of non-DAE (Department of Atomic Energy) facilities. However, for DAE facilities, industrial safety should be ensured by compliance with the applicable provisions of the Factories Act, 1948 and the Atomic Energy (Factories) Rules, 1996.

This manual has been prepared in-house by AERB staff. It has been reviewed by experts and the 'Advisory Committee for Preparation of Codes, Guides and Manuals on Governmental Organisation for Nuclear and Radiation Facilities' (ACCGORN).

AERB wishes to thank all individuals and organisations who have prepared and reviewed the draft document 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

Approval

A type of regulatory 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 the 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')

Commissioning

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

Competent Authority

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

Consent

A written permission issued to the 'consentee' by the regulatory body to perform specified activities related to nuclear and radiation facilities. The types of consents are 'licence', 'authorisation', 'registration' and 'approval', and will apply according to the category of the facility, the particular activity and radiation source involved. Accordingly the consents are graded ranging from a 'licence' for high hazard to a 'registration' for low hazard facility and an 'approval' issued to a proposal.

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

Decommissioning

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

Decontamination

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

Disposal (Radioactive Waste)

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

Emergency

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

Employer

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

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.

Handle

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

Inspector (Regulatory)

A person authorized by the regulatory body to carry out regulatory inspection.

Licence

A type of regulatory consent, granted by the regulatory body for all sources, practices and uses for nuclear facilities involving the nuclear fuel cycle and also certain categories of radiation facilities. It also means authority given by the regulatory body to a person to operate the above said facilities.

Monitoring

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

Occupational Worker

Any person, working full time or part time in a nuclear or radiation facility, who may be employed directly by the 'Consentee' or through a contractor.

Occupier

One who has been given the ultimate control over the affairs of the installations.

Operation

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

Operating Personnel

Members of the site personnel who are involved in operation of the nuclear/radiation facility.

Operational Limits (Radiation)

Limits on levels of radiation or levels of contamination as the competent authority may specify from time to time. However, in the case of diagnostic X-ray equipment and installation, contamination levels are not relevant.

Personal 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.

Prescribed Limits

Limits established or accepted by the regulatory body.

Quality Assurance (QA)

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

Quality Control (QC)

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

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, ultra-violet light.

Radiation Facility

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

Radiation Protection Survey/Radiological Survey

An evaluation of radiation safety, using appropriate radiation measuring instruments.

Radiation Surveillance

Measures that may be specified by the competent authority to provide adequate protection either generally or in an individual case.

Radiation Worker

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

Registration

A type of regulatory consent issued by the regulatory body for sources and practices of low hazard.

Regulatory Body

(See 'Atomic Energy Regulatory Board')

Regulatory Consent

(See 'Consent')

Regulatory Inspection

An examination through review of documents, observation, measurement or test undertaken by or on behalf of the regulatory body during any stage of the regulatory consenting process, to ensure conformance of materials,

components, systems and structures as well as operational and maintenance activities, processes, procedures, practices and personnel competence with predetermined requirements.

Security Survey

A detailed examination, made by the competent authority, of proposed physical protection measures in order to evaluate them for approval.

Test

An experiment carried out in order to measure, quantify or classify a characteristic or a property of an entity.

Testing (QA)

The determination or verification of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental or operational conditions.

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 Safety Manual)

Competent Person

A person, who is having the degree in the discipline mentioned or equivalent, followed by experience as specified in Rule 31 of Atomic Energy (Factories) Rules, 1996, in responsible position in the field and designated by the competent authority.

Enforcement

The action taken by the regulatory body intended to correct non-compliance by a consentee with the relevant regulations and conditions stipulated in the consent.

Technical Support Organization (TSO)

An organization that provides technical support to the regulatory body.

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1. INTRODUCTION

1.1 General

- 1.1.1 Radiation facilities (RF) need to be sited, constructed, commissioned, operated and decommissioned in conformity with the current applicable safety standards and codes. The standards ensure adequate margin of safety, so that the RF can be operated safely without undue risk to the occupational workers, the members of the public and the environment. The Safety Code on 'Regulations of Nuclear and Radiation Facilities' (AERB/SC/G) requires the Atomic Energy Regulatory Board (AERB) to be responsible for regulatory control over matters relating to safety in the siting, construction, commissioning, operation and decommissioning of radiation facilities.
- 1.1.2 This Safety Manual on "Regulatory Inspection and Enforcement in Radiation Facilities" (AERB/RF/ SM/G-3) has been prepared to elaborate the provisions given in the AERB Safety Guide entitled "Regulatory Inspection and Enforcement in Nuclear and Radiation Facilities" (AERB/SG/G-4), for conducting the regulatory inspection and initiating enforcement actions for radiation facilities under siting, construction, commissioning, operation and decommissioning, as applicable.
- 1.1.3 The following facilities have been identified as radiation facilities as per AERB Safety Guide entitled "Consenting Process for Radiation Facilities" (AERB/RF/SG/G-3). Consents issued to the RF are categorised as per the hazard potential and listed accordingly.

Licence for facilities operating/engaged in:

- (i) Land-based high intensity gamma irradiators (other than Gamma Irradiation Chamber)
- (ii) High energy particle accelerators used for research and industrial processing applications
- (iii) Production of radioactive material such as medical cyclotron or radiation generating equipment
- (iv) Telegamma and accelerators used in radiotherapy
- (v) Computed tomography (CT) unit
- (vi) Interventional radiological X-ray unit
- (vii) Industrial radiography
- (viii) Neutron generators

Authorisation for facilities operating/engaged in:

- (i) Brachytherapy
- (ii) Gamma irradiation chamber
- (iii) Nuclear medicine
- (iv) Production of nucleonic gauges and consumer products containing radioactive material
- (v) Radioactive sources in well logging

Registration for facilities operating/engaged in:

- (i) Medical diagnostic X-ray equipment including therapy simulator
- (ii) Analytical X-ray equipment used for research
- (iii) Nucleonic gauges
- (iv) Radioimmunoassay (RIA) laboratories

- (v) Radioactive sources in tracer studies
- (vi) Biomedical research using radioactive material
- (vii) Calibration laboratory for radiation monitoring instruments

AERB may from time to time identify certain sources or practices which will require regulatory consent and specify the category of consent.

Certain other facilities set up with the objective of manufacture and supply of sealed sources, radiation generating equipment, package design for transport of radioactive material and shipment also require regulatory consent in the form of approval.

1.2 Objective

The objective of the manual is to outline the methodology of carrying out the regulatory inspections and enforcement actions in the radiation facilities effectively and efficiently.

1.3 Scope

- 1.3.1 This manual is applicable to all types of radiation facilities (RF) for regulatory inspection and enforcement action by AERB.
- 1.3.2 The areas to be covered in inspections during siting, construction, commissioning, operation and decommissioning are addressed in detail.
- 1.3.3 The manual also covers the methodology of enforcement actions by AERB in the event of violations of safety requirement by a radiation facility.
- 1.3.4 This manual also covers industrial and fire safety aspects, as applicable, to radiation facilities under the Department of Atomic Energy.

2. REQUIREMENTS OF INSPECTION AND ENFORCEMENT

2.1 General

- 2.1.1 Being the custodian of radiation sources, the prime responsibility for ensuring radiation safety and security of the radiation sources lies with the employer. As part of this responsibility the employer should carry out regular physical verification of radiation sources, maintain inventory of all the radiation sources and conduct verification of radiation safety and regulatory compliance through appropriate internal audit.
- 2.1.2 The objective of the regulatory inspection and enforcement is, to ensure that the activities performed by the consentee during all the stages of the consenting process (siting, construction, commissioning, operation and decommissioning) are in compliance with the safety requirements as stipulated in the Act, Rules and regulations including:
 - (i) Atomic Energy Act, 1962
 - (ii) Atomic Energy (Factories) Rules, 1996 (applicable for DAE units)
 - (iii) Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987 (GSR 125)
 - (iv) Atomic Energy (Radiation Protection) Rules, 2004 (GSR 303)

In addition, compliance with requirements specified in the following documents is considered as appropriate:

- (i) The safety codes, standards, guidelines and directives issued by AERB
- (ii) Relevant safety documents published by national and international agencies (IAEA, BSS, ISO, ANSI, IEC, IEEE, ICRP, BIS etc.)
- (iii) Stipulations of AERB including those on QA while authorizing to perform the particular activity
- (iv) Emergency response plan and preparedness procedures of the radiation facility
- (v) Observations/recommendations brought out during the earlier inspections/reviews.
- 2.1.3 The specimen formats of authorisation letters, inspection schedule and its approval, inspection reports and typical formats of checklist covering the regulatory inspection requirements are part of annexures. The checklist may be revised/updated based on experience and can be issued separately.
- 2.1.4 Normally inspections are planned for various types of radiation facilities on case by case basis during all the consenting stages depending on the hazard potential of the facility as specified in AERB Safety Guide on 'Consenting Process for Radiation Facilities' (No. AERB/RF/SG/G-3). As per this safety guide, the RF requiring inspection at various consenting stages are as given below, however, AERB may change/modify the requirements of regulatory inspection of the RF on case by case basis for each consenting stage. These inspections are carried out before and/or after issuance of the relevant consent. The inspections should cover the following areas, as applicable in each consenting stage:
- A. Siting Stage
 - (i) Verification of physical characteristics of site and its immediate surroundings, including any modification to siting report
 - (ii) Verification of implementation of AERB stipulations, if any.

The typical checklist for regulatory inspection of site for installation of radiation facility is as given in **Annexure-1**, and it may be revised based on inspection feedback, as it is not a routine inspection and will be practice specific. The facilities requiring site inspection are:

- (a) Land-based high intensity gamma irradiators
- (b) High energy particle accelerators used for research and industrial processing applications
- (c) Facilities engaged in commercial production of radioactive material.
- B. Construction Stage
 - (i) Construction schedule and procedures
 - (ii) Specification for construction of structure, systems and components (SSC)
 - (iii) Compliance with AERB stipulations and recommendations of safety committees
 - (iv) QA plans and procedurs and QA records
 - (v) Storage/preservation of safety related equipment
 - (vi) Records and documentation.

The typical checklist for regulatory inspection of the RF during construction is as given in **Annexure-**2, and it may be revised based on inspection feedback, as it is not a routine inspection and will be practice specific. The facilities requiring inspection during construction are:

- (a) Land-based high intensity gamma irradiators
- (b) High energy particle accelerators used for research and industrial processing applications
- (c) Facilities engaged in commercial production of radioactive material.
- C. Commissioning/Trial Runs Stage
 - (i) Completion of construction
 - (ii) Commissioning schedule
 - (iii) Operational limits and controls (Technical specification)
 - (iv) Commissioning/Acceptance tests procedures and results
 - (v) QA programme
 - (vi) Radiation measuring and monitoring equipment
 - (vii) Safety manpower : Qualification, training and certification
 - (viii) Safety and security measures of radiation facility and radioactive sources including transport
 - (ix) Radiation protection programme (RPP)
 - (x) Emergency response plans and preparedness (EPP)
 - (xi) Records and documentation
 - (xii) Modifications carried out based on commissioning feedback.

Detailed checklist for regulatory inspection during commissioning stage is same as the check list for operation stage. Typical facilities requiring inspection at this stage are:

- (a) Land-based high intensity gamma irradiators
- (b) High energy particle accelerators used for research and industrial processing applications
- (c) Nuclear medicine
- (d) Facilities engaged in commercial production of radioactive material.

D. Operation Stage

- (i) Operational limits and controls (OLCs)
- (ii) Standard operating procedures (SOP)
- (iii) Operating procedures under emergency conditions
- (iv) Results of tests, measurements etc.
- (v) Radiation safety surveillance procedure and records
- (vi) QA programme
- (vii) Safety manpower : Qualification, training and certification
- (viii) Training-induction, refresher, training in radiological safety aspects
- (ix) Radiation protection programme (RPP)
- (x) Emergency response plans and preparedness (EPP)
- (xi) Servicing and maintenance, ageing management programme
- (xii) Radioactive waste management system and authorisation for transfer/disposal of radioactive waste
- (xiii) Modifications carried out based on operational experience with copy of approval from AERB
- (xiv) Records and documentation
- (xv) Safety and security measures of radiation facility and radioactive sources including transport
- (xvi) Event reporting criteria and procedure and inspection reports of the same, if any.

The inspection during operation is applicable to all the categories of the RF as given in para 1.1.3. Typical checklists are given in the annexures.

E. Decommissioning Stage

Decommissioning of the RF is undertaken before releasing the RF from regulatory control. In some of the facilities, where possibility of hazard exists, inspection at the time of decommissioning is made to ensure that the following aspects are covered :

- (i) Procedures for decommissioning /dismantling
- (ii) Storage and disposal of radioactive material
- (iii) Prevention and mitigation measures commensurate with radioactive contamination potential
- (iv) Safety manpower : Qualification, training and certification
- (v) Personnel training and qualification for carrying out the specific activities
- (vi) Radioactive waste management system
- (vii) Emergency response plans and preparedness (EPP)
- (viii) Records and documentation

The typical checklist for regulatory inspection during decommissioning of the RF is as given in **Annexure 3**, and it may be revised based on inspection feedback, as it is not a routine inspection and will be practice specific. The facilities requiring inspection during decommissioning are:

(a) Land-based high intensity gamma irradiators

- (b) High energy particle accelerators used for research, medical and industrial processing applications
- (c) Facilities engaged in commercial production of radioactive material.
- 2.1.5 Special inspections are undertaken for witnessing type approval test of radioactive sources, radiation devices and radiation generating equipment and package design approval.
- 2.1.6 Surprise inspection may be undertaken at any consenting stage for all radiation facilities.
- 2.1.7 Regulatory enforcement actions are initiated in case the consentee does not comply with the safety requirements and stipulations laid down in the regulatory documents listed in para 2.1.2.

2.2 Authorisation of Inspector and Empowerment

Chairman, AERB has been notified as the "Competent Authority" for carrying out the regulatory and safety functions envisaged in the Atomic Energy Act, 1962 and the Rules framed thereunder.

The Atomic Energy (Radiation Protection) Rules, 2004 (Rule nos. 30 & 31) empower the competent authority to authorise any person/agency to undertake inspection, and to define the responsibilities and the powers of such authorised person/agency.

The competent authority may, accordingly, authorize the inspector (format of authorisation is given in **Annexure 4**) to undertake the activity related to regulatory inspection and enforcement.

2.2.1 Authorisation of Inspector

The inspector along with his/her team of inspectors is empowered to :

- (i) enter at all reasonable hours, for inspection purpose, the premises of any RF during any stage of consenting process (siting, construction, commissioning, operation and decommissioning);
- (ii) observe, inspect, examine, measure, copy, photograph, sketch or test as the case may be, any of the instrument/equipment, question any personnel, review and verify relevant documents and records etc., for the purpose to ensure safety;
- (iii) inspect, from safety point of view, to ensure that the licensee has fulfilled the radiological safety requirements for carrying out the practices at the radiation installation as per the stipulations laid down in the consent;
- (iv) check whether the safety related structures, systems, components and devices are of approved quality, based on the relevant safety codes and safety standards specified by the competent authority and that they are functioning as per the design intent;
- (v) examine the respective operating personnel for their competence to operate the facility;
- (vi) ensure that the facilities are operating as per the approved technical specifications;
- (vii) conduct all such examinations as may be considered necessary;
- (viii) make such tests and measurements as may be necessary for the purpose of assessing radiation safety;
- (ix) investigate unusual incidents or accidents, if any, that had occurred at the radiation facility and arrive at the reasons for the same and recommend corrective and remedial measures;
- (x) review and verify whether the corrective and remedial measures/actions have been implemented; and
- (xi) inspect radioactive consignments in any conveyance carrying radioactive material and inspect any package containing radioactive material.

2.2.2 Investigation and Enforcement

The inspector has the power to investigate and to give direction to the employer/licensee.

- The inspector has power to seal or seize the radiation installation in consultation with Chairman, AERB. Any person duly authorized under Section 17 of the Atomic Energy Act, 1962, may, after inspection, carry out investigation for the purposes of determining contravention of any of the provisions of these rules;
- (ii) The investigation may be carried out against a complaint or on suspicion or after an unusual incident or accident;
- (iii) The person authorised to investigate may :
 - (a) seal any radiation installation or any conveyance carrying radioactive materials or seize any radioactive material or contaminated equipment; and
 - (b) indicate in writing to the employer any recommendation aimed at ensuring adequate protection and the licensee shall comply with the same.

2.3 Designations of Regulatory Inspection Team Members

An inspection team may consist of following members as designated below:

Inspector	:	A person authorised by AERB to carry out regulatory inspection.
Team Member	:	The person in the process of qualifying to become an inspector.
Expert Member	:	An officer from AERB or from technical support organisation (TSO) or individual having relevant expertise besides academic qualification as required for inspector, drawn for a particular purpose, during inspection.

2.4 Qualification and Training of Inspectors

The officers who have been assigned the responsibilities for carrying out regulatory inspection of RF should have adequate understanding of the radiation facilities and safety systems. He/she should be trained and qualified as indicated below:

2.4.1 Academic Qualification

The inspector should be at least a graduate in science/engineering.

2.4.2 Training

The inspectors should have the capability to interact independently with the radiation facility personnel to assess safety culture, security measures of the radiation facility and conduct appropriate discussions in order to report the findings in crisp, clear and accurate manner.

To develop these abilities, the candidates should be trained by AERB or an agency authorized by AERB, to impart adequate knowledge in relevant areas for carrying out inspections. The candidates should be trained in the following areas of regulatory requirements prior to certifying him/her as inspector:

- (i) Statutory powers, responsibilities and functions of AERB
- (ii) Atomic Energy Act and Rules issued thereunder
- (iii) Relevant AERB safety documents (Safety codes, standards, guides, manuals and directives)
- (iv) Consenting process for various radiation facilities
- (v) General regulatory inspection principles and regulatory inspection procedures

- (vi) Safety principles and concepts (i.e. including hazards other than that from ionizing radiation that may be encountered during inspection)
- (vii) Safety analysis and its importance
- (viii) Objective of various commissioning tests
- (ix) Quality assurance programme during various consenting stages
- (x) Handling of radioactive material and transportation
- (xi) Radiation protection survey techniques for different radiation facilities
- (xii) Decontamination procedures and disposal of radioactive waste
- (xiii) Applicable national and international safety requirements, safety guides and technical documents
- (xiv) Radiation protection programme (RPP)
- (xv) Emergency response plan and preparedness
- (xvi) Safety and security of radioactive sources in radiation facilities and during transport of radioactive material
- (xvii) Environmental safety aspects
- (xviii) Ongoing technology developments
- (xix) Code of conduct for inspector (as given in **Annexure 5**)
- (xx) Enforcement actions and procedures
- (xxi) Safety culture and assessment.

The entire training requirements should be programmed in a structured way including assessment of the candidate, so that the inspectors develop the capability to independently draw conclusion and confirm the finding based on review of relevant/related documents, field observations, consultation with radiation facility personnel and his/her own judgment.

The training should be imparted normally within a period of one year after joining AERB. The required training material and module should cover the requirements of inspector's training. The relevant practical exercise, on-the-job training and closely supervised inspection related activities should supplement the formal training.

2.4.3 Upgradation of Team Member to Inspector

The team member should undergo the up-gradation programme after on-the-job training for at least six months under the supervision of an inspector, and carry out sufficient number of regulatory inspections.

The short-term training including assessment should be carried out before qualifying the team member as Inspector. The topics covered in up-gradation programme should include:

- (i) Team management & team work
- (ii) Time management
- (iii) Communication skills and methods for effective inspections
- (iv) Interviewing/questioning of facility personnel on radiation safety
- (v) Interviewing and evidence gathering requirement

- (vi) Quick grasp of issues like non-adherence and non-compliance
- (vii) Sense of prioritisation of safety significant areas
- (viii) Report writing and summarisation
- (ix) Ongoing technological developments
- (x) Confidentiality.

2.4.4 *Retraining*

The inspectors should be periodically sent to appropriate training programmes, workshops, seminars etc. to keep their knowledge updated.

2.5 Experience of Inspector/Expert Member/Team Member

- (i) The inspectors should have adequate knowledge in their area of specialisation, should have worked as team member and field experience of at least of one year in operation or safety review of RF or similar facility.
- (ii) The expert members should have three years experience in their area of expertise.
- (iii) Team members should have undergone on-the-job training for at least six months under the supervision of an inspector.

2.6 Confidentiality of Regulatory Inspection

- 2.6.1 In case the inspections related to physical security systems are covered along with routine inspections, then security related observations and the report should be kept fully confidential.
- 2.6.2 Inspector may include proprietary details, information on occupation related personnel health, classified information and matters which may create administrative problems to the facility management in a separate note for the information and necessary action by the RF management and AERB.

2.7 Responsibilities of a Licensee/Consentee for Regulatory Inspection

- 2.7.1 The licensee/consentee should extend full co-operation for carrying out the regulatory inspection of his/her facility including prompt-entry for the authorised regulatory inspection team. The nature of co-operation to be extended to the inspection team is elaborated in the following paragraphs.
- 2.7.2 The Licensee/Consentee should make the following Arrangements
 - (i) Provide access to any area of the facility and its site for regulatory inspection at any time as desired by inspector; however, licensee/consentee should inform the inspectors to follow necessary procedures to access the hazardous areas, if any.
 - (ii) Ensure that all concerned personnel at the facility are available for discussion and they properly respond to the queries or provide assistance in obtaining response from the concerned persons.
 - (iii) Provide access to all relevant documents.
 - (iv) Provide access to other associated and required facilities including that of the vendors and contractors, where it is deemed necessary for fulfillment of regulatory inspection.
 - (v) Facilitate the inspection team to observe the exercises, tests, measurements, surveillance and major maintenance activities that are in progress.
 - (vi) Provide radiation protection/monitoring equipment and other personal protective equipment and gadgets for carrying out the inspection, as required.
- 2.7.3 The licensee/consentee should provide the logistics to the inspector(s) including equipment, assistance and support as may be necessary for carrying out their functions.

This may include:

- (i) Access to the means of communication;
- (ii) Means to take photographs and/or sketch of relevant location/building and equipment for the purpose of reporting;
- (iii) Provision of photocopies of relevant reports, records/measurements, documents for the purpose of reporting; and
- (iv) On-site work facilities and secretarial assistance to prepare the reports in time.
- 2.7.4 Documents to be Made Available

Typical list of documents and reports to be submitted to inspection team for review during siting, construction, commissioning/operation and decommissioning inspection are as listed below. The list is not exhaustive and may include any other document as applicable to specific RF and required by the inspection team members for their review.

- 2.7.4.1 Siting
 - (i) Documented evidence demonstrating site characteristics (Physical aspects)
 - (ii) Land ownership document, for installation of radiation facility; and
 - (iii) Copy of certificates from concerned authorities regarding the proposed site.
- 2.7.4.2 Construction Stage
 - (i) Stipulations of AERB, relevant layout/construction approvals;
 - (ii) Preliminary safety analysis report (PSAR);
 - (iii) Safety stipulations including status of pending implementation thereof;
 - (iv) Specification for construction of structure, system and components (SSC);
 - (v) Design basis report (DBR) and manuals;
 - (vi) Construction safety manual and construction methodology document;
 - (vii) QA manual for construction;
 - (viii) Current status of construction;
 - (ix) Documents on physical security aspects;
 - (x) Previous inspection reports and the RF response and follow up of previous regulatory inspections; and
 - (xi) Non-conformance control procedures.
- 2.7.4.3 Commissioning/Operation Stage
 - (i) Regulatory consents at various consenting stages;
 - (ii) Commissioning/acceptance test report (ATR);
 - (iii) Final safety analysis report (FSAR);
 - (iv) Special tests/certificates/inspection report;
 - (v) Safety stipulations including status of pending implementation;
 - (vi) Safety and operating personnel: Qualification, training and certification;

- (vii) Personnel monitoring services (PMS) records;
- (viii) Inventory of radioactive material/radiation generating equipment;
- (ix) Periodic safety status reports;
- (x) Servicing and maintenance schedules;
- (xi) Standard operating procedures (SOP) for equipment/systems, and modification of operating procedures, if any;
- (xii) Control room logbooks for the duration from previous inspection period or as desired by inspecting officials;
- (xiii) Radiation protection survey reports including protection level dosimetry;
- (xiv) Radiation protection programme (RPP);
- (xv) Emergency response plan and preparedness/procedures (EPP);
- (xvi) Unusual occurrence reports, if any;
- (xvii) Radioactive waste disposal data and relevant records;
- (xviii) Records of modification carried out in any structure, system and components;
- (xix) Report on follow-up of previous regulatory inspection and safety committees recommendations;
- (xx) Documents on physical security aspects;
- (xxi) Minutes of local safety committee (LSC), as applicable; and
- (xxii) Authorisation obtained from various statutory authorities, as applicable.
- 2.7.4.4 Decommissioning Stage
 - (i) Copies of NOC/authorisation for import/procurement of radiation sources;
 - (ii) Authorisation for decommissioning;
 - (iii) Procedures for dismantling of the unit and source removal;
 - (iv) Decontamination procedures;
 - (v) Storage and disposal of all radioactive wastes;
 - (vi) Radiation protection program/manual (RPP/RPM); and
 - (vii) Emergency response plan and preparedness/procedures (EPP).

3. REGULATORY INSPECTION PROGRAMME

3.1 General

3.1.1 In order to establish the objectives set out in para 2.1.2 of this manual, following criteria should be used while selecting the type of inspection and the inspection areas for formulating the regulatory inspection programme.

The inspector/team members should go through the past history of the radiation facility to be inspected and related documents to identify areas of inspection prior to proceeding for inspection and finalising the inspection programme.

3.1.2 Reference Documents

Typical list of reference documents which can be used during siting, construction, commissioning and operation stages of radiation facilities, as applicable, is given in **Appendix 1**.

3.1.3 Preparation for Inspection

Except in the case of 'surprise inspections', the concerned Division of AERB should inform the RF at appropriate time regarding the inspection programme, areas of inspection along with the names of the inspector(s). The RF should also be intimated about the requirement of the availability of staff and relevant documents required during inspection and arrangement/provision of other logistic supports (e.g. security clearances and entry to radiation facility, if any). The inspectors should carry with them relevant reference documents to facilitate effective inspection.

3.2 Classification and Objectives of Inspections

3.2.1 Classification

Inspections are of three types based on their nature and requirements.

- (i) Planned Regulatory Inspection: Planned and announced inspections
- (ii) Special Regulatory Inspection: Reactive and announced inspections
- (iii) Surprise Regulatory Inspection: Reactive/Pro-active and un-announced inspections

3.2.2 Objectives

3.2.2.1 Planned Regulatory Inspections

The main objective of planned regulatory inspections is to cover all the activities of RF periodically to check compliance with the statutory requirements, consent stipulations, overall procedures and various requirements laid down in regulatory documents, such as safety codes, standards, guides and manuals; preliminary/final safety analysis reports (PSAR/FSAR), acceptance test report (ATR), QA manual. These inspections will be carried out in line with the checklist as given in annexures. The details of the regulatory inspection programme should be intimated to radiation facility in advance (preferably a week before).

3.2.2.2 Special Regulatory Inspections

The main objective of special regulatory inspections is to conduct reactive type of inspections depending on the importance and urgency. These inspections should be conducted as announced ones, and the inspection programme may be intimated at short notice. The number of these special inspections may vary depending upon the situations prevailing in the RF and also based on the decisions of the AERB.

During siting, construction, commissioning/operation, decommissioning stages, as the case may be, special inspections are carried out either as part of consenting process or in response to any unusual

occurrence. AERB may conduct special inspections also due to any other requirement and during the course of safety review.

Illustrative examples of unusual incidents/events that may call for special inspections are listed below for commissioning/operation stage.

- Incidents of theft, loss and/or sabotage involving radioactive material
- Incidents of source not retrievable to safe position
- Damage to source housing/transport package
- Higher levels of radiation and contamination
- Excessive personnel radiation exposure
- Fire/explosion in radiation facility
- Extensive damage due to natural calamities/events
- Discharge of radioactive effluents beyond the prescribed limits.
- 3.2.2.3 Surprise Regulatory Inspections

The main objective of surprise regulatory inspections is to carry out reactive/proactive and unannounced inspection to get first hand information about the realistic safety status of the RF, its documentation and systems, e.g. safety implications and violations of safety procedures, if any, prevailing unsafe situations pertaining to radiation safety practices by the RF.

These inspections should be conducted as unannounced ones, based on the importance and urgency felt by AERB. The inspector should have prompt and free access to the facility/work or incident spot.

3.2.3 Areas of Coverage of Regulatory Inspection

Regulatory aspects to be covered during regulatory inspection at various stages of RF, i.e. siting, construction, commissioning/operation and decommissioning, are given in **Appendix 2**.

3.3 Annual Planning of Regulatory Inspections of Operating Radiation Facilities

A key component of a successful inspection programme is establishing inspection priorities and frequencies. The annual schedule/plan of the inspections with established frequency for radiation facilities should be drawn towards the end of the year, previous to the inspection year and should be approved by the Competent Authority in the format as given in **Annexure 6**.

Frequency of the planned inspection should be commensurate with the potential risk associated with different types of radiation facilities, such as the type and quantity of radioactivity handled; availability of qualified and trained personnel, periodicity of safety status report submission, mobility of source, working condition, vulnerability for loss of sources based on past experiences and reported unusual occurrences, overall regulatory compliance with safety requirements by particular type of RF based on past experience. The performance check of the device by the user/supplier of the source is also considered for deciding frequency of low hazard potential sources.

Recommended frequency intervals for planned regulatory inspections for various operating radiation facilities are as given in the **Annexure 7**.

While identifying the RF for planned inspection, priority should be given to the RF on the basis of following consideration:

- (i) There is no communication from the RF
- (ii) The facility is not in operation due to planned/unplanned reason

- (iii) Significant number of devices in possession
- (iv) Possessing disused sources pending for safe disposal
- (v) Frequent non-compliance of regulatory requirements by the RF
- (vi) Non-compliance of regulatory requirements by the RF over a period of time
- (vii) Complaints against the radiation facility or information on unauthorised possession of radiation sources/radiation generating equipment
- (viii) Legal disputes
- (ix) Feedback from previous regulatory inspection (RI)
- (x) Newly authorised and commissioned facilities
- (xi) Consent/licence renewal requirements.

3.4 Inspection Team Formation and Correspondence

- 3.4.1 The inspection co-ordinator identified for particular type of the RF should submit the composition of proposed inspection team for approval in the prescribed format and get it duly approved from Head/ Director of Concerned Division. The inspection team may consist of one or more members depending on the hazard potential of the RF and nature of work to be carried out. A senior inspector of the team should be designated as team leader. A specimen format for regulatory inspection programme and team formation is given in **Annexure 8**.
- 3.4.2 The inspection programme should be communicated to each member of the inspection team and to other respective divisions (either within AERB or other technical support organisations) whose representatives are required, as necessary. The inspector(s) should follow the planned schedule of regulatory inspections, unless/otherwise consented/notified by Head/Director of the Concerned Division of AERB.

3.5 Intimation to Licensee/Consentee

For planned and special regulatory inspections, intimation of inspection programme should be expeditiously communicated to the RF in advance (preferably a week before) by letter/fax/e-mail. The intimation regarding the inspection/travel programme indicating the areas of inspection and team members with due approval from Head/Director of the Concerned Division is as given in **Annexure 9**.

The RF licensee/employer should also be requested to provide access and hassle free entry to radiation facilities.

3.6 Documentation for Regulatory Inspection and Enforcement

Concerned Division of AERB should maintain the following documents for future inspections, followup and enforcement actions:

- (i) A master file containing description and functioning of the RF, inspection reports, facility responses and other relevant documents such as inspection programme, details of inspection team, correspondence, filled in check-lists, draft findings, notings, modification reports, charts and data collected at the RF
- (ii) Periodic safety status reports
- (iii) Pending AERB stipulations, as applicable
- (iv) Pending items of previous inspections and their latest status
- (v) Latest approved design specifications/drawings during construction
- (vi) Reports on unusual occurrences, if any.

3.7 Documents/Equipment to be carried by Inspection Team

Following is the typical list of documents/equipment, which should be carried during inspection:

- (i) Authority letter issued by Competent Authority to inspector(s)
- (ii) Photo ID card of inspector(s), preferably office ID
- (iii) Personnel monitoring devices (PMD) supplied by AERB
- (iv) Radiation measuring and monitoring instruments
- (v) Latest periodic safety status report
- (vi) Checklist for regulatory inspections as applicable for respective RF (as given in Annexures)
- (vii) Copy of regulatory consents issued to the radiation facility
- (viii) Previous inspection report(s) and the facility response
- (ix) Latest approved design specifications/drawings during construction
- (x) Pending AERB stipulations, if any
- (xi) Records of unresolved issues
- (xii) Atomic Energy Act, 1962 (Relevant part)
- (xiii) Atomic Energy (Radiation Protection) Rules, 2004
- (xiv) Atomic Energy (Safe Disposal of Radioactive Waste) Rules, 1987
- (xv) Atomic Energy (Factories) Rules, 1996 (in case of DAE units)
- (xvi) Relevant directives issued by AERB
- (xvii) Radiation surveillance procedures, as applicable
- (xviii) Relevant RF safety documents such as codes, standards and guides
- (xix) Safety documents related to the RF (eg. PSAR/ATR/FSAR etc.)
- (xx) Telephone directory/telephone numbers of important persons of AERB and the RF to be inspected
- (xxi) Required stationery
- (xxii) Photographic equipment, as required
- (xxiii) Laptop computer; and
- (xxiv) Safety glasses, safety shoes and safe head gear etc, if required.

4. METHODOLOGY AND REPORTING OF REGULATORY INSPECTION

4.1 General

The objective of the regulatory inspection of the RF can be achieved only by adopting proper methodology during the conduct of inspection, and by detailed preparation and issuance of appropriate inspection report. The inspector(s) should take all efforts to achieve the objectives.

4.2 Preparations for the Inspection

4.2.1 Administrative Aspects

The regulatory inspection (RI) co-ordinator should co-ordinate all the necessary administrative arrangements for conduct of an inspection from planning stage to formation of inspection team and issue of final inspection report. All steps should be followed and completed as a part of the preparation for the inspection as brought out in sections 2 and 3. The inspector(s) should ensure the availability of authority card/letter issued by the Competent authority to conduct inspection and enforcement.

4.2.2 Technical Aspects

The Inspector/Team members should study all the relevant documents received from the licensee/ consentee. The inspector should identify the items which need to be followed-up based on the RF response to previous inspection report. Compliance checking of implementation of AERB safety stipulations by RF should also be identified. Similarly the inspector should identify the generic or specific issues from national and/or international experiences for checking at RF with prior intimation to RF.

4.2.3 Study Materials for the Inspector

The inspector should study the relevant technical materials to visualize the present condition of the RF systems under the assigned area of inspection. The typical list of reference documents for each stage of RF is as given in **Appendix 1**.

4.2.4 Inspection Check-list

During the inspection, the inspector should use the appropriate checklist as given in the annexure. New items may be added in the inspection checklist based on RI feedback. The use of an inspection checklist contributes to the efficiency of the inspection process and allows procedures to be reviewed in a systematic manner.

The various stages of the inspection process are described in flow chart given below:



4.3 Inspection Methodology

4.3.1 Meeting with the RF Management

An introductory meeting with the RF management should be arranged on the day of inspection. In case the inspection is being carried by a team, the senior person i.e. team leader, should introduce all the members of the team to the RF personnel. The RF in turn will introduce its representative(s) who will co-ordinate with inspector(s). The management should present the current safety status of the RF and the status of implementation on the recommendations made during the previous inspection, if any. In the brief introductory meeting, the inspector should give an outline of the objectives of the inspection and the anticipated duration. The schedule of inspection and exit meeting timings should also be finalised.

For unannounced inspection, the inspector may undertake surprise visit to work area, review the practices in vogue at the site. Further process remains the same as that of an announced inspection.

4.3.2 Inspection Time Management

After the introductory meeting, the inspector(s) should plan inspection activity based on the importance and nature of inspection, may be in consultation with other inspectors in case of inspection team. Inspection time should be properly scheduled considering the following aspects:

- (i) radiation facility visit;
- (ii) safety audit/review of documents;
- (iii) interaction with the RF personnel and assessment of safety culture; and
- (iv) consolidation of inspection findings, report preparation and exit meeting.

4.3.3 Visit to Radiation Facility

At the start of the inspection, the inspector may take an overview visit of the radiation facility. During inspection, the inspector(s) should move with the RF representative(s) and should remain alert all the time. Readings of radiation monitoring instruments should be specifically checked. The status and condition of equipment, instruments etc. should be observed, as applicable. The inspector should also verify that the facility status is as described in the application for consent and that any subsequent modifications of safety significance have been approved by AERB.

Housekeeping measures, radiological safety practices, security of radioactive sources and fire prevention and protection measures by the facility, being followed (as applicable), should be checked. During the course of inspection, if any tests/surveillance checks are done, they can be witnessed and reported.

4.3.4 Control Room Visits (Commissioning/operation)

Inspector(s) should visit the control room to observe the system status, operator's activities, logbook management and general work practices followed by the operating staff etc. Important control room parameters may also be noted and verified for their correctness. The inspector should not carry out any operation of the RF equipment by himself/herself. The inspector may check through interaction that the operators/workers have required knowledge to safely carry out his/her responsibilities.

4.3.5 Witnessing the Activities in the RF

During the inspection, activities in the RF should be observed to check compliance with procedures. Examples of typical activities are given below:

- (i) performance test verification of safety system/components;
- (ii) interlock and logic test;

- (iii) dosimetry;
- (iv) radiation protection survey;
- (v) quality check/quality assurance of equipment; and
- (vi) source loading/unloading operations.

4.3.6 Tests and Measurements

Inspector(s) should review the documents to verify satisfactory completion of tests and measurements. In case deficiencies are noticed in the testing procedures, test results and equipment used, a repeat test should be recommended and witnessed, if necessary. If it is not feasible to carry out the test immediately, appropriate recommendations should be given. Typical tests or measurements may include the following:

- (i) performance test verification of safety system/components;
- (ii) radiation protection survey and area monitoring;
- (iii) clinical/product dosimetry, as applicable; and
- (iv) contamination checks, if any.

If the results based on above tests are not meeting the requirements and operation/use of the RF is unsafe, then appropriate enforcement action should be taken as given in Section 5.

4.3.7 Examination of Records and Documents

The inspector(s) should select records/documents relevant to the RF on sample basis for review during inspection or all records/documents, if possible.

4.3.8 Discussions with the RF Personnel

All observations made during inspection should be discussed with concerned RF personnel. Important deviations should be reconfirmed/verified for correctness. Appropriate corrective actions should be arrived at.

4.3.9 Recording of Inspection Findings

Necessary assistance for documenting/recording the inspection findings and collection of evidences should be provided by the RF personnel who are coordinating the regulatory inspection. In case of any difficulty, the inspector should bring the matter to the notice of the RF management.

The inspector should cite the relevant RF documents from where information/evidences have been extracted. Similarly while giving the recommendations or conclusions, it is always necessary to quote the requirements from statutory provisions, safety codes, standards, approved procedures, besides AERB stipulations/directives, if any, to be complied with by the RF to overcome the observed deficiencies.

4.4 Inspection Report Preparation

- 4.4.1 Findings of the regulatory inspection have to be documented for the following purposes:
 - (i) assessment of safety practices of the consentee;
 - (ii) collation of information gathered during inspection;
 - (iii) recording findings and the conclusions of the inspectors;
 - (iv) recording the recommendations, if any, for future action by the consentee or by safety committees of AERB;

- (v) providing basis for notifying the consentee about the findings of inspection and any noncompliance with regulatory requirements, to be complied with;
- (vi) bringing out any good practices and achievement beyond the mandatory requirements aimed at improving safety; and
- (vii) highlighting any non-compliances/deficiencies/violations etc. for proper corrective actions.

4.4.2 Content of Inspection Report

While deciding the scope and contents of inspection report, following are taken into consideration:

- (i) type of the RF and its consenting stage/operating status;
- (ii) type of the inspection, i.e. whether planned, special or surprise; and
- (iii) venue of inspection (either at the RF or supplier's/vendor's place).

Inspection reports may typically contain:

- (a) type and date of inspection with name and unique number for a particular RF, names of the members of the inspection team and inspection co-ordinator;
- (b) present status of activities at the RF;
- (c) method used for inspection (interaction/document review/observations);
- (d) details of the RF areas, activities, processes, systems, or components which have been inspected, assessed or reviewed;
- (e) status of earlier regulatory actions/compliance status of earlier findings;
- (f) details of radiation source that were physically verified/inspected;
- (g) safety and operating staff: Qualification, training and certification;
- (h) procedures for management of radioactive waste generated, if any;
- (i) criteria used in the assessment;
- (j) reference to consent stipulations of AERB and relevant statutory provisions;
- (k) copy of documentary evidences, if any;
- (l) deficiency or violation found during regulatory inspections;
- (m) record of any regulations or authorisation condition that have been contravened;
- (n) record of findings and conclusions of the inspector including any corrective action or enforcement actions that should be taken;
- (o) a record of the recommendations for future action; and
- (p) outcome of the exit meeting.

A specimen format of an inspection report for the RF is given in Annexure 10.

4.4.3 A draft report should be prepared and consolidated by inspector(s). Any documentary evidence shown by the RF management before the exit meeting should be considered.

The draft copy of the observations/RI report, as applicable, should be given to the RF management prior to the start of exit meeting, so that if the management needs any clarification that can be discussed in the exit meeting.

4.4.4 Categorisation of Observations/Recommendations in the Inspection Report for further Review and follow-up:

To facilitate follow-up review, enforcement and corrective actions, observations and recommendations made during the inspection should be categorized, generally based on severity of safety significance and follow-up of the re-quired measures. The categorisation should help the RF in submitting detailed and in depth responses giving full credence to the category level. The RF should be asked to submit their response to the reported observations/deficiencies/recommendations, which should include the corrective measures taken or proposed, along with the target dates, within a month to the AERB. If the categorisation is completed before the exit meeting, the RF management should discuss the items more appropriately based on categorisation. However, if the recommendations are not categorised before exit meeting, the same should be categorised at AERB and the report should be sent with enforcement letter, if applicable, by head/director of the concerned Division of AERB.

The findings of the inspections should be categorised based on the guidelines given below:

Category-I: Violation of Act(s), Rules, AERB safety codes, guidelines;

Licence stipulations, AERB Safety Directives,

Inadequacies of qualification, training and certification of safety and operating staff.

Category-II: Deficiencies in operating systems and safety systems as specified by safety standards;

Deficiencies in surveillance procedures of safety related equipment;

QA deficiencies;

Shortcomings identified in the design of safety related equipment and working conditions, etc.

- Category-III: Inadequacies with respect to the following:
 - (i) Organisational control;
 - (ii) Operation and maintenance procedures;
 - (iii) Radiation protection procedures/manual (RPP/RPM), as applicable;
 - (iv) Emergency response plans and preparedness/procedures (EPP);
 - (v) Physical security aspects; and
 - (vi) Radioactive waste management.

Category-IV: General observations/deficiencies regarding:

- (i) Good operating/maintenance practices;
- (ii) Housekeeping; and
- (iii) Documents and records.

Specific format of inspection report with categorisation is given in Annexure 10.

4.5 Exit Meeting with the Facility Management

At the end of the inspection, an exit meeting preferably with the RF management and/or RI coordinator should be arranged. The purpose of this meeting is to brief the management about the strengths and weaknesses along with pending issues from previous inspection report noticed during the inspection, and also to get additional information, if any, from the management, to review/modify the observations/ recommendations. The briefing should outline:

- (i) preliminary findings from the inspection;
- (ii) any matters of non-compliance with regulatory requirements;
- (iii) safety-related concerns;
- (iv) unresolved items identified during the inspection; and
- (v) status of any previously identified non-compliant items.

Cordial atmosphere should prevail in the meeting and the deliberations should be professional. The inspector(s) may acknowledge good practices noticed, which may help in improving radiological safety, physical security of sources and that may be mentioned in the report.

If deficiencies of serious concern that affect safe operation of the facility are identified, the inspector(s) should take a firm stand and quote the requirement laid down in various regulatory documents. The management must be directed to initiate prompt corrective action. Although deficiencies identified in some areas do not always reflect non-compliance, the inspector should also bring such deficiencies to the attention of the radiation facility management at the exit meeting.

Inspector may discuss confidential matters/issues as covered under para 2.6 during exit meeting if agreed by the RF management.

4.6 Report Submission and Facility Response

The inspection report should be finalised by taking in to account the outcome of exit meeting appropriately.

Original copy of the report should be submitted by inspector(s) to the head/director of the concerned division of AERB as soon as possible. The head/director of the concerned division may change any of the inspection recommendation and/or the categorisation, if felt necessary, before issuing the final inspection observations/recommendations. The observations/ recommendations letter, and enforcement letter, if required, should be issued within a month's time by the Head/Director of the concerned Division of AERB. Compliance/responses to the inspection report should be submitted by radiation facility within a month.

Specimen format for regulatory inspection observations/recommendations letter is as given in Annexure 11.

4.7 Reporting of Confidentiality Matters

Inspector should exercise due care while reporting proprietary information and on the health of facility personnel, as this may create unwarranted apprehensions among facility personnel. Such confidentiality matters may be dealt with separately instead of including in the inspection report.

4.8 Publication of Inspection Findings

In order to inform the public about the safety of radiation facilities and about the effectiveness of functioning of AERB, findings of inspection and regulatory decisions may be made public through AERB annual reports and/or newsletter, related professional journals, etc., without revealing the identity of the RF.

5. ENFORCEMENT ACTIONS

5.1 General

- 5.1.1 The AERB has been empowered by the Government of India to enforce compliance with the requirements as laid down in relevant Acts, Rules and regulation issued there under. The mandate of AERB includes the authority to enforce the consentee to modify, correct or curtail any activity/aspect of the RF under siting, construction, commissioning/operation, decommissioning stages; procedures, practices, structures system or components, as necessary, to ensure the required level of safety.
- 5.1.2 AERB has authorised its concerned Divisions to enforce radiation safety requirements in the RF during siting, construction, commissioning/operation and decommissioning. The concerned Divisions should ensure that the consentee has effectively carried out corrective actions to comply with the recommendations stated in the inspection report. The consentee is required to rectify the non-compliance, in an agreed time scale and take all necessary measures to prevent a recurrence. The Division/inspector(s) should carry out enforcement actions as described in following paragraphs.
- 5.1.3 Enforcement actions are designed to address the non-compliance with specified conditions and requirements. These actions should commensurate with the possible consequences of the non-compliance. Thus there are different kinds of enforcement actions such as written warning or directive¹ requiring corrective action with specified time period, seal the radiation installation or seize radioactive sources, penalties and withdrawal/suspension/ modification of consent or licence.

During an inspection, if some serious unsafe conditions are observed and require immediate enforcement, inspectors are authorised to take necessary action on-the-spot after obtaining prior approval from the Competent Authority. Specimen letter format for on-the-spot enforcement by inspector is given in **Annexure12**. Specimen letter format for authorisation of inspector is given in **Annexure 4**.

5.2 Consideration for Enforcement Actions

The factors to be taken into account in deciding which enforcement action is appropriate in each case should include:

- (i) the safety significance of the deficiency and the complexity of the corrective action that is needed;
- (ii) seriousness of the violation;
- (iii) whether the violation is a repeated violation of a less serious nature;
- (iv) whether there has been a deliberate or willful violation of the prescribed limits of radiation exposures/levels and relevant statutes and/or AERB Directives;
- (v) lack of safety culture;
- (vi) lack of adequate security measures;
- (vii) whether the violation is identified and reported by consentee or AERB and others;
- (viii) the past performance of the RF and trend in their performance; and
- (ix) the need for consistency and transparency in the treatment of the RF.

5.3 Methods of Enforcement and Normalisation

Various enforcement actions are:

(i) enforcement letter for the deficiencies observed/noted during inspection;
- (ii) written warning or directives¹;
- (iii) orders to curtail² activities including sealing radiation facility and seizure of radioactive material;
- (iv) modification, suspension or revocation of consents; and
- (v) initiation of other penal actions.
- 5.3.1 Enforcement Letter

Soon after the inspector submits the inspection report, concerned division should send an enforcement letter, if required, to the consentee asking for responses for the enforcement letter within a month.

The issuing authority may modify any of the inspection recommendations and the categorization, if felt necessary, before issuing the inspection report. The consentee should submit immediately his/her response for any issue of concern depending on severity. The specimen format of enforcement letter along with inspection report is given in **Annexure 13**.

Consentee's response to the inspection report should be reviewed to:

- (i) discuss the important items of inspection report having safety significance in the respective safety committees of AERB, if required;
- (ii) decide the further type of enforcement actions; and
- (iii) identify those items to be referred to the competent authority for issuance of directive regarding further enforcement actions.
- 5.3.2 Written Warning or Directive

In case of deviations from or violation of consent requirements, or unsatisfactory situations which have minor safety significance and which was identified at the radiation facility during the inspection. The concerned division of AERB should issue a written warning or directive to the RF with concurrence of the competent authority.

The written warning or directive should specify the nature of and the regulatory basis for each violation, deviation or unsatisfactory situation. It should also specify a period of time permitted for taking corrective/remedial action(s).

5.3.3 Orders to Curtail Activities

The concerned division of AERB dealing with the safety of radiation facility should recommend to the competent authority to direct the consentee to curtail specified activities in the event of:

- (i) evidence of a deterioration in the level of safety or apparent deterioration of the RF's structures, systems or components;
- (ii) serious violations which may pose unsafe situations or an imminent radiological hazard to the RF personnel or members of the public or the environment;
- (iii) unsafe act/unsafe practices in the RF; and
- (iv) any serious non-compliance observed during any of the phases of the RF life cycle (commissioning/operation/decommissioning).

¹ Directives: AERB informs in writing to the consentee to submit unusual occurrence report (UOR)/ incident report in case it was not submitted or the incident itself was not reported by the RF for the observed deviations from consent stipulation, violation of Atomic Energy (Radiation Protection) Rules, 2004, deviations from AERB safety codes and standards.

² Order to curtail: An order issued by AERB to the consentee to curtail the authorised activity in order that the observed deteriorations in structures, systems and components, and/or serious violations do not pose an imminent radiological hazard to the RF personnel, members of the public and the environment.

For example during the commissioning/ operation stage, this could mean suspension of handling of radioactive material, sealing of the RF, seizure of sources, if necessary.

5.3.4 Modification, Suspension or withdrawal of Consents

In the event of continual (chronic), persistent or extremely serious non-compliance, highly deteriorated condition or significant release of radioactive material to the environment/contamination due to serious malfunction or damage to the radiation facility, AERB may modify, suspend or revoke the consent (licence/authorisation/registration/approval) depending on the nature and severity of the situation. The radiation facility will be directed to eliminate any unsafe conditions, and continue to perform activities important to safety and security.

5.3.5 Other Penal Action(s)

In the case of persistent/deliberate non-compliance with the applicable provisions of the Atomic Energy Act, 1962 and the Rules issued thereunder and the requirements stipulated by AERB, penal action, as prescribed in sections 24, 25 and 26 of the said Act may be initiated.

5.3.6 Normalisation

- 5.3.6.1 AERB may lift the enforcement action and authorize the consentee for resumption of particular activity after ensuring the following, as applicable:
 - (i) Successful completion of identified corrective measures by the consentee
 - (ii) Successfully carrying out the required test/measurements by the consentee
 - (iii) Satisfactory actions taken by the consentee to prevent recurrence of same or similar issue/ situations
 - (iv) Special regulatory inspections by AERB or its authorised representatives to check compliance with all directives and to confirm measures taken to improve safety are satisfactory
 - (v) Completion of safety review by AERB.

Normalisation of enforcement action should be intimated to the consentee in the specimen format as is given in **Annexure 14**.

- 5.3.6.2 The process of normalisation for each of the enforcement actions is mentioned in the subsequent paragraphs. AERB may follow any or all of the measures listed below for normalising the various enforcement actions already taken.
 - (i) Enforcement Letter

The enforcement letter is sent to the consentee for compliance and the response to the enforcement letter submitted by the consentee is reviewed in the concerned division. If the responses along with corrective actions are satisfactory, the issue is treated as resolved.

In case the issue has already been referred to safety committee or would be referred to safety committee based on the radiation facility response, the recommendations of the safety committee will be continuously followed up in subsequent inspections till the issue is resolved. Based on the findings of the inspection and/or the review in safety committees, if any major modifications are carried out by the RF, the same are reviewed/verified during the inspections to ensure satisfactory implementation.

(ii) Written Warning or Directive

In general, for written warning or directives issued by AERB, the consentee's responses are reviewed first in the concerned division and subsequently by appropriate safety committees, if necessary. The corrective measures suggested by the division are to be followed-up during

the subsequent inspections. If required, special inspections are conducted either before or after normalizing the enforcement action.

In case, on-the-spot enforcement actions are taken, the clearance to resume the activity would be given by the competent authority based on satisfactory verification of compliance and through special inspections.

In case a written warning or directive is issued for non-reporting of unusual occurrences / incidents, the explanatory response and the incident investigation report submitted by the consentee should be reviewed in the concerned Division and if required, by the appropriate safety committees. Further, a review of the general performance of the RF and the steps taken to prevent recurrence of such issues in future is also done, before normalising the written warning or directive action.

In case a written warning or directive is issued for non-compliance to certain stipulations of the consent, the explanatory response submitted by the consentee, bringing out the corrective measures taken to prevent recurrence of such issues should be reviewed in the concerned division and if required, by the appropriate safety committees. Review of the general performance of the radiation facility is done before normalizing the written warning or directive action.

(iii) Curtailment

In case any specified activity was curtailed based on non-compliance with the stipulations of the consent (licence/authorisation/registration/approval), AERB will review the consentee's response and carry out special inspection to check that all the safety related deficiencies noticed earlier are addressed fully to assure that there is no radiological hazard to the RF personnel, members of the public and the environment.

The concerned division of AERB may investigate, in detail, to understand the reasons for the occurrence of the following:

- (i) Deterioration of structures, systems and components;
- (ii) Equipment malfunction;
- (iii) Serious violations;
- (iv) Non-compliance with safety and security requirements; and
- (v) Unsafe act and/or practices.

The investigation includes checking the corrective actions taken and incorporation of lessons learnt in the specific RF (and others, if applicable). Based on satisfactory compliance with all the regulatory requirements, the concerned division will grant the relevant clearances/ authorisations with concurrence from the competent authority.

(iv) Modifications, Suspension or Revocation:

In case of modification or suspension or revocation of the consent (licence/ authorisation/ registration/approval) issued depending on the nature and severity of the situation, AERB may conduct detailed review:

- (i) to determine the root cause for particular unusual occurrence/incident;
- (ii) to arrive at corrective actions to prevent recurrence; and
- (iii) the implementation of lessons learnt.

While modification and suspension of consent can be normalised after the above steps, thought has to be given in the case of revoking of consent, whether any of the earlier reviews done during the issue of initial consent needs to be repeated in view of changed circumstances.

(v) Penal Action

Since the penal action is envisaged after invoking the Sections 24, 25 and 26 of the Atomic Energy Act, 1962 by court of law, penal action will be normalised as per the directives of the court. Enforcement actions taken in addition to the penal actions, may be normalised as per the guidelines given above.

5.4 Enforcement Procedures

- 5.4.1 All enforcement decisions shall be intimated to the consentee in writing and the records of the same shall be maintained.
- 5.4.2 On-the-spot enforcement actions by the inspector are appropriate only in situations where it is determined by the inspector that if the same are not implemented immediately, the RF operation would be rendered unsafe.
- 5.4.3 In other situations, head/director of concerned division shall take enforcement actions particularly those involving curtailment of activity or suspension of consents and other punitive actions with approval of the competent authority.
- 5.4.4 A special inspection, if required, should be planned to check whether
 - (i) the consentee/licensee has complied with the recommendations/stipulations within the period of time, specified in the AERB enforcement order; and
 - (ii) the enforcement measures intended to protect the facility personnel, members of the public and the environment from an imminent radiological hazard, have been implemented by the consentee.

APPENDIX 1

TYPICAL LIST OF REFERENCE DOCUMENTS AT VARIOUS STAGES OF INSPECTION

The inspector should study the relevant technical materials to visualize the present condition of the RF systems under the assigned area of inspection. A typical list of reference documents which can be used during siting, construction, commissioning, operation and decommissioning stages of radiation facilities, as applicable, is given below:

1. Siting

- (i) Site characteristics (physical aspects)
- (ii) Physical aspects of the vicinity of the RF
- (iii) Geological and geo-technical aspects
- (iv) Hydrological aspects, as applicable
- (v) AERB safety codes, standards and guides, as applicable
- (vi) Land ownership documents.

2. Construction

- (i) AERB safety codes, standards, guides and manuals, as applicable
- (ii) Preliminary safety analysis report (PSAR)
- (iii) Safety stipulations including status of pending implementation thereof
- (iv) Construction safety manual and construction methodology document
- (v) QA manual for construction
- (vi) Design basis reports (DBR) and manuals
- (vii) Current status of construction
- (viii) Previous inspection reports and the RF response and follow up of previous regulatory inspections
- (ix) Safety committee recommendations based on the safety review by AERB and facility response
- (x) Non-conformance control procedures
- (xi) Documents on physical security, safeguards and access control
- (xii) Any relevant feedback from the RF under construction (national/international).

3. Commissioning/Operation

- (i) Commissioning/Acceptance test reports (FSAR/ATR)
- (ii) Regulatory consents, if any
- (iii) Safety stipulations including status of pending implementation thereof
- (iv) Safety and operating personnel: Qualification, training and certification
- (v) Personnel monitoring services (PMS) records
- (vi) Inventory of radioactive material/radiation generating equipment
- (vii) Periodic safety status reports
- (viii) Radiation protection survey reports including protection level dosimetry
- (ix) Standard operating procedures for equipment/systems

- (x) Special tests/certificates/inspection reports
- (xi) Directives of the AERB, recommendations of the AERB safety committees based on the safety review and facility compliance reports
- (xii) Previous inspection reports and facility response and unresolved issues, if any
- (xiii) Minutes of the local safety committee (LSC) meetings
- (xiv) Unusual occurrences reports, if any
- (xv) Radiation Protection Programme (RPP)
- (xvi) Emergency response plans and preparedness/procedures (EPP)
- (xvii) Radioactive waste disposal data and relevant records
- (xviii) Authorisation obtained from various statutory authorities, as applicable
- (xix) Documents on physical security, safeguards and access control
- (xx) Any relevant feedback from RF (national/international).

4. Decommissioning

- (i) Copies of NOC/authorisation for import/procurement of sources
- (ii) Regulatory consents for decommissioning and disposal of radioactive material
- (iii) Decontamination procedures including dismantling of the unit and the removal of radioactive material
- (iv) Safety and operating personnel : qualification, training and certification;
- Management strategy for handling, treatment, conditioning, storage and safe disposal of all radioactive wastes
- (vi) Radiation protection programme (RPP)
- (vii) Emergency response plan and preparedness/procedures (EPP)
- (viii) Radiological monitoring and surveillance, including occupational and public protection plan
- (ix) Approved plan for storage of disused radioactive sources
- (x) Authorisations for disposal of radioactive material at authorised waste management facility or export back to country of origin; and
- (xi) Documents on physical security, safeguards and access control.

APPENDIX 2

INSPECTION ASPECTS AT VARIOUS STAGES

A.1 General

Inspection requirements during various consenting stages of radiation facility are described briefly in the subsequent paragraphs based on AERB safety guide entitled 'Consenting Process for Radiation Facilities' (AERB/RF/SG/G-3) and 'Regulatory Inspection and Enforcement of Nuclear and Radiation Facilities' (AERB/SG/G-4). The inspection areas mentioned here are broadly applicable to different types of radiation facilities. However, detailed inspection areas during the major consenting stages may be identified and facility specific checklist may be prepared and followed as required.

A.2 Siting

- A.2.1 The inspection for this stage is not normally fixed on yearly basis instead they are conducted depending on type of the RF requiring site inspection. Preparation of site activities undertaken by the consentee, including verification of site characteristics, should be inspected, as applicable.
- A.2.2 Regulatory inspections during siting stage to verify
 - (i) the site characteristics (physical aspects) remain consistent with the information presented by the consentee in its application and in the subsequent supporting documentation;
 - (ii) the site characteristics are in compliance with the AERB applicable safety codes, standards and guides;
 - (iii) the status of implementation of AERB recommendations, if any; and
 - (iv) any new information being revealed as a result of the activities during the site preparation, which will be useful in making subsequent consenting decisions.
- A.2.3 The typical checklist for inspection during siting is as given in **Annexure-1**. This may be revised based on feedback of each inspection, as it is not a routine inspection and will be practice specific.

A.3 Inspection During Construction Stage

The inspection for this stage is not normally fixed on yearly basis but conducted depending on the progress of construction and type of the RF requiring inspection.

- A.3.1 Regulatory inspections during construction stage would broadly cover the following:
 - (i) site-specific data are acceptable and appropriately incorporated in the design;
 - (ii) checking of layout of the facility;
 - (iii) safety related structures, systems and components (SSCs), conform to the requirements of relevant safety codes and standards and/or established good practices;
 - (iv) construction activities associated with fabricating and installing these SSCs are carried out in accordance with regulatory requirements;
 - (v) design concession records are maintained and concurrence obtained from various statutory authority/agencies, including those requiring regulatory review;
 - (vi) QA requirements are established and are adhered to during all stages of construction;
 - (vii) safety committee recommendations and stipulations of AERB are complied with;
 - (viii) adequacy of civil construction as applicable for the relevant facilities;

- (ix) details of major changes including design modification affecting safety; and
- (x) industrial and safety aspects, as applicable.

However the inspector(s) are free to cover any other area affecting safety and security during the inspection, if required.

For certain types of radiation facilities there is no separate construction stage as such, in which case during site and layout plan approval stage itself the aspects covered under items A.2 and A.3 are checked/verified for compliance, as applicable.

A.4 Commissioning

A.4.1 The commissioning phase for radiation facilities should be identified. These inspections are required to check the readiness of the RF before going to operating stage and to provide an opportunity for the examination of the consentee's activities in order to confirm safety in the RF performance and to identify problems, if any, at an early stage.

For certain type of facilities, commissioning/operation may be a combined consent stage.

Regulatory inspections during commissioning stage would broadly cover the following:

- (i) status of regulatory consents at various stages and implementation of AERB recommendations;
- (ii) compliance with the AERB safety codes, standards and guides;
- (iii) verification of acceptance test report (ATR) and commissioning tests and results;
- (iv) verification of compliance with approved design specification as given in PSAR including any non-conformances;
- (v) review of the 'as-built' design of the RF;
- (vi) details of major changes including design modifications affecting safety;
- (vii) safety manpower: qualification, training and certification;
- (viii) radiation protection programme (RPP) and its implementation;
- (ix) quality assurance manual/programme;
- (x) emergency response plans and preparedness (EPP);
- (xi) maintenance of records and system of reporting to the RF management and AERB;
- (xii) inventory of radioactive material, if any;
- (xiii) radioactive waste management;
- (xiv) documents on physical security aspects; and
- (xv) industrial and fire safety aspects.

However the inspector(s) are free to cover any other area affecting safety and security, during the inspection, if required.

A.4.2 Activities associated with commissioning of the RF will normally begin before construction is completed. Accordingly, AERB should be prepared to inspect areas of commissioning activity concurrently with inspection of construction phase activities. Based on review of the commissioning programme, certain hold points may be identified by safety review committees to be covered by inspections prior to next stage of consenting.

A.5 Operation

A.5.1 Once the RF has completed all the relevant commissioning activities, the licence for routine operation may be granted. During routine operation, the planned inspections are conducted, which provide an opportunity for the examination of the consentee's activities and conformance to general safety objectives and to identify potential problems. This verification should include direct observation of activities, interviews with the RF personnel, review of qualification, training and certification of safety and operating personnel, and a sample documentation review.

In case of facilities where radioactive waste is generated, the waste management system particularly waste disposal facilities, limit for the controlled discharge of liquid and gaseous waste etc. should be examined.

- A.5.2 Regulatory inspections during the operation should broadly cover the following:
 - (i) Compliance with the AERB safety codes, standards and guides;
 - (ii) Implementation of AERB recommendations;
 - (iii) Visit to control room, source storage room and associated facility area, as applicable;
 - (iv) Verification of compliance with approved design specification as given in FSAR;
 - (v) Details of major changes including design modifications affecting safety;
 - (vi) Counting/calibration/ source preparation laboratories (as applicable);
 - (vii) Inventory of radioactive material;
 - (viii) Radioactive waste storage facility, waste management system and discharges to environment;
 - (ix) Operational experience, generic problems and lessons learnt at the RF and other RF;
 - (x) Seriousness of the reported and non-reported incidents and overall safety practices;
 - (xi) Critical preventive measures including monitoring system and alarm setting, (if applicable);
 - (xii) Safety manpower : Qualification, training and certification;
 - (xiii) Personal protective equipment (PPE), as applicable: availability and storage;
 - (xiv) Radiation protection programme (RPP);
 - (xv) Emergency response plans and preparedness/procedures (EPP);
 - (xvi) Periodic safety status reports;
 - (xvii) Physical security measures related to safety;
 - (xviii) Operational and servicing maintenance aspects;
 - (xix) Industrial and fire safety aspects; and
 - (xx) Housekeeping.

Detailed checklist to inspect all types of RF in operating stage is given in **Annexures 15 to 34**. Same checklists may be used for commissioning inspection of the RF, as applicable.

A.6 Industrial and Fire Safety for DAE units

In case of industrial and fire safety aspects of all radiation facilities of the DAE that come under the surveillance of AERB, various requirements as laid down in Factories Act, 1948, the Atomic Energy (Factories) Rules, 1996, other directives of AERB and other applicable Acts/Rules such as Environment Act, 1986 and its rules etc. should be checked at each radiation facility during all stages of consent.

Certificates issued by other statutory authorities dealing with industrial activities may be checked to ensure compliance by radiation facilities.

Fire safety requirements as per AERB fire standard and AERB safety guide should be checked at each radiation facility during all stages.

Detailed checklist for regulatory inspection of DAE units for industrial and fire safety aspects is as given in **Annexure 35**.

A.7 Decommissioning Stage

A.7.1 Decommissioning of the RF is taken up before releasing the RF from regulatory control. Regulatory inspection should be carried out for certain RF during decommissioning stage to confirm that the residual activity, if any, has been reduced to specified acceptable levels for use of the premises/area by general public.

Detailed checklist for inspection during decommissioning of the RF is as given in Annexure 3.

However following activities should be covered, as applicable:

- (i) Decontamination procedures including dismantling of the unit and the removal of radioactive material;
- (ii) Management strategy for handling and storing of radioactive material;
- (iii) Waste management strategy for the treatment, conditioning, storage and disposal of all radioactive wastes;
- (iv) Characterisation of the residual activity;
- (v) Safety and operating personnel: Qualification, training and certification;
- (vi) Radiation protection programme (RPP);
- (vii) Emergency response plan and preparedness/procedures (EPP);
- (viii) Radiological monitoring and surveillance, including occupational and public protection plan;
- (ix) Approved plan for storage of disused radioactive sources;
- (x) Authorisations for disposal of radioactive material at authorised waste management facility or export back to country of origin; and
- (xi) Documents on physical security, safeguards and access control.

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF SITE FOR INSTALLATION OF RADIATION FACILITY

Date of Inspection:

1.1 **Details of the Radiation Facility (RF):**

1.1.1 Institution Number:

> Name and address of the RF: Telephone No: (O): Fax No:

- 1.1.2 Address of site for Installation of the RF:
- 1.2 Type of the Facility: Govt/Semi-Govt/Autonomous/Private/Joint venture/Others

1.3 **Employer:**

(a)	Name:		
(b)	Designation:		
	Telephone No.	(O):	(R)
	Mobile No.		
	E-mail		

1.4 **Applicant:**

(a) Name: (b) Designation: Telephone No. (O): (R) Mobile No. E-mail

1.5 **Inspection Coordinator from Institution:**

(a)	Name:		
(b)	Designation:		
	Telephone No.	(O):	(R)
	Mobile No.		
	E-mail		

Particulars of the RF 2.

- (i) Type of the proposed RF:
- (ii) Purpose of Radiation Facility:
- (iii) Proposed designer, manufacturer of the RF:
- Proposed supplier of the Radiation Generating Equipment: (iv)
- Max. Activity/Rating of the Machine: (v)

3. Verification of Site Characteristics of Proposed RF (as applicable)

Yes \Box No \Box NA \Box Any neighboring site with hazardous nature: (i) (Explosives storage/fuel storage/chemical plant)

(ii) If yes, distance of following installation from proposed site:

(a)	Ammunition and explosive dumps :	 km
(b)	Storage of inflammable materials :	 km
(c)	Direction of runway of civilian/military airfields:	 km
(d)	Public and residential localities:	 km
(e)	Chemical plant :	 km
(f)	Water reservoir (River/ Dam) :	 km

(iii) Nature of occupancy around the site up to 30 m from the boundary wall of the facility including high-rise buildings, if any and the nature of population around the site

- Seismic Zone of the site location as per IS-1893 (Part-I) : 2002 : _____ (iv)
- Nature of the site terrain: Rocks/soil/water bodies/ocean/in the vicinity (v)
- (vi) Height from Mean Sea Level (MSL) :
- (vii) Nature of access road to the proposed site : Access road available \Box / Proposed \Box
- (viii) Maximum level of ground water and maximum flood level for the past hundred years: ----

(ix)	Chance of flooding during rains :	Yes 🗆 No 🗆
(x)	Proper physical security provisions :	Yes 🗆 No 🗆
(xi)	Average natural background ionising radiation level at the site: ——	— μSv/h
Avai	lability of Documents/Records:	
(i)	Land ownership of the proposed site and its Legal status :	Yes 🗆 No 🗆
(ii)	Seismic Zoning of site for installation of the RF as specified in IS-1893 (Part-I):2002 :	
(iii)	Documents on location of capable fault, if any and its distance (at least 0.5 m away):	Yes 🗆 No 🗆
(iv)	Meteorological data in respect of maximum level of ground water and maximum flood level for the past hundred years :	Yes 🗆 No 🗆
Any	other observations:	

5.

4.

(Attach extra sheet if required)

(Signature of inspector(s) with date)

Name of Inspector(s):

I/We was/were informed about the above observations.

(Signature of Coordinator of the Institution)	(Signature of Employer/Head of Institution)
Name:	Name:
Designation:	Designation:

TYPICAL CHECKLIST FOR REGULATORY INSPECTION DURING CONSTRUCTION OF RADIATION FACILITY

Date of Inspection:

1.1 Details of the Radiation Facility (RF):

1.1.1 Institution number:

Name and address of the RF: Telephone No. (O): Fax No.

1.2 Type of the Facility: Govt/Semi-Govt/Autonomous/Private/Joint venture/Others

1.3 Employer:

(a)	Name :		
(b)	Designation:		
	Telephone No.	(O):	(R)
	Mobile No.		
	E-mail		

1.4 Applicant:

- (a) Name :
- (b) Designation: Telephone No. (O): (R) Mobile No. E-mail

1.5 Inspection Coordinator of Institution:

(a) Name:
(b) Designation: Telephone No. (O): Mobile No. E-mail

2. Particulars of the RF:

- (i) Type of the proposed RF:
- (ii) Purpose of Radiation Facility:
- (iii) Designer, manufacturer of the RF:
- (iv) Supplier of the Radiation Generating Equipment, as applicable:
- (v) Max. Activity of RF/Rating of the Machine:

3. On-Site Verification of Consents/Approvals issued

(i)	Site Approval issued by AERB:	Yes 🗆 No 🗆
(ii)	Layout approval available:	Yes 🗆 No 🗆
(iii)	Construction Approval issued by AERB:	Yes 🗆 No 🗆
(iv)	Others statuary Authorities Approval(s):	Yes 🗆 No 🗆
	Comments:	

4. Verification of Construction Activity

(i)	Whether the RF layout is as per approved plan?	Yes 🗆 No 🗆
(ii)	Any modifications done to the existing approved radiation installation: If yes, whether permission obtained for the same ?	Yes □ No □ Yes □ No □
(iii)	Whether QA programme for construction is available?	Yes 🗆 No 🗆
(iv)	Whether safety related structures, systems and components (SSCs) conform to the requirements of relevant safety codes and standards ?	Yes 🗆 No 🗆
(v)	Whether construction activities associated with fabricating and installing these SSC are conducted in accordance with regulatory requirements ?	Yes 🗆 No 🗆
(vi)	Whether design construction records are maintained and concurrence obtained from various statutory authority/agencies ?	Yes 🗆 No 🗆
(vii) Whether QA requirements are established and adhered to during all stages of construction ?	Yes 🗆 No 🗆
(vii	i) Current status of construction :	
	Comments:	

5. Availability of Documents/Records:

Whether the following documents and records are being maintained:

(i)	Detailed layout and civil engineering drawings of the RF with peripheral occupancy:	Yes 🗆 No 🗆
(ii)	Preliminary Safety Analysis Report (PSAR):	Yes 🗆 No 🗆
(iii)	Construction Schedule:	Yes \Box No \Box
(iv)	Specification for construction of structure, system and components (SSC):	Yes 🗆 No 🗆
(v)	Quality assurance (QA) manual for construction:	Yes \Box No \Box
(vi)	Design Basis Report (DBR):	Yes \Box No \Box
(vii)	Construction safety manual and construction methodology document:	Yes \Box No \Box
(viii)	Detailed report from accredited agency on geological and geotechnical investigation:	Yes 🗆 No 🗆

(ix)	Detailed report from accredited agency on testing of various construction samples:	Yes 🗆 No 🗆
(x)	Document on physical security aspects of the facility:	Yes 🗆 No 🗆
Any o	ther observations:	
(Attac	h extra sheet if required)	

(Signature of inspector(s) with date)

Name of Inspector(s):

6.

I/we was/were informed about the above observations.

(Signature of Co-ordinator of the Institution)	(Signature of Employer/Head of the Institution)
Name :	Name :
Designation :	Designation:

TYPICAL CHECKLIST FOR REGULATORY INSPECTION DURING DECOMMISSIONING OF RADIATION FACILITY

Date of Inspection:

1.1 Details of the Radiation facility (RF):

1.1.1 Institution number:

Name and address of the RF: Telephone No. (O): Fax No.

1.2 Type of the Facility: Govt./Semi-Govt/Autonomous/Private/Joint venture/Others

1.3	Emp (a) (b)	loyer: Name: Designation: Telephone No. Mobile NO. E-mail:	(O):	(R):
1.4	Lice	nsee:		
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail:	(0):	(R)
1.5	RSO	:		
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail:	(O):	(R)
1.6	Insp	ection Coordinator	of Institution:	
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail:	(O):	(R)
2.	Part	iculars of the RF:		
	(i)	Type of the RF to	be decommissioned:	
	(ii)	Reason for decor	nmissioning of the RF:	
	(iii)	Type of radiation X-ray, accelerato	sources (sealed and unsealed radioactive sources) handled in the facility:	urces
		Comments:		

3. **On-Site Verification of Consents/Approvals issued** (i) Authorisation for decommissioning of the RF: Yes \Box No \Box (ii) Copies of NOC/authorisation for import/procurement of sources: Yes \Box No \Box (iii) Approval for disposal of radioactive material (RAM): Yes \Box No \Box (iv) Whether RSO certificate is valid? Yes \Box No \Box (v) Approval for radioactive material transport container: Yes \Box No \Box Comments:

4. Personnel Monitoring

4.1	Institu	Institution's personnel monitoring service (PMS) number:		
4.2	Numł	per of personnel monitoring devices (PMD) in the RF:		
4.3	State			
	(a)	PMD is provided to all radiation workers involved in decommissioning ?	Yes 🗆 No 🗆	
	(b)	PMD are being worn by workers appropriately ?	Yes 🗆 No 🗆	
	(c)	Dose records available ?	Yes 🗆 No 🗆	
	(d)	Any over-exposure reported during last three years ?	Yes 🗆 No 🗆	
	(e)	If yes, whether dose recorded was found to be genuine ?	Yes 🗆 No 🗆	
	Γ	Comments:		

5. Measuring Instruments/Protection Level Equipment

	Working (Yes/No/NA)	Calibration valid (Yes/No/NA)
Radiation Survey Meter (RSM)		
Pocket Dosimeter		
Area Monitor		
Whether dosimetric equipment/protection level equipment are appropriate for radiation type and energy ?		Yes □ No □ If no, then details:

6. Details of Disused Sources:

(i)	Any decommissioning/disposal carried in the past:	Yes \Box No \Box NA \Box
(ii)	Type of disused sources for disposal:	
(iii)	Number of sources with activity of each source:	
(iv)	Whether material is proposed to be transported in the original package supplied by the supplier ?	Yes 🗆 No 🗆
	If yes, whether the packaging is in good condition ?	Yes 🗌 No 🗌

	(v)	Type of Transport package : Excepted/IP-1/2/3/Type A/Type B(U)	/B(M)		
	(vi)	Whether design approval certificates of Type $B(U)/(M)$ packages are valid ?	Yes 🗆	No 🗆	NA 🗆
	(vii)	Whether the packages properly labeled and marked ?	,	Yes 🗆	No 🗆
	(viii)	Whether a management strategy for handling and storing of radioactive material is available ?	Yes 🗆	No 🗆	NA 🗆
	(ix)	Whether any exclusive storage room is identified for interim storage of transport package ?	Yes 🗆	No 🗆	NA 🗆
	(x)	Whether adequate security measures are available for radioactive material ?		Yes 🗆	No 🗆
	(xi)	Whether storage area has appropriate barriers and warning signs in English, Hindi and local language ?		Yes 🗆	No 🗆
	(xii)	Whether original source supplier/authorised representative has been involved in removal of disused sources and their packaging ?	1	Yes 🗆	No 🗆
		If no, then particulars of the agency/personnel involved in removal of the sources :	_		
	(xiii)	Name and address of the agency where the waste material is to be disposed off :	_		
		Comments :			
7.	Radia	tion Contamination and Residual Activity (as applicable)			
	(i)	Whether any residual activity will be present in the RF ?	Yes 🗆	No 🗆	NA 🗆
		If yes, whether the method for characterisation of the residual activity available ?	Yes 🗆	No 🗆	NA 🗆
	(ii)	Whether any object is contaminated ?	Yes 🗆	No 🗆	NA 🗆
		If yes, particulars of the radioactive contamination:			
		Disposal procedures for contaminated objects:			
	(iii)	Whether potential for exposure of workers to airborne radioactive substances exists ?	Yes 🗆	No 🗆	NA 🗆
	(iv)	Monitoring for airborne radioactivity conducted:	Yes 🗆	No 🗆	NA 🗆
		Comments :			
8.	Trans	port of Radioactive Material:			
	(i)	Whether permission for transport of radioactive material has obtained ?		Yes 🗆	No 🗆
	(ii)	Name and address of the facility to which the source will be transported for disposal:			
	(iii)	How the package is proposed to be immobilized in the vehicle during transport ?			
	(iv)	Do the shipper's declaration papers have correct details and used when shipping sources ?		Yes 🗆	No 🗆

	(v)	Whether TERM CARD is provided to the driver:	Yes 🗆 No 🗆
	(vi)	Whether any vehicle tracking system will be provided during transport of RAM ?	Yes 🗆 No 🗆 NA 🗆
		If yes, type of tracking system provided:	
9.	Availal	bility of Documents/Records	
	(i)	Procedures for dismantling of the unit and removal of source:	Yes 🗆 No 🗆
	(ii)	Decontamination procedures:	Yes 🗆 No 🗆
	(iii)	Action for disposal/decommissioning of the disused sources:	Yes 🗆 No 🗆
	(iv)	Radiation Protection Programme/Manual (RPP/RPM):	Yes 🗆 No 🗆
	(v)	Emergency response plan and preparedness/procedures (EPP):	Yes 🗆 No 🗆
	(vi)	Radiological monitoring and surveillance, including occupational and public protection plan:	Yes 🗆 No 🗆
	(vii)	Procedure for declaring that the site is free from contamination and fit for use by public:	Yes 🗆 No 🗆
10.	Any ot	her observations:	

(Attach extra sheet if required)

(Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed about the above observations.

(Signature of Coordinator of the Institution)	(Signature of Licensee/Employer)	
Name:	Name:	
Designation:	Designation:	

SPECIMEN FORMAT : AUTHORISATION OF INSPECTOR

GOVERNMENT OF INDIA ATOMIC ENERGY REGULATORY BOARD

No. AERB/Division/File No. /Year

Date

Sub : Authorisation of Inspector

In pursuance of Section 17(4) of the Atomic Energy Act 1962 and in exercise of the powers vested in me vide Rules 30 and 31 of the Atomic Energy (Radiation Protection) Rules 2004. I hereby authorise Shri/Smt. _______, {Designation} ______, ID no/employment no. ______, of _______ {affiliation}, to exercise powers as an Inspector in connection with the regulatory inspections of radiation facility assigned to him/her by AERB.

For implementing on-the-spot enforcement action if any, the Inspector shall obtain prior approval from Chairman, AERB.

Chairman, AERB

Smt/Shri

Designation

Affiliation

Copy to : Vice-Chairman, AERB Secretary, AERB Director / Head of Division, AERB

SALIENT POINTS OF CODE OF CONDUCT FOR INSPECTORS

- (i) Where an inspection involves two or more officers, the senior inspector will take the lead role in discussions and interviews.
- (ii) Inspectors will refrain from any public display of dissent.
- (iii) Inspectors will identify themselves by showing their ID card.
- (iv) ID cards or other appropriate identification should be worn at all times when conducting an inspection unless site health and safety considerations require otherwise.
- (v) A professional appearance should be presented and maintained during the inspection. A firm but courteous attitude should be adopted at all times.
- (vi) Irrelevant discussion should be avoided as it can irritate facility personnel.
- (vii) Questions to radiation workers and managers should be courteous and carefully considered to ensure relevant information is obtained. Open questions preferably should be used provided that the answer received includes the expected information on the specific subject of interest.
- (viii) Where practicable, issues should be discussed as and when they arise.
- (ix) Open criticism of individuals especially in the presence of other colleagues should be avoided.
- (x) Listen in a fair and objective way to what others have to say.
- Inspectors should not act as consultants on means of achieving regulatory requirements.
- (xii) Advice to radiation facility on how compliance can be achieved may be given but, while doing it, it should be stressed that the practical actions necessary are, and will continue to be, the responsibility of the employer/licensee.
- (xiii) The role of our colleagues should be respected and the role of radiation facility personnel should be recognised and acknowledged. All peers, subordinates and licensee should be respected and all individuals should be treated with dignity and courtesy.
- (xiv) It is to be ensured that regulatory decisions are not influenced by personal preferences and biased.
- (xv) Do not compromise with actions or decisions for personal gain or doing favour to someone.
- (xvi) Conflicts wherever possible should be avoided and should be resolved in creative ways.

SPECIMEN FORMAT: APPROVAL OF ANNUAL INSPECTION PROGRAMME

GOVERNMENT OF INDIA ATOMIC ENERGY REGULATORY BOARD

AERB/Division/File No./Year/

Date

Sub : Tentative Annual Regulatory Inspection Plan

It is proposed to conduct the planned regulatory inspection of the radiation facilities (RF) as envisaged in the Safety Manual. Proposed target frequency for regulatory inspections for different RF are as per Sec. 3.3 and Annexure-7 of AERB/RF/SM/G-3. The inspection program of RF to be inspected for the year — is attached herewith as an annexure(s).

The special/surprise inspections of the RF will be carried out on as and when required basis.

Chairman, AERB may kindly approve the above annual schedule of RI for the year ———.

Director/Head of Division AERB

Through: Vice-Chairman, AERB

Chairman, AERB

Copy to: RI Coordinator

FREQUENCY OF PLANNED REGULATORY INSPECTIONS FOR RADIATION FACILITIES

S. No.	Type of Radiation Facility	Inspection Frequency
1	Land-based high intensity gamma irradiators (Gamma Radiation Processing Facilities (GRAPF)	Once in 3 years
2	Industrial Accelerator Radiation Processing Facilities (IARPF)	Once in 5 years
3	Industrial Radiography (IGRED/X-ray)	Once in 3 years
4	Gamma Irradiation Chamber (GIC)	Once in 3 years
5	Nucleonic Gauges/Well Logging incorporating high activity sources (Category-2 sources)	Once in 3 years
6	High Energy Particle Accelerator Research Facilities (PARF)	Once in 5 years
7	Radiotherapy (with Telegamma Therapy)	Once in 3 years
8	Radiotherapy (without Telegamma Therapy)	Once in 5 years
9	Medical Cyclotron	Once in 3 years
10	Nuclear Medicine	Once in 3 years
11	Facilities engaged in commercial production of radiation generating equipment (with test facilities)	Once in 5 years
12	Facilities engaged in commercial production of devices containing radioactive sources	Once in 5 years
13	Facilities engaged in commercial production of radioactive sources/ source supplier	Once in 3 years
14	Consumer Products Manufacturers	Once in 5 years
15	Container scanner (Gamma, Accelerator)	Once in 5 years
16	Nucleonic Gauges (Category-3 gamma sources)	On Sample basis
17	Nucleonic Gauges incorporating low activity sources (e.g. beta sources and X-ray based gauges)	On Sample basis
18	Diagnostic Radiology with complex equipment (CT, interventional radiology i.e. Cath Lab., fluoroscopy, mammography)	On sample basis
19	Diagnostic Radiology (Conventional X-ray equipment only)	On sample basis
20	Radio-Immuno-Assay (RIA)	On sample basis
21	Research institutions using sealed/unsealed sources (Including biomedical research and tracer studies)/Analytical X-ray equipment/ Calibration Laboratories for Radiation Monitoring Instruments	On sample basis

In case of facilities possessing devices/equipment of high inspection frequency and low inspection frequency, the high frequency facility will be the criteria for inspection for both the types of facilities. (e.g. RT with Telegamma and Accelerator)

The frequency mentioned in the manual is indicative and not construed as binding for AERB to comply with and same shall be reviewed based on regulatory inspection feedback.

SPECIMEN FORMAT : APPROVAL OF INSPECTION TEAM AND **PROGRAMME FOR RADIATION FACILITIES**

Government of India Atomic Energy Regulatory Board

No. AERB/Div./File No./Year/

Date

Sub : Proposal for Regulatory Inspection of RF {RF Name}

It is proposed to carry out the regulatory inspection of radiation facilities as detailed below. :

:

:

Name of the RF to be inspected

Date(s) of inspection

Type of inspection with details, if any

Proposed inspection team is as follows.

INSPECTION TEAM

S. No	Name	RI Designation (Inspector/Team member/ Expert Member)	Type of Insp. (Planned/Special/ Surprise)
1	Shri		
2	Shri		
3	Shri		

Approval for the above regulatory inspection programme is requested.

RI Coordinator, Division, AERB

Director / Head of Division

Copy to : All team members

SPECIMEN FORMAT : REGULATORY INSPECTION SCHEDULE

Government of India Atomic Energy Regulatory Board

No. AERB/Div/RF File No./ Year/

Date

Sub: Intimation of Regulatory Inspection of the RF {RF Name}

The safety in use of radiation sources/radiation generating equipment in radiation facility is governed by Atomic Energy Act 1962 and Rules published there under, i.e. the Atomic Energy (Radiation Protection) Rules, 2004. It is mandatory for radiation facility to abide by the above rules, and relevant safety regulations and stipulations made by AERB in Licence/Consent.

S. No	Name
1	Shri
2	Shri
3	Shri

The arrival schedule of the inspection team will be intimated to you later.

It is therefore requested to provide full cooperation for the inspection team to carry out the inspection effectively.

It shall be ensured that all the concerned personnel of your facility and relevant records are available during the inspection.

(Director/Head of Division) AERB

Licensee/Employer

Copt to : All team members

SPECIMEN FORMAT: REGULATORY INSPECTION REPORT OF RADIATION FACILITY ALONG WITH TABLE OF CATEGORISATION

Government of India Atomic Energy Regulatory Board

Ref. No. AERB/Division/RI/File No./Year/

Date:

Sub: Regulatory Inspection of RF {RF Name}

Inspection date:

1. General

1.1 Regulatory inspection of RF *{RF Name}* was carried by AERB inspection team on ——— /or during the period from _____ to _____.

Based on field observations and review of the RF documents, observations of the inspection team/ inspector were brought out. The inspection findings were discussed with the RF management/ representative in the exit meeting held on ______.

1.2 Inspection team

Division/organisation (RI Designation)
Division/organisation
Division/organisation

1.3 References

- (i) Stipulations of AERB of relevant consent;
- (ii) Rules and AERB Safety documents, as applicable
- (iii) Atomic Energy (Radiation Protection) Rules, 2004;
- (iv) Previous regulatory inspection reports issued by AERB and the RF response submitted;
- (v) Periodic safety status report of the RF.
- 1.4 The RF status :Siting/Construction/Pre-commissioning/Commissioning/Operation/Decommissioning
- 1.5 Observations/recommendations : *Include following as applicable:*
 - (i) method used for inspection (interaction/document review/observations);
 - (ii) details of the RF areas, activities, processes, systems, or components which have been inspected, assessed or reviewed;
 - (iii) details of radiation source that were physically verified/inspected;
 - (iv) safety and operating staff: Qualification, training and certification;
 - (v) procedures for management of radioactive waste generated, if any;
 - (vi) criteria used in the assessment;

- (vii) reference to consent stipulations of AERB and relevant statutory provisions;
- (viii) status of earlier regulatory actions/compliance status of earlier findings;
- (ix) copy of documentary evidences, if any;
- (x) deficiency or violation found during regulatory inspections;
- (xi) record of any regulations or authorisation condition that have been contravened;
- (xii) record of findings and conclusions of the regulatory inspector including any corrective action or enforcement actions that should be taken;
- (xiii) a record of the recommendations for future action; and
- (xiv) outcome of the exit meeting.
- 1.6 Categorisation of observations/recommendations in the inspection report for further review and followup recommendations of the inspection team.

(Name & Sign. of Inspector(s))

Director/Head of Division AERB

Copy to : All team members RI Coordinator

CATEGORISATION OF OBSERVATIONS/DEFICIENCIES BROUGHT OUT DURING THE REGULATORY INSPECTIONS OF THE RF (THIS IS AN ANNEXURE TO THE INSPECTION REPORT)

Category	Particulars	Item no. of the RI Report
Category-I (CAT.I)	Violation of Act(s), Rules, AERB safety codes, guidelines; Licence stipulations, AERB Safety Directives, Inadequacies of qualification, training and certification of safety and operating staff	
Category-II (CAT.II)	 (i) Deficiencies in operating systems and safety systems as specified by safety standards; (ii) Deficiencies in surveillance procedures of safety related 	
	equipment;	
	(iii) QA denciencies; (iv) Shortcomings identified in the design of safety related	
	equipment and working conditions, etc.	
Category-III	Inadequacies with respect to the following :	
(CAT.III)	(i) Organisational control;	
	(ii) Operation and maintenance Procedures;	
	(iii) Radiation Protection Procedures /Manual (RPP/RPM), as applicable;	
	 (iv) Emergency Response Plans and Preparedness/ Procedures (EPP); 	
	(v) Physical security aspects;	
	(vi) Radioactive waste management	
Category-IV	General observations/deficiencies regarding :	
(CAT.IV)	(i) Good operating/maintenance practices	
	(ii) Housekeeping	
	(iii) Documents and records	

SPECIMEN FORMAT : REGULATORY INSPECTION RECOMMENDATIONS LETTER

Government of India Atomic Energy Regulatory Board

No. AERB/Division/RI/Inst. File No. / RF Name /Year/

Date:

Sub : Recommendation followed by regulatory inspection of RF {RF Name}

This refers to the regulatory inspection carried out by officers from this Division — {name of Inspector, Designation) on {date of Insp.} to verify compliance with the regulatory requirement and physical verification of radioactive sources in possession of {Name of RF}, (City, State)

In this regard, following are the observations/ recommendations for immediate implementation by {Name of the RF}, from consideration of radiation safety and security viewpoint.

Particulars of observations and recommendations:

1.

2.

3.

4.

{Name of the RF} should ensures that the above recommendations are implemented at the earliest and implementation status of these recommendations should be submitted to this Division within a period of one month from the date of issuance of this letter for further necessary action.

Kindly note that failure to submit the implementation status report may lead to initiation of appropriate regulatory action under the Atomic Energy (Radiation Protection) Rules, 2004.

(Director/Head of Division, AERB)

Encl: As above Name Employer/Licensee RF Address

Copy to: RI Coordinator

for necessary follow up

SPECIMEN LETTER : LETTER FOR ON-THE-SPOT ENFORCEMENT BY INSPECTOR

Government of India Atomic Energy Regulatory Board

No. AERB/Division/File No./Year/

Date:

Sub: On-the-spot enforcement action against the RF{RF Name}

In view of the prevailing unsafe situation in the RF {Name of the RF}, with the authority given to me by the Competent Authority (i.e. Chairman, AERB), I am requesting you to take the following corrective measures immediately and that no operation of your facility shall be carried out till further orders from AERB.

(i)

(ii)

It is requested to submit a detailed report of action/ measures taken to ensure safety of radiation facility.

You are also required to intimate the status of your facility to AERB immediately.

Inspector(s) (Name and Signature)

Employer/Licensee/RF Management/Representative

Through : Director/Head of Division

- Copy to: (i) Chairman, AERB
 - (ii) Vice-Chairman, AERB
 - (iii) RI Coordinator
 - (iv) All team members

SPECIMEN FORMAT : ENFORCEMENT LETTER ALONG WITH REGULATORY INSPECTION REPORT ON OBSERVATIONS/RECOMMENDATIONS

Government of India Atomic Energy Regulatory Board

No. AERB/Division/RI/RF File No../ RF Name /Year/

Date:

RI No.

Period of Inspection

Sub: Enforcement letter after Regulatory Inspection of RF {RF Name}

Regulatory inspection of RF *{RF Name}* was carried out from ______ to _____ by AERB inspection team/inspector by {Name of Inspector, Designation}_____. A copy of the observations/ recommendations is enclosed herewith. These were discussed and explained for required actions to be taken by the RF authorities during the feedback at the end of inspection with the RF management/representative.

Response to the above inspection report should be submitted to this Division within a period of one month from the date of issuance of this letter. The response should indicate status of implementation of recommendations and methodology with target dates for carrying out the required actions. In case the RF {name of the the RF} does not concur with any observation/recommendation the same should be clearly brought out for further consideration of AERB.

(Director/Head of Division, AERB)

Encl: As above

Employer/Licensee

Copy to: (i)

——— for necessary follow-up

(ii) All team members

RI Coordinator ----

SPECIMEN FORMAT : LETTER TO THE RADIATION FACILITY FOR NORMALIZATION OF ENFORCEMENT ACTIONS

Government of India Atomic Energy Regulatory Board

No. AERB/Division/RF file No./Year/

Date:

Sub: Intimation of the normalisation of enforcement action initiated against RF (name of the RF)

This refers to our earlier Directive/enforcement letter intimating about the enforcement action initiated against your radiation facility vide letter ref. no. ______ dated ______ for serious violations of category ______.

The subsequent reply to our Directive/Enforcement letter received from your institution vide letter dated ______ intimating the actions initiated by your facility to prevent recurrence of the violations of such serious nature in future has been reviewed by this Division.

Based on review of the reply, this Division hereby intimates that the actions as initiated against your facility are being normalised and your facility may resume the intended use of radiation sources or handling radioactivity adhering to safe work practice associated with radiation sources.

It shall be ensured that the violation of this nature does not recur in future.

(Director/Head of Division, AERB)

Employer/Licensee

Copy to: RI Coordinator

— for information

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF RADIOTHERAPY FACILITY

Date of inspection:

Type of inspection: Pre-commissioning Planned Special Surprise 1.1 **Details of the Radiation Facility (RF):** 1.1.1 Institution number: Name and address of the RF Telephone No. (O): Fax No. **Type of the Facility:** 1.2 Govt./ Semi-Govt./Autonomous/Private/Joint venture/Others 1.3 **Employer:** (a) Name : (b) Designation: Telephone No. (O): (R) Mobile No. E-mail 1.4 Licensee: (a) Name : Designation: (b) Telephone No. (R) (O): Mobile No. E-mail 1.5 **RSO:** Name: (a) Designation : (b) Telephone No. (O): (R) Mobile No. E-mail 1.6 **Inspection Coordinator from Institution:** (a) Name: Designation: (b) Telephone No. (O): Mobile No. E-mail 2. Compliance with recommendations based on Last Inspection Date of last inspection, if any: (i)

	(ii)	Whether all the recommendations are already complied ?	Yes 🗆 No 🗆
	(iii)	Particulars of pending recommendation, if any:	
3.	On-Si	te Verification of Consents/Approvals issued	
	(i)	Whether license for operation is valid?	Yes 🗆 No 🗆
	(ii)	Layout approval available:	Yes 🗆 No 🗆
	(iii)	Commissioning authorization/approval available:	Yes 🗆 No 🗆
	(iv)	Whether RSO certificate is valid ?	Yes 🗆 No 🗆
	(v)	Whether Licensee is the same as mentioned in the licence ?	Yes 🗆 No 🗆
		If no, whether any amendment of licence was sought and obtained	? Yes \Box No \Box
		Comments:	
4.	Sourc	es/Facilities Available	
4.1	Source	es/Equipment No.	of Units
	(i)	Linear accelerator	
	(ii)	Telecobalt	
	(iii)	HDR	
	(iv)	LDR	
	(v)	MAL	
	(vi)	Discrete sources	
	(vii)	Simulator/CT simulator	
	(viii)	Any other	
	(ix)	Details of disused sources, if any	
	(a)	Whether above sources/equipment are in accordance with the licence issued ?	Yes □ No□
	(b)	Any decommissioning/disposal carried out after last RI ?	Yes 🗆 No 🗆
	(c)	Whether permission taken for decommissioning/disposal ?	Yes 🗆 No 🗆
	(d)	Is there any disused source ?	Yes 🗆 No 🗆
		If yes, details of disused sources	Yes 🗆 No 🗆
		Whether the institute has plan of action for disposal/ decommissioning the same ?	Yes 🗆 No 🗆
		Comments:	

4.2 Particulars of the RT Equipment (if not available in Safety Status Report)

Type of Equipment	Make	Model	Year of Commissioning	Maximum Activity/Rating	Remarks

5. Availability of Operating Personnel

- (i) Number of qualified Radiation Oncologists available:
- (ii) Number of RSO available :
- (iii) Number of qualified Medical Physicists available:
- (iv) Number of qualified Radiotherapy Technologists available:
- (v) Whether above operating personnel are adequate in number ?
 Yes □ No □

 Comments:
 Yes □ No □

6. Personnel Monitoring

6.1	Instit	Institute personnel monitoring service (PMS) number :				
6.2	Num	Number of personnel monitoring devices (PMD) in RT :				
6.3	State	State whether;				
	(a)	PMD is provided to all radiation workers ?	Yes 🗆 No 🗆			
	(b)	PMD is provided to the trainees (if any)?	Yes 🗆 No 🗆 NA 🗆			
	(c)	PMD are being worn by workers appropriately ?	Yes 🗆 No 🗆			
	(d)	Proper storage of PMD is available ?	Yes 🗆 No 🗆			
	(e)	Dose records available ?	Yes 🗆 No 🗆			
	(f)	Radiation workers have access to their personnel monitoring records ?	Yes 🗆 No 🗆			
	(g)	PMS was suspended any time during last three years ?	Yes 🗆 No 🗆			
	(h)	Any over-exposure is reported during last three years ?	Yes 🗆 No 🗆			
		If yes, whether dose recorded was found to be genuine ?	Yes 🗆 No 🗆			
	(i)	Adequate measures have been taken to avoid recurrence of over-exposure ?	Yes 🗆 No 🗆			
6.4	Whet	ther pocket dosimeters are available ?	Yes 🗆 No 🗆			
	If yes	s, whether used by radiation workers any time?	Yes 🗆 No 🗆			
	If yes	s, whether dose records are maintained ?	Yes 🗆 No 🗆			
	[Comments:				

7. Measuring Instruments/Protection Level Equipment

Equipment	Available (Yes/No/NA)	Working (Yes/No/NA)	Calibration valid (Yes/No/NA)
Secondary Standard Dosimeter (SSD)			
Parallel plate chamber			
Well type ionisation chamber			
Radiation Field Analyzer (RFA)			
Radiation Survey Meter (RSM)			
Gamma zone monitor			
Thermometer			
Barometer			
Appropriate phantom and QA tools			
Whether dosimetric equipment/protection level equipment are appropriate for radiation type and energy ?			Yes □ No □ If no, then details:

8. Teletherapy: Operational Parameters, Functionality and Procedures

(a) Where relevant are the following operational ?

S.No.	Safety Systems/Interlocks	Available Yes/No/NA	Working Yes/No/NA
(i)	Door interlock		
(ii)	Emergency switches		
(iii)	Gamma zone monitor		
(iv)	Beam ON/OFF indicator (Alarm, a warning light indicators at entrance door of the unit)		
(v)	Warning symbol displayed on entrance door and at appropriate places		
(vi)	Control console displays		
(vii)	Patient viewing system (eg. CCTV/Window)		
(viii)	Emergency devices (like T-rod) available near control panel		
(ix)	Emergency handling procedures displayed		
(x)	Conventional safety ensured (preventive measures for flooding and fire safety)		
(h)	Whether physical security of the source is ensured:		Ves 🗆 No 🗆

(b)	Whether physical security of the source is ensured:	Yes 🗆 No 🗆	
(c)	Room is solely dedicated to the equipment ?	Yes 🗆 No 🗆	
	If no, what other RT equipment installed in same room ?		
	Whet one u	her interlocks are provided for operation of only nit at a time ?	Yes 🗆 No 🗆
-----	-------------------------------	---	--------------------------------
(d)	Whet Radia (Mod once	her dose prescription in the patient chart is signed by tion Oncologist ? ification of treatment recorded, chart review at least in a week, review shall be signed and dated by reviewers)	Yes 🗆 No 🗆
(e)	Quali Whet	ty Assurance her:	
	(i)	Daily checks performed ?	Yes 🗆 No 🗆
	(ii)	Weekly checks performed ?	Yes 🗆 No 🗆
	(iii)	Monthly checks performed ?	Yes 🗆 No 🗆
	(iv)	Annual checks performed ?	Yes 🗆 No 🗆
	(v)	QA after major repairs ?	Yes 🗆 No 🗆
	(vi)	TPS QA performed periodically ?	Yes 🗆 No 🗆
	(vii)	MLC QA performed ?	Yes 🗆 No 🗆
	(viii)	QA records maintained ?	Yes 🗆 No 🗆
	(ix)	QA Patient viewing system performed ?	Yes 🗆 No 🗆
(f)	Whet	her any up-gradation carried out in the unit ?	Yes 🗆 No 🗆
	If yes	, whether permission obtained for the same ?	Yes 🗆 No 🗆
(g)	Any r instal	nodifications done to the existing approved radiation lation:	Yes 🗆 No 🗆
	If yes	, whether permission obtained for the same ?	Yes 🗆 No 🗆
(h)	Whet	her radiation protection survey performed ?	Yes 🗆 No 🗆
(i)	Whet	her survey records maintained ?	Yes 🗆 No 🗆
(j)	Servi	cing/maintenance records of the unit available:	Yes 🗆 No 🗆
(k)	TLD	dose inter-comparison results (if any) satisfactory:	Yes \Box No \Box NA \Box
	Comme	nts:	

9. Brachytherapy-Operational Parameters, functionality and procedures

9.1 Where relevant, are the following operational ?

S.No.	Safety Systems/Interlocks	Available Yes/No/NA	Working Yes/No/NA
(i)	Door interlock		
(ii)	Emergency switches		
(iii)	Gamma Zone monitor		
(iv)	Beam ON/OFF indicator (Alarm, a warning light indicators at entrance door of the unit)		
(v)	Warning symbol displayed on entrance door and a appropriate places	t	
(vi)	Patient viewing system		
(vii)	Control console displays		
(viii)	Emergency container		
(ix)	Emergency handling procedures displayed		
(x)	Conventional safety ensured (preventive measures for flooding and fire safety)	3	
(b)	Whether physical security of the source is ensured	1?	Yes 🗆 No 🗆
(c)	Whether dose prescription in the patient chart is si Radiation Oncologist ?	igned by	Yes 🗆 No 🗆
(d)	Quality Assurance, whether;		
	(i) Daily QA checks performed ?		Yes 🗆 No 🗆
	(ii) Weekly QA checks performed ?		Yes 🗆 No 🗆
	(iii) Monthly QA checks performed ?		Yes 🗆 No 🗆
	(iv) Annual QA checks performed ?		Yes 🗆 No 🗆
	(v) TPS QA performed periodically ?		Yes 🗆 No 🗆
	(vi) QA after major repair performed ?		Yes 🗆 No 🗆
	(vii) QA of patent viewing system performed ?		Yes 🗆 No 🗆
Practic	e Specific Procedures, Whether:		
(a)	Records of source application, treatment parameter and source removal are documented and maintaine	ers ed ?	Yes 🗆 No 🗆
(b)	Removal of sources done by radiation oncologist	?	Yes 🗆 No 🗆
(c)	Patient survey is conducted immediately after rem of sources and records maintained ?	oval	Yes 🗆 No 🗆
(d)	Source inventory is confirmed before patient leave treatment area ?	es the	Yes 🗆 No 🗆
(e)	Protective measure (i.e. L-bench, lead bricks, Ir-1) and temporary: storage container etc) for handling Manual Brachytherapy sources is available ?	92 cutter 3 of Ye	s 🗆 No 🗆 NA 🗆

9.2

(f)	Inventory of source movement (MAL) maintained ?	Yes 🗆 No 🗆
(g)	Radiation protection survey performed ?	Yes 🗆 No 🗆
(h)	Survey records maintained ?	Yes 🗆 No 🗆
(i)	Results of leak test/swipe test performed to check the integrity of sources are satisfactory ?	Yes 🗆 No 🗆
(j)	QA records maintained ?	Yes 🗆 No 🗆
(k)	Servicing/maintenance records available ?	Yes 🗆 No 🗆
	Comments:	

10. Simulator/CT Simulator/Imaging Systems

(a)	Radiation warning symbol available at appropriate places:	Yes \Box No \Box
(b)	QA performed periodically:	Yes 🗆 No 🗆
(c)	QA records maintained:	Yes 🗆 No 🗆
(d)	Whether radiation protection survey performed ?	Yes 🗆 No 🗆
(e)	Whether survey records maintained ?	Yes 🗆 No 🗆
	Comments:	

11. Unusual Occurrences/Accidents

(a)	Any unusual occurrence/accident encountered after the last RI ? If yes, then details	$Yes \square No \square NA \square$
(b)	AERB was informed about the incident/accident	Yes 🗆 No 🗆
(c)	Actions taken to prevent recurrence	Yes 🗆 No 🗆
	Comments:	

12. Availability of Documents/Records

13.

	(a)	Minutes of Local Safety Committee (LSC):	Yes \Box No \Box
	(b)	Disposal of disused radioactive sources:	Yes 🗆 No 🗆
	(c)	Radiation protection survey report:	Yes 🗆 No 🗆
	(d)	Instruments calibration records:	Yes 🗆 No 🗆
	(e)	PMS records:	Yes 🗆 No 🗆
	(f)	Servicing/maintenance records:	Yes 🗆 No 🗆
	(g)	Documents on security aspects of RF:	Yes 🗆 No 🗆
	Resear	ch and Development in the RF:	
Any clinical trial going on in the institute. Yes \Box No.			Yes 🗆 No 🗆
	If yes, v	whether reviewed by Ethical Review Committee ?	Yes 🗆 No 🗆

14. Any other observations:

(Attach extra sheet if required)

(Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed about the above observations.

(Signature of Coordinator of the Institution)

Name:

Designation:

(Signature of Licensee/Head of the Institution)

Name:

Designation:

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF NUCLEAR MEDICINE FACILITY

Date of inspection:

Type of inspection:

Pre-commissioning

Planned

Special

Surprise

1.1 Details of the Radiation Facility (RF):

1.1.1 Institution number:

Name and address of the RF: Telephone No. (O): Fax No.

1.2 Type of the Facility: Govt./Semi-Govt./Autonomous/Private/Joint venture/Others

1.3 Employer:

	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):		(R)
1.4	Licen (a) (b)	see: Name: Designation: Telephone No. Mobile No. E-mail	(O):		(R)
1.5	RSO: (a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):		(R)
1.6	Inspe (a) (b)	ction Coordinator Name: Designation: Telephone No. Mobile No. E-mail	from Instituti (O):	on:	(R)

2.	Compliance with recommendations based on Last Inspection		
	(i)	Date of last inspection, if any:	
	(ii)	Whether all the recommendations are already complied ?	Yes 🗆 No 🗆
	(iii)	Particulars of pending recommendation, if any:	
3.	On-Si	te Verification of Consents/Approvals issued	
	(i)	Commissioning authorization/approval available:	Yes 🗆 No 🗆
	(ii)	Whether licence for operation is valid ?	Yes 🗆 No 🗆
	(iii)	Layout approval available	Yes 🗆 No 🗆
	(iv)	Whether the facility has been constructed as per the approved plan ?	Yes 🗆 No 🗆
	(v)	Whether RSO certificate is valid ?	Yes 🗆 No 🗆
	(vi)	Whether licensee is the same as mentioned in the licence ?	Yes 🗆 No 🗆
		If no, whether any amendment of licence was sought and obtained ?	Yes 🗆 No 🗆
		Comments:	

4. Sources/Facilities Available

4.1

Procedures carried out:	
In-vitro assay	
In-vivo non-imaging	
In-vivo imaging	
Low Dose Therapy	
High Dose Therapy	
Any other procedures carried out, please specify:	

4.2 Radioisotopes Handled:

4.3 Imaging Equipment:	
------------------------	--

- (i) Gamma Camera
- SPECT (ii)
- (iii) SPECT-CT
- (iv) PET
- (v) PET-CT
- (vi) PET-MRI

4.4 Non-imaging Equipment:

- (i) Thyroid Uptake Probe
- Any Other (ii)

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- 4.5 High Dose Therapeutic Facilities:
 - (i) No. of Isolation Rooms
 - (ii) Capacity of delay tanks (in liters)

4.6 Practice Specific

(i)	Whether separate area is earmarked for low dose therapy administered patients ?	Yes 🗆 No 🗆
(ii)	Facility is in accordance with the licence issued:	Yes 🗆 No 🗆
(iii)	Name of sealed sources (calibration and check Sources):	
(iv)	Name of disused sources (calibration and check Sources):	
(v)	Whether permission taken for disposal/decommissioning?	Yes 🗆 No 🗆
(vi)	In case of disused sources, whether the institute has plan of action for disposal of the same ?	Yes 🗆 No 🗆
(vii)	Any decommissioning/disposal carried out during last year:	Yes 🗆 No 🗆
(viii)	Whether physical security of the source is ensured ?	Yes 🗆 No 🗆
[Comments:	

5. Availability of Operating Personnel

(i)	Number of Nuclear Medicine (NM) Physician available:	_
(ii)	Number of Nuclear Medicine Technologists available:	_
(iii)	Whether the qualifications of qualified NM staff are as per current AERB Safety Code for NM facilities ?	Yes 🗆 No 🗆

Comments:

6. Personnel Monitoring

6.1	Institu	Institute personnel monitoring service (PMS) number :				
6.2	Numb	Number of personnel monitoring devices (PMD) in NM:				
6.3	State v	whether;				
	(a)	PMD is provided to all radiation workers ?	Yes 🗆 No 🗆			
	(b)	PMD is provided to the trainees (if any) ?	Yes 🗆 No 🗆 NA 🗆			
	(c)	PMD are being worn by workers appropriately ?	Yes 🗆 No 🗆			
	(d)	Proper storage of PMD is available ?	Yes 🗆 No 🗆			
	(e)	Dose records available ?	Yes 🗆 No 🗆			
	(f)	Radiation workers have access to their personnel				
		monitoring records ?	Yes 🗆 No 🗆			
	(g)	PMS was suspended any time during last three years ?	Yes 🗆 No 🗆			
	(h)	Any over-exposure is reported during last three years ?	Yes 🗆 No 🗆			

		If yes, whether dose recorded was found to be genuine ?	Yes 🗆 No 🗆
	(i)	Adequate measures have been taken to avoid recurrence of over-exposure ?	Yes 🗆 No 🗆
6.4	Whet	ner pocket dosimeters are available ?	Yes 🗆 No 🗆
	If yes	, whether used by radiation workers any time ?	Yes 🗆 No 🗆
	If yes	, whether dose records are maintained ?	Yes 🗆 No 🗆
	Γ	Comments:	

7. Measuring Instruments/Protection Level Equipment:

Equipment	Available (Yes/No/NA)	Working (Yes/No/NA)	Calibration valid (Yes/No/NA)
Radiation Survey Meter (RSM)			
Gamma zone monitor			
Contamination monitor			
Dose calibrator			
Direct Reading Dosimeters (DRD)			
Appropriate phantom and QA tools			
Whether dosimetric equipment/protection level equipment are appropriate for radiation type and energy ?	Yes \Box No \Box If no, then details:		

Comments:

8. Handling/General Facilities: Operation, Functionality and Procedures

(a) Are the following, where relevant, operational ?

S.No.	Facilities	Available (Yes/No/NA)	Working (Yes/No/NA)
(i)	Fume hoods		
(ii)	L-Bench		
(iii)	Lead bricks		
(iv)	Sink		
(v)	Remote handling tools		
(vi)	Lead apron and gloves		
(vii)	Decontamination kit		
(viii)	Hand gloves		
(ix)	Syringe shield		
(x)	Syringe carrier		

S.No.	Facilities	Available (Yes/No/NA)	Working (Yes/No/NA)
(xi)	Patient viewing system (eg. CCTV/Window)		
(xii)	Emergency handling procedures displayed		
(xiii)	Conventional safety ensured (preventive measures for flooding and fire safety)		
(b)	Whether the flooring in the laboratory is satisfactory	?	Yes 🗆 No 🗆
(c)	Whether work surface is smooth and covered with ab	sorbent sheet ?	Yes 🗆 No 🗆
(d)	Whether doors & walls are painted with smooth and	washable paints?	Yes 🗆 No 🗆
(e)	Whether separate rooms are provided for each of the operations as per guidelines ?	radioactive	Yes 🗆 No 🗆
(f)	Whether sinks are provided in each of the rooms whe material is handled ?	re radioactive	Yes 🗆 No 🗆
(g)	Whether sinks are made of non-porous material like S Glazed Ceramic ?	SS or	Yes 🗆 No 🗆
(h)	Whether type of taps fitted at the sinks are elbow-ope	erated ?	Yes 🗆 No 🗆
(i)	Whether radiation warning symbols are displayed wh	ere required ?	Yes 🗆 No 🗆
(j)	Whether emergency procedures for radioactive spilla misadministration are pasted at appropriate place in t	Yes 🗆 No 🗆	
(k)	Whether ventilation of the radioactive handling room	Yes 🗆 No 🗆	
(1)	Whether illumination inside the radioisotope laboratory is satisfactory ?		Yes 🗆 No 🗆
(m)	Whether separate drainage system provided for Nucle Medicine facility ?	ear	Yes 🗌 No 🗌
(n)	Whether the delay tank is properly cordoned off?		Yes 🗆 No 🗆
(0)	Whether the delay tank is maintained properly?		Yes 🗆 No 🗆
(p)	Whether any provision is made for indication of radio effluent levels in the delay tank ?	pactive	Yes 🗌 No 🗆
(q)	Quality Assurance		
	(i) Daily checks performed:(ii) Weekly checks performed:		Yes □ No □ Yes □ No □
	(iii) Monthly checks performed:		Yes 🗆 No 🗆
	(iv) Annual checks performed:		Yes 🗆 No 🗆
	(v) QA records maintained:		Yes ⊔ No ⊔
(r)	Whether any up-gradation carried out in the unit?		Yes \Box No \Box
(a)	Any modifications does to the solution optimized for the same ?	otion in stall die	
(8)	Any modifications done to the existing approved radi	ation installation	
	If yes, whether permission obtained for the same		Yes ⊔ No ⊔

	(t)	Whether periodic radiation protection survey performed ?	Yes 🗆 No 🗆
	(u)	Whether survey records maintained ?	Yes 🗆 No 🗆
9.	Unusu	al Occurrences/Accidents	
	(a)	Any unusual occurrences/accident encountered after last RI:	Yes 🗆 No 🗆 NA 🗆
		If yes, then details:	
	(b)	AERB was informed about the incident/accident:	Yes 🗆 No 🗆
	(c)	Action taken to prevent recurrence:	Yes 🗆 No 🗆
		Comments:]
10.	Availa	ability of Documents/Records	
	(i)	Minutes of Local Safety Committee (LSC):	Yes 🗆 No 🗆
	(ii)	Patient information data:	Yes 🗆 No 🗆
	(iii)	Activity procurement and usage:	Yes 🗆 No 🗆
	(iv)	Disposal of radioactive waste:	Yes 🗆 No 🗆
	(v)	Radiation protection survey report:	Yes 🗆 No 🗆
	(vi)	PMS records:	Yes 🗆 No 🗆
	(vii)	Instruments calibration records:	Yes 🗆 No 🗆
	(viii)	Sample Collection data for delay tank:	Yes 🗆 No 🗆
	(ix)	Servicing/maintenance records of the imaging equipment available:	Yes 🗆 No 🗆
		Comments:]
11.	Resea	rch and Development in the RF	
	Any cl	linical trial going on in the institute:	Yes 🗌 No 🗌
	If yes,	whether reviewed by Ethical Review Committee ?	Yes 🗆 No 🗆
12.	Any o	other observations	

(Attach extra sheet if required)

Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed the above observations.

(Signature of Coordinator of the Institution) (Signature of the Licensee/Head of the Institution) Name: Name: Designation:

Designation:

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF MEDICAL CYCLOTRON FACILITY

Date of inspection:

Type of inspection:

Pre-commissioning

Planned

Special

Surprise

1.1 Details of the Radiation Facility (RF):

1.1.1 Institution number:

Name and address of the RF: Telephone No. (O): Fax No.

1.2 Type of the Facility: Govt./Semi-Govt./Autonomous/Private/Joint venture/Others

1.3 Employer:

	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)
1.4	Licens (a) (b)	ee: Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)
1.5	RSO: (a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)
1.6	Inspec (a) (b)	tion Coordinator Name: Designation: Telephone No. Mobile No. E-mail	from Institution: (O):	(R)

2.	Com	Compliance of recommendation based on Last Inspection						
	(i)	Date of last inspection, if any:						
	(ii)	Whether all the recommendation	eady complied ?	Yes 🗆 No 🗆				
	(iii)	Particulars of pending recommen	idation,	if any:				
3.	On-S	On-Site Verification of Consents/Approvals issued						
	(i)	Whether licence for operation is	valid ?		Yes 🗆 No 🗆			
	(ii)	Layout approval available:	Yes 🗆 No 🗆					
	(iii)	Whether RSO certificate is valid	?		Yes 🗆 No 🗆			
	(iv)	Whether licensee is same as mer	tioned in	n the licence ?	Yes 🗆 No 🗆			
		If no, whether any amendment of	f licence	was sought and obtained ?	Yes 🗆 No 🗆			
		Comments:						
4.	Deta	ils of Cyclotron						
	(a)	Cyclotron Unit Make & Model	:					
	(b)	Serial No.	:					
	(c)	Type of shielding	:	Unshielded/Self Shielded				
	(d)	Beam Type	:	Protons/Deuterons/Both				
	(e)	Nominal Beam Energy	:	Protons : MeV				
				Deuterons : MeV				
				Single	Dual			
	(f)	Maximum Beam Current	:	Protons : μA	µA			
				Deuterons : µA	µA			
	(g)	No. of Target ports available for						
	(h)	No. of Target ports used at the tit						
	(i)	Radioisotopes produced:						
		Comments:						
_								
5.	Avai	lability of Operating Personnel		\ !!!!				
	(1)	Number of qualified Cyclotron of	perator(s) available: –				
	(ii)	Number of qualified Radio Phan	nacist av	vailable: –				
		Comments:						

6. Personnel Monitoring

6.1	Institut	e personnel monitoring service (PMS) number :				
6.2	Numbe	er of personnel monitoring devices (PMD) in Cyclotron Department:				
6.3	State whether;					
	(a)	PMD is provided to all radiation workers ?		Yes 🗆	No 🗆	
	(b)	PMD is provided to the trainees (if any)?	Yes 🗆	No 🗆	$NA \square$	
	(c)	PMD are being worn by workers appropriately ?		Yes 🗆	No 🗆	
	(d)	Proper storage of PMD is available ?		Yes 🗆	No 🗆	
	(e)	Dose records available ?		Yes □	No 🗆	
	(f)	Radiation workers have access to their personnel monitoring records ?		Yes 🗆	No 🗆	
	(g)	PMS was suspended any time during last three years ?		Yes 🗆	No 🗆	
	(h)	Any over-exposure is reported during last three years ?		Yes □	No 🗆	
		If yes, whether dose recorded was found to be genuine ?		Yes 🗆	No 🗆	
	(i)	Adequate measures have been taken to avoid recurrence of over-exposure?		Yes 🗆	No 🗆	
6.4	Wheth	er pocket dosimeters are available ?		Yes 🗆	No 🗆	
6.4	If yes,	whether used by radiation workers any time?		Yes 🗆	No 🗆	
	If yes, whether dose records are maintained ? Yes \Box N					

7.1 Interlocks, Access Control and Other Safety Features:

S.No.	Safety Systems/Interlocks	Provided Yes □ No □	Working Yes □ No □
(i)	Control console access password/key		Secured : Yes □ No □
(ii)	Cyclotron vault door interlock		
(iii)	Emergency switch 'OFF' on control console		
(iv)	Emergency switch 'OFF' button inside cyclotron vault (Easily accessible)		
(v)	Self shielding interlock (Applicable for self shielded cyclotron only)		
(vi)	Uninterrupted power supply/ standby power supply		
(vii)	Provision for safe 'STANDBY' mode for cyclotron in case of power failure		
(viii)	Provision of emergency power (UPS) for air ventilation system, access control system and radiation monitoring system		

	S.No.	Safety Systems/Interlocks	Provided Yes □ No □	Working Yes □ No □	
	(ix)	Interlock for access prevention into cyclotron vault, if residual radiation inside vault is high (Radiation Interlock)			
	(x)	Beam 'ON' alarm/signal/a warning light at the entrance of the vault			
	(xi)	Cooling System/vacuum system/compressed air system interlock			
	(xii)	Criteria of beam turn 'OFF' mechanism in normal operation of the Cyclotron (Pl. specify)			
	(xiii)	Area monitors inside cyclotron vault with audible warning signal set to a radiation level			
	(xiv)	Area monitor in control console room, hot lab, chemistry module and other room			
	(xv)	Portable contamination monitors/area survey meter (for neutron and gamma)/pocket dosimeter/area monitoring meter available ?			
7.2	Does o	operation of cyclotron feasible without mode selection ?		Yes 🗌 No 🗆	
7.3	Is there before	Is there a provision of system self check of various parameters before beam 'ON' ?			
7.4.1	Wheth button	Whether cyclotron can be turned 'ON' if emergency switch 'OFF' button is not released ?			
7.4.2	Is there	e any beam 'ON' indication inside the cyclotron vault ?		Yes 🗆 No 🗆	
7.5	Wheth	er it is possible to open cyclotron vault door when Bean	n is in 'ON' ?	Yes 🗆 No 🗆	
7.6	Provis	ion for opening cyclotron vault door from inside cyclotr	on vault:	Yes 🗆 No 🗆	
7.7	Warm	up time for cyclotron: Provided :		Yes 🗆 No 🗆	
7.8	Wheth	er cyclotron can be turned 'ON' bypassing warm-up mo	de ?	Yes 🗆 No 🗆	
7.9	Beam	'ON' time/remaining time display on the control console	2:	Yes 🗆 No 🗆	
7.10	Contro Beam	ol of access to the cyclotron vault for maintenance just a 'OFF' is by means of ?	fter		
	(i)	Timer set on the control console		Yes 🗆 No 🗆	
	(ii)	Radiation level inside the cyclotron vault		Yes 🗆 No 🗆	
7.11	Availa	bility of beam intensity measurement method			
	(i)	Beam probe		Yes 🗆 No 🗆	
	(ii)	Current in stripper foil		Yes 🗆 No 🗆	
	(iii)	Target collimator method		Yes 🗆 No 🗆	
	(iv)	Target itself		Yes 🗆 No 🗆	

7.12	Maximum quantity of target can be irradiated in a single port at a time							
	(i)	Liquid Target Material:	Quantity: ——					
	(ii)	Gas Target Material:	Quantity: ——					
7.13	Status	of target irradiation/status of radioisotope transfer	Provided:	Yes 🗆	No 🗆			
			Working:	Yes 🗆	No 🗆			
7.14	Transf vault f transfe	For interlock provided to prevent opening of cyclotron For maintenance, when the radioactive material is not erred to synthesis and pharmacy lab.		Yes 🗆	No 🗆			
7.15	Metho synthe	d of transfer of radioactive product from the targets to esis hot cell:						
	Comm	Interation between synthesis not cen and cyclotron roo	erlock provided:	Yes 🗆	No 🗆			
			or Manual :	Yes 🗆	No 🗆			
7.16	Indica	tion of various parameter on the control console displa	У					
	(i)	Various interlock position		Yes 🗆	No 🗆			
	(ii)	Beam parameter		Yes 🗆	No 🗆			
	(iii)	Beam current		Yes 🗆	No 🗆			
	(iv)	Target selection		Yes 🗆	No 🗆			
	(v)	Utility parameter (Temp, water level, cooling agents, compressed air p vacuum, nitrogen, helium etc.)	pressure,	Yes 🗆	No 🗆			
	(vi)	Beam ON/ OFF indication		Yes 🗆	No 🗆			
	(vii)	Ventilation /Exhaust control system		Yes 🗆	No 🗆			
	(viii)	Transfer of radionuclide's status		Yes 🗆	No 🗆			
	(ix)	Beam 'ON' time display		Yes 🗆	No 🗆			
	(x)	Other important parameters (Please specify)						
7.17	Provis transfe	ion for containment of leak during target foil rupture/ra er from cyclotron to Hot cell	adioisotope	Yes 🗆	No 🗆			
7.18	Contro	ol of airborne activity						
	(i)	Cyclotron vault ventilation interlock	Provided:	Yes 🗆	No 🗆			
			Working:	Yes 🗆	No 🗆			
	(ii)	Provision for negative pressure inside cyclotron vaul and other room ?	lt	Yes 🗆	No 🗆			
			Pressure level .					
	(iii)	Standby exhaust pump/fan at the end of ventilation d	luct?	Yes 🗆	No 🗆			
	(iv)	HEPA/charcoal filter/other high efficiency filter prov	vided ?	Yes 🗆	No 🗆			
	(v) Air circulation rate/air exchange rate (no. of air changes):							

	(vi)	Provision of decontamination and containment of used air filter ?	Yes 🗆 No 🗆
7.19	Magne metall	etic field/RF field warning on cyclotron magnet for pace makers/ ic prosthetic devices/tools	Yes 🗆 No 🗆
7.20	High r cyclot	adiation field/significant radioactive contamination warning at ron parts/cyclotron vault	Yes 🗆 No 🗆
7.21	Provis assem	ion for storage of repaired/replaced parts of cyclotron unit/target bly inside cyclotron vault along with proper radiation warning sign	Yes 🗆 No 🗆
7.22	Mobile lead sh lead st	e radiation protection accessories provided (forceps/tongs/mobile nield/lead bricks/protective clothing/gloves/air masks/lead glasses/ orage pots etc.)	Yes 🗆 No 🗆
7.23	Wheth	er fire alarm system available ?	Yes 🗆 No 🗆
	Туре с	of fire extinguishers:	
7.24	Writte contro	n Emergency procedures displayed and its availability in led and supervised area	
	(i)	Target foils rupture	Yes 🗆 No 🗆
	(ii)	Radioactive source stuck in transfer line	Yes 🗆 No 🗆
	(iii)	Power failure	Yes 🗆 No 🗆
	(iv)	Containment rapture in chemistry hot cell	Yes 🗆 No 🗆
	(v)	Vial break in the QC lab	Yes 🗆 No 🗆
	(vi)	Fire breakout	Yes 🗆 No 🗆
	(vii)	Failure of ventilation system	Yes 🗆 No 🗆
	(viii)	Spillage of the activity in controlled/ supervised areas	Yes 🗆 No 🗆
	(ix)	Other emergency situations (Please specify)	Yes 🗆 No 🗆
7.25	Provis	ion for bypassing interlocks Available \Box	Unavailable 🗆
	To wh	om the interlock bypass authority assigned ?	
7.26	Numb	er of synthesis module available:	
7.27	The ch	nemistry module is designed to handle the maximum activity of	
7.28	List th	e QC modules available in the chemistry Lab.:	
7.29	Radiat	ion warning symbol displayed in all the radiation area	Yes 🗆 No 🗆
7.30	Wheth	er logbook is maintained for	
	(i)	Cyclotron operation	Yes 🗆 No 🗆
	(ii)	Data login	Yes 🗆 No 🗆
	(iii)	Stripper foils life	Yes 🗆 No 🗆
	(iv)	Target life	Yes 🗆 No 🗆
	(v)	Net activity produced	Yes 🗆 No 🗆

	(vi)	Maintenance of ventilation system	Yes 🗆 No 🗆
7.31	Wast efflu	e disposal related records with respect to liquid and gaseous ent is maintained	Yes 🗆 No 🗆
		Comments:	
8.	Unu	sual Occurrences/Accidents	
	(a)	Any unusual occurrence /accident encountered after last RI ?	Yes 🗆 No 🗆 NA 🗆
		If yes, then details:	
	(b)	AERB was informed about the incident/accident:	Yes 🗆 No 🗆
	(c)	Actions taken to prevent recurrence:	Yes 🗆 No 🗆
	[Comments	
9.	Avai	lability of Documents/Records	
	(i)	Minutes of Local Safety Committee (LSC):	Yes 🗆 No 🗆
	(ii)	Disposal of disused radioactive sources:	Yes 🗆 No 🗆
	(iii)	Radiation protection survey report:	Yes 🗆 No 🗆
	(iv)	Servicing/maintenance record:	Yes 🗆 No 🗆
	(v)	Instruments calibration record:	Yes 🗆 No 🗆
	(vi)	PMS records:	Yes 🗆 No 🗆
10.	Any	other observations:	

(Attach extra sheet if required)

(Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed about the above observations.

(Signature of Coordinator of the Institution)	(Signature of the Licensee/Head of the Institution)
Name:	Name:
Designation:	Designation:

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF DIAGNOSTIC RADIOLOGY FACILITY

Date of inspection: Type of inspection: Planned Special Surprise 1.1 **Details of the Radiation Facility (RF):** 1.1.1 Institution number: Name and address of the RF: Telephone No. (O): Fax No. 1.2 Type of the Facility: Govt./Semi-Govt./Autonomous/Private/Joint venture/Others 1.3 **Employer:** (a) Name (b) Designation Telephone No. (R) (O): Mobile No. E-mail 1.4 **Consentee (For Licence/Authorisation/Registration) :** (a) Name: Designation: (b) Telephone No. (0):(R) Mobile No. E-mail 1.5 **RSO:** Name: (a) Designation: (b) Telephone No. (O): (R) Mobile No. E-mail 1.6 **Inspection Coordinator from Institution:** (a) Name: Designation: (b) Telephone No. (O): (R) Mobile No. E-mail 2. Compliance of recommendation based on Last Inspection Date of last inspection, if any (i) :

(ii)	Whether all the recommendations are complied ?	Yes \Box No \Box NA \Box
(iii)	Particulars of pending recommendation, if any:	Yes \Box No \Box NA \Box
On- Sit	e Verification of Consents/Approvals issued	
(i)	Whether Licence/Authorisation/Registration for operation is valid ?	Yes 🗆 No 🗆
(ii)	Copy of authenticated layout of all X-ray installations is available:	Yes 🗆 No 🗆
(iii)	Whether RSO certificate is valid?	Yes 🗆 No 🗆
(iv)	Whether Licensee/Registrant is the same as mentioned in the licence ?	Yes 🗆 No 🗆
	If no. whether any amendment of licence was sought and obtained ?	Yes 🗆 No 🗆

4. Radiation Generating Equipment Availability

3.

Type of Equipment	No. of units	Average No. of patients/day	Licence/Authorisation Registration obtained (Yes/No)
Computed Tomography (CT scan)			
Interventional Radiology			
Radiography (Fixed)			
Radiography (Mobile)			
Radiography (Portable)			
C-Arm			
O-Arm			
Radiography & Fluoroscopy			
Mammography			
Orthopantomography (OPG)			
Dental CBCT			
Dental (IOPA, Hand-held)			
Bone Mineral Densitometer (BMD)			
Any other (Please specify)			

5. Availability of Operating Personnel:

- (i) Number of X-ray Technologist available:
- (ii) Number of Medical Practitioner available:

Comments:

6. Personnel Monitoring:

6.1	Institute p	personnel	monitoring	service (PMS) number :	
-----	-------------	-----------	------------	-----------	-----	------------	--

6.2 Number of personnel monitoring devices (PMD) in Department: _____

6.3 State whether;

6.4

(a)	PMD is provided to all radiation workers ?		Yes 🗆	No 🗆
(b)	PMD is provided to the trainees (if any)?	Yes 🗆	No 🗆	NA 🗆
(c)	PMD are being worn by workers appropriately ?		Yes 🗆	No 🗆
(d)	Proper storage of PMD is available ?		Yes 🗆	No 🗆
(e)	Dose records are available ?		Yes 🗆	No 🗆
(f)	Radiation workers have access to their personnel monitoring records ?		Yes 🗆	No 🗆
(g)	PMS was suspended any time during last three years ?		Yes 🗆	No 🗆
(h)	Any over-exposure is reported during last three years ?		Yes 🗆	No 🗆
	If yes, whether dose recorded was found to be genuine ?	Yes 🗆	No 🗆	$NA \square$
(i)	Adequate measures have been taken to avoid recurrence of over-exposure ?	Yes 🗆	No 🗆	NA 🗆
Whethe	r pocket dosimeters are available ?		Yes 🗆	No 🗆
If yes, w	whether used by radiation workers any time?		Yes 🗆	No 🗆
If yes, v	whether dose records are maintained ?		Yes 🗆	No 🗆
	Comments:]		

7. Operational Parameters: Availability, Functionality and Procedures

(a)	Whether protective barrier with lead glass viewing window provided to each installation (as applicable) ?	Yes 🗆	No 🗆	NA 🗆
(b)	Whether adequate number of lead aprons available ?	Yes 🗆	No 🗆	NA 🗆
(c)	Couch hanging lead rubber flaps, ceiling suspended lead glass, (for Cath. Lab) available:	Yes 🗆	No 🗆	NA 🗆
(d)	DAP meter (for Cath. Lab) available:	Yes 🗆	No 🗆	NA 🗆
(e)	X-ray caution symbol, warning placards is displayed at the entrance door of each DR installation		Yes 🗆	No 🗆
(f)	Whether red warning light available outside each DR installation and is in working condition ?		Yes 🗆	No 🗆
(g)	Whether periodic radiation safety status report(s) are maintained ?		Yes 🗆	No 🗆
(h)	Whether periodic quality assurance tests are carried out and records are maintained ?		Yes 🗆	No 🗆
(i)	Whether periodic radiological protection survey are carried out and records are maintained ?		Yes 🗆	No 🗆
(j)	Whether two or more X-ray units are installed in a single room ?		Yes 🗆	No 🗆
(k)	Whether door(s) of X-ray rooms are lead lined ?	Yes 🗆	No 🗆	$NA \square$

(1)	During procedure/examination, whether attendees/comforters of patients are crowding in the X-ray room(s) ?		Yes 🗆	No 🗆
(m)	Whether protective aprons are properly stored, when not in use ?		Yes 🗆	No 🗆
(n)	Whether X-ray room shielding is proper/ as per regulatory requirements ?		Yes 🗆	No 🗆
(0)	Whether collimator bulb(s) and BLD in fixed radiography X-ray equipment are in working condition ?		Yes 🗆	No □
(p)	Any modifications done to the existing approved radiation installation:		Yes 🗆	No □
	If yes, whether permission obtained for the same ?	Yes 🗆	No 🗆	NA 🗆
	Comments:			
Unu	sual Occurrences/Accidents			
(a)	Any unusual occurrence/incident encountered after the last RI ? If yes, then details:	Yes 🗆	No 🗆	NA 🗆
(b)	AERB was informed about the incident/accident		Yes 🗆	No 🗆
(c)	Actions taken to prevent recurrence		Yes 🗆	No 🗆
	Comments:			
Avai	lability of Documents/Records			
(i)	Quality Assurance records:		Yes 🗆	No 🗆
(ii)	Periodic radiation safety status report:		Yes 🗆	No 🗆
(iii)	Radiation protection survey report:		Yes 🗆	No 🗆
(iv)	Personnel overexposure investigation records:	Yes 🗆	No 🗆	NA 🗆
(v)	Instruments calibration record (if applicable):		Yes 🗆	No 🗆
(vi)	PMS records:		Yes 🗆	No 🗆

(vii) Servicing/maintenance records:

10. Any other Observations

8.

9.

(Attach extra sheet, if required)

(Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed the above observation noted by the inspector(s).

(Signature of Licensee/Head of the
Institution)
Name of the Head:
Designation of the Head

Yes \Box No \Box

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF PARTICLE ACCELERATOR RESEARCH FACILITY

				Date of inspection:
				Type of inspection:
				Pre-commissioning
				Planned
				Special
				Surprise
1.1	Detai	ls of the Radiation	Facility (R	F):
1.1.1	Institu	ution number:		
	Name Telep Fax N	e and address of the hone No. Io.	RF: (O):	(R)
1.2	Туре	of the Facility: G	ovt./Semi-Ge	ovt./Autonomous/Private/Joint venture/Others
1.3	Empl (a) (b)	oyer: Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.4	(a) (b)	Name: Designation : Telephone No. Mobile No. E-mail	(0):	(R)
1.5	RSO : (a) (b)	: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.6	Inspe (a) (b)	ection Coordinator Name: Designation: Telephone No.	(O):	stitution: (R)
		Mobile No. E-mail		

2.	Com	pliance of recommendation based on Last Inspection			
	(i)	Date of last inspection, if any:			
	(ii)	Whether all the recommendations are already complied ?		Yes 🗆	No 🗆
	(iii)	Particulars of pending recommendation, if any:			
3.	On-S	ite Verification of Consents/Approvals issued			
	(i)	Whether Licence for operation is valid ?		Yes 🗆	No 🗆
	(ii)	Layout approval available:		Yes 🗆	No 🗆
	(iii)	Whether RSO certificate is valid ?		Yes 🗆	No 🗆
	(iv)	Whether Licensee is the same as mentioned in the licence ?		Yes 🗆	No 🗆
		If no, whether any amendment of licence was sought and obtained	?	Yes 🗆	No 🗆
		Comments:			
4.	Detai	ils of Particle Accelerator(s)			
	(a)	Type of Accelerator :			
	(b)	Make, Model, S.No. :			
	(c)	Ions accelerated :			
	(d)	Maximum beam rating :			
	(e)	Maximum beam current :			
	(f)	Maximum beam power :			
	(g)	The vacuum system pressure :			
	(h)	Maximum beam dimensions :			
	[Comments:			
5.	Avail	ability of Operating Personnel			
	(i)	Number of qualified accelerator operator(s) available:	_		
	(ii)	Number of RSO available:			
6.	Perso	onnel Monitoring			
6.1	Instit	ute personnel monitoring service (PMS) number:	_		
6.2	Numl	ber of personnel monitoring devices (PMD) in Accelerator Facility:	—		
6.3	State	whether:			
	(a)	PMD is provided to all radiation workers ?		Yes 🗆	No 🗆
	(b)	PMD is provided to the trainees (if any)?	Yes 🗆	No 🗆	$NA \square$
	(c)	PMD are being worn by workers appropriately ?		Yes 🗆	No 🗆
	(d)	Proper storage of PMD is available ?		Yes 🗆	No 🗆

(e)	Dose records available ?	Yes 🗆 No 🗆
(f)	Radiation workers have access to their personnel monitoring records ?	Yes 🗆 No 🗆
(g)	PMS was suspended any time during last three years ?	Yes 🗆 No 🗆
(h)	Any over-exposure is reported during last three years ?	Yes 🗆 No 🗆
	If yes, whether dose recorded was found to be genuine?	Yes 🗆 No 🗆
(i)	Adequate measures have been taken to avoid recurrence of over-exposure ?	Yes 🗆 No 🗆
Wheth	ner pocket dosimeters are available ?	Yes 🗆 No 🗆
If yes,	whether used by radiation workers any time?	Yes 🗆 No 🗆
If yes,	, whether dose records are maintained ?	Yes 🗆 No 🗆
Γ	Comments:	

7. Measuring Instruments /Protection Level Equipment

7.1 **Protection Level Equipment:**

6.4

Type of device	No. of Monitors	Make, Model and S. No.	Range	Working (Yes/No)	Calibration valid (Yes/No)
Zone Monitor(s)					
Radiation Survey Meter(s)					
Any other					

7.2 Measuring /Detection Instruments:

Type of device	Number of monitors	Make, Model and S. No.	Ranges	Working (Yes/No)	Calibration valid (Yes/No)
SF ₆ Leak Detector					
Monitoring of Cooling system					
Beam Energy Calibrator					
Beam Current Calibrator					
Instrument to monitor prompt high energy radiation					

7.3 Whether dosimetric equipment/ protection level equipment are appropriate for radiation type and energy ?

Yes \Box No \Box

If no, then details:

8.1 Safety Interlocks & Access Control:

S. No.	Safety Interlock	Action Anticipated	Action Observed	Remark
(i)	Pressure plate	When stepped on or removed -turns 'OFF' the beam; sounds audio-visual alarm		
(ii)	Trip wire	When pulled or broken - cancels search, turns 'OFF' the beam; sounds audio-visual alarm		
(iii)	Search operation (eg. SPB1, SPB2 —)	If not depressed in sequence - Prevents beam turn 'ON'		
(iv)	Emergency push button (e.g., EB1, EB2,)	When pressed - turns 'OFF' the beam; sounds audio-visual alarm		
(v)	Service keys (e.g., SK1, SK2,)	If service key is not in its position - Prevents beam turn 'ON'		
(vi)	Heat detector	If temperature exceeds 55°C - actuates fire extinguisher, turns 'OFF' the beam; sounds audio-visual alarm		
(vii)	Smoke detector	If detects smoke - turns 'OFF' the beam voltage; sounds audio-visual alarm		
(viii)	Exhaust fan (fan1, fan2)	When off - turns 'OFF' the beam; sounds audio-visual alarm or Prevents beam turn 'ON'		
(ix)	Power supply	Turns 'OFF' the beam, Indication of emergency (backed up by UPS) when power supply is OFF		
(x)	PLC	Turns 'OFF' the beam or prevents beam turn 'ON' when PLC is OFF		
(xi)	Personnel Access Door (PAD) to Beam Hall/Cell Roof	When door is Open - Turns 'OFF' the beam or Prevents beam turn 'ON'		
(xii)	Electrical/Radiation interlocks on PAD	When beam is 'ON' - prevents opening of door		
(xiii)	Beam status indicator or warning sign	When beam status indicator is not functional - prevents beam turn 'ON'		
(xiv)	Cooling system for target/ beam stopper	When cooling system is not functional - turns 'OFF' the beam or Prevents beam turn 'ON'		
(xv)	Additional safety systems/interlocks (if any)			

8.2 Other Safety Features

(a)	Criter of the	ria of beam turn 'OFF' mechanism in normal operation Accelerator (Please. specify):	
(b)	Cooli	ng system/vacuum system/compressed air system interloc	k : Provided:Yes □ No □ Working: Yes □ No □
(c)	Area	monitors inside vault with audible warning signal set to a	radiation level : Provided: Yes □ No □ Working: Yes □ No □
(d)	Accel	lerator vault ventilation interlock	Provided: Yes □ No □ Working: Yes □ No □
(e)	Provi	sion for negative pressure inside the vault and other room	? Yes \Box No \Box
			Pressure level
(f)	Stand	by exhaust pump/fan at the end of ventilation duct ?	Yes 🗆 No 🗆
(g)	HEPA	A/charcoal filter/other high efficiency filter provided ?	Yes 🗆 No 🗆
(h)	Air ci	rculation rate/air exchange rate:	
(i)	Provi	sion of decontamination and containment of used air filter	r? Yes \Box No \Box
(j)	Magr pace	netic field/RF field warning on accelerator magnet for makers/metallic prosthetic devices/tools.	Yes 🗆 No 🗆
(k)	Provi unit/t radiat	sion for storage of repaired/replaced parts of accelerator arget assembly inside accelerator vault along with proper tion warning sign	Yes 🗆 No 🗆
(1)	Mobi tongs air m	le radiation protection accessories provided (Forceps/ /mobile lead shield/lead bricks/protective clothing/gloves/ asks/lead glasses/lead storage pots etc.)	/ Yes 🗆 No 🗆
(m)	Whet Type	her fire alarm system provided ? of fire extinguisher:	Yes 🗆 No 🗆
(n)	Writte in cou	en emergency procedures displayed and its availability ntrolled and supervised area	
	(i)	Power failure	Yes 🗆 No 🗆
	(ii)	Fire breakout	Yes 🗆 No 🗆
	(iii)	Failure of ventilation system	Yes 🗆 No 🗆
	(iv)	Other emergency situations (Please specify)	Yes 🗆 No 🗆
(0)	Provi	sion for bypassing interlocks: A	vailable 🗆/Unavailable 🗆
(p)	Interl	ock bypass authority assigned to:	
(q)	Radia	ation warning symbol displayed in all the radiation area	Yes 🗆 No 🗆
(r)	Whet	her logbook is maintained for:	
	(i)	Accelerator operation	Yes 🗆 No 🗆
	(ii)	Data login	Yes 🗆 No 🗆

		(iii) Stripper foils life	Yes 🗆 No 🗆
		(iv) Target life	Yes 🗆 No 🗆
		(v) Maintenance of ventilation system	Yes 🗆 No 🗆
9.	Unus	ual Occurrences/Accidents	
	(a)	Any unusual occurrence/accident encountered after last RI ?	Yes \Box No \Box NA \Box
		If yes, then details:	
	(b)	AERB was informed about the incident/accident:	Yes 🗆 No 🗆
	(c)	Actions taken to prevent recurrence:	Yes 🗆 No 🗆
		Comments	
10.	Availa	ability of Documents/Records	
	(i)	Minutes of Local Safety Committee (LSC):	Yes 🗆 No 🗆
	(ii)	Disposal of radioactive waste/activated components	Yes 🗆 No 🗆
	(iii)	Radiation protection survey report:	Yes 🗆 No 🗆
	(iv)	Instruments calibration record:	Yes 🗆 No 🗆
	(v)	PMS records :	Yes 🗆 No 🗆
	(vi)	Serving/maintenance records :	Yes 🗆 No 🗆

11. Any other Observations:

9.

(Attach extra sheet, if required)

(Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed about the above observations.

(Signature of the Licensee/Head of the
Institution)
Name:
Designation:

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF LAND-BASED HIGH INTENSITY GAMMA IRRADIATOR [GAMMA RADIATION PROCESSING FACILITY (GRAPF)]

Date of inspection: Type of inspection: Pre-commissioning Planned Special Surprise

1.1 Details of the Radiation Facility (RF):

1.1.1 Institution number:

Name and address of the RF: Telephone No. (O): Fax No.

1.2 Type of the facility: Govt./Semi-Govt./Autonomous/Private/Joint venture/Others

1.3	Emplo	yer :		
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.4	Licens	see:		
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.5	Facilit (a) (b)	y in Charge: Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)
1.6	RSO:			
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)

(a)	Name:	
(b)	Designation: Telephone No. (O): (R) Mobile No. E-mail	
Com	pliance of recommendation based on Last Inspection	
(i)	Date of last inspection, if any:	
(ii)	Whether all the recommendations are already complied ?	Yes \Box No \Box
(iii)	Particulars of pending recommendation, if any:	
On-S	Site Verification of Consents/Approvals issued	
(i)	Whether Licence for operation is valid ?	Yes 🗆 No 🗆
(ii)	Layout approval available:	Yes 🗆 No 🗆
(iii)	Construction approval available:	Yes 🗆 No 🗆
(iv)	Whether RSO certificate is valid ?	Yes 🗆 No 🗆
(v)	Whether Licensee is the same as mentioned in the licence ?	Yes 🗆 No 🗆
	If no, whether any amendment of licence was sought and obtained ?	Yes 🗌 No 🗍
	Comments:	
Deta	Comments: ils of Radioisotope Available	
Deta (i)	Comments: ils of Radioisotope Available Max. Licensed Activity : PBq (kCi)	
Deta (i) (ii)	Comments: ils of Radioisotope Available Max. Licensed Activity : PBq (kCi) Present Source Activity : PBq (kCi) {as on data the second seco	ite}
Deta (i) (ii) (iii)	Comments: ils of Radioisotope Available Max. Licensed Activity : PBq (kCi) Present Source Activity : PBq (kCi) {as on da Number of sources pencils installed (ISUs) :	ite}
Deta (i) (ii) (iii) (iv)	Comments: ils of Radioisotope Available Max. Licensed Activity : PBq (kCi) Present Source Activity : PBq (kCi) {as on da Number of sources pencils installed (ISUs) : Name of the Test/Reference source available:	ite}
Deta (i) (ii) (iii) (iv)	Comments: ils of Radioisotope Available Max. Licensed Activity : PBq (ite}
Deta (i) (ii) (iii) (iv) (v)	Comments: iils of Radioisotope Available Max. Licensed Activity : PBq (tte} Yes □ No □
 Deta (i) (ii) (iii) (iv) (v)	Comments: ils of Radioisotope Available Max. Licensed Activity : PBq (tte} Yes □ No □
 Deta (i) (ii) (iii) (iv) (v) (v)	Comments: ils of Radioisotope Available Max. Licensed Activity : PBq (tte} Yes □ No □
 Deta (i) (ii) (iii) (iv) (v) (v) (v) (v) (v) (v)	Comments: ils of Radioisotope Available Max. Licensed Activity : PBq (tte} Yes □ No □
 Deta (i) (ii) (iii) (iv) (v) (v) (v) (v) (v) (v) (v) (v) (v) (Comments: ils of Radioisotope Available Max. Licensed Activity : PBq (tte} Yes □ No □
 Deta (i) (ii) (iii) (iv) (v) (v) (v) (v) (v) (v) (v) (v) (v) (Comments: ills of Radioisotope Available Max. Licensed Activity : PBq (tte} Yes □ No □

6. Personnel Monitoring

6.1	Institute personnel monitoring service (PMS) number :			
6.2	Num	ber of personnel monitoring devices (PMD) in the RF:		
6.3	State			
	(a)	PMD is provided to all radiation workers ?	Yes 🗆 No 🗆	
	(b)	PMD is provided to the trainees (if any)?	Yes \Box No \Box NA \Box	
	(c)	PMD are being worn by workers appropriately ?	Yes 🗆 No 🗆	
	(d)	Proper storage of PMD is available ?	Yes 🗆 No 🗆	
	(e)	Dose records available ?	Yes 🗆 No 🗆	
	(f)	Radiation workers have access to their personnel monitoring records ?	Yes 🗆 No 🗆	
	(g)	PMS was suspended any time during last three years ?	Yes 🗆 No 🗆	
	(h)	Any over-exposure is reported during last three years ?	Yes 🗆 No 🗆	
		If yes, whether dose recorded was found to be genuine ?	Yes 🗆 No 🗆	
	(i)	Adequate measures have been taken to avoid recurrence of over-exposure ?	Yes 🗆 No 🗆	
6.4	Whet	ther pocket dosimeters are available ?	Yes 🗆 No 🗆	
	If yes	s, whether used by radiation workers any time?	Yes 🗆 No 🗆	
	If yes, whether dose records are maintained ?		Yes 🗆 No 🗆	
	[Comments:		

7. Radiation Measuring/Protection Level Equipment

(a)	Whether the area/zone monitors interlocked with source	
	raise/lower system ?	Yes 🗆 No 🗆

Yes \Box No \Box

(b) Whether periodic radiation protection survey carried out and records maintained ?

Type of equipment	Available (Yes/No/NA)	Working (Yes/No)	Calibration valid (Yes/No)
Gamma Zone Monitors (Location of installation) (i) Personnel Access Door (ii) DM Plant (iii) Product Exit Locations (iv) Product Exit Labyrinth (v) Any, Other Locations, pl. specify			
Radiation Survey Instruments			
Pocket Dosimeters			
Teletector			
Any other Radiation Measuring Device			

8. Functional Performance of Safety Systems/Components/Interlocks

8.1 Source Raise System

(i)	Whether functional performance of wire rope tension interlockYes \Box No \Box is satisfactory ?Yes \Box No \Box	
(ii)	Whether movement of source raise system is possible with lowHydraulic/Air Pressure or Oil level low ?Yes <a> No	
(iii)	Whether functional performance of following source moving indicator is satisfactory ?	
	(a) Audio : Yes \Box No \Box	
	(b) Visual : Yes \Box No \Box	
(iv)	Whether the condition of source raise wire rope is satisfactory ? Yes \Box No \Box	
	If no, whether any wire trends are visible on sources wire rope ? Yes \Box No \Box	
(v)	Whether the source shroud provided to prevent source rack and conveyor system interface is in proper condition ?Yes <a> No	
(vi)	Source rack up & down counter/chart, as applicable: Provided : Yes No NA Working : Yes No NA	
(vii)	Source position indicators on PAD and any other location: Provided : Yes \Box No \Box Working : Yes \Box No \Box	
	If yes, specify the position indicators location with functional status: $Working : Yes \square No$	
[Comment:	

8.2 Source Storage Water Pool & D. M. Plant

(i)	Pool water clarity:	Good/Poor/Clearly Visible
(ii)	Whether the conductivity monitor is available ?	Yes 🗆 No 🗆
(iii)	Whether the water conductivity is within the limit (10-30 $\mu S/$	(cm) ? Yes \Box No \Box
	The present water conductivity is : $\hfill \hfill \hfill$	
(iv)	Whether contamination monitor is available ?	Yes 🗆 No 🗆
	If yes, is it interlocked with source raise system:	Yes 🗆 No 🗆
(v)	Whether audio & visual indicators are provided with contamination monitor ?	Yes 🗆 No 🗆
(vi)	Whether physical guard/barrier and cover is provided over the water pool ?	Yes 🗆 No 🗆
(vii)	Whether pH of pool water is maintained within the limit (7.5	and 8)? Yes \Box No \Box
	The present pH of pool water is:	

(viii)	whether functional performance of following safety interfocks is satisfactory ?		
	(a)	Pool water low level float switch (WL_1) is working:	Yes 🗆 No 🗆
	(b)	Pool water low level float switch (WL ₂) is working:	Yes 🗆 No 🗆
	(c)	On activation of WL_2 , whether DM water enters the water pool :	Yes 🗆 No 🗆
	(d)	Pool water very low level float switch (WL_3) is working:	Yes 🗆 No 🗆
	(e)	On activation of WL_3 , water from DM storage and emergency storage tank enters the water pool:	Yes 🗆 No 🗆

(viii) Whether functional performance of following safety interlocks is satisfactory ?

Comment: **Personnel Access Door (PAD)** Availability of warning light indicators on PAD: Available \Box /Not Available \Box (i) Radiation warning placards displayed on PAD : Yes \Box No \Box (ii) (iii) The source position/ source exposed warning light Yes \Box No \Box indicators provided over PAD: (iv) Whether functional performance of PAD Safety interlocks satisfactory ? Yes \Box No \Box Radiation interlock solenoid: (a) - Solenoid operated plunger sits in the grove on latch bar while raising the source : Yes \Box No \Box NA \Box - Radiation interlock actuates when check source is taken near to the radiation detector inside the cell: Yes \Box No \Box (b) Hydraulic valve interlock : Yes \Box No \Box (c) Mechanical Interlock: Yes \Box No \Box - Door open condition: Yes \Box No \Box - Door closed condition: Yes \Box No \Box NA \Box (d) Electrical interlock: Main door closure limit switch: Yes \Box No \Box NA \Box (e) Yes \Box No \Box NA \Box (f) Multipurpose key/PSI lock:

(g)Does source return automatically to shielded
position in case of power failure ?Yes □ No □

8.4 Cell Ventilation/Exhaust Fan

Comment:

8.3

(i)	Whether adequate no. of exhaust ventilation fans (min.2) provided in radiation cell ?	Yes 🗆 No 🗆
(ii)	Is it possible to raise the source in exhaust fan 'OFF' condition ?	Yes 🗆 No 🗆
(iii)	Is it possible to run the irradiator plant during non-functioning of ventilation/exhaust system ?	Yes 🗌 No 🗆

(iv)	Whether source returns to shielding from exposed position in case of ventilation failure ?	Yes 🗌 No 🗌
	Comment	
Fire S	Safety	
Speci	fy the following, whether:	
(i)	Required number of fire extinguishers are available in the plant ?	Yes 🗆 No 🗆
(ii)	Plant personnel trained for fire fighting ?	Yes 🗆 No 🗆
(iii)	Functional performance of heat and smoke detector is satisfactory ?	Yes 🗆 No 🗆
(iv)	Heat detector interlocked with source raise/lower system ?	Yes 🗆 No 🗆
(v)	Temperature interlock system activates once temperature exceeded to 55° C ?	Yes 🗆 No 🗆
(vi)	Smoke detector interlocked with source raise/lower system ?	Yes 🗆 No 🗆
(vii)	Smoke detector gets activated once fire is detected in ventilation system ?	Yes 🗆 No 🗆
	Comment	

8.6 Emergency Safety Systems

8.5

(i)	Whether all hooters for different purposes are distinguishable ?	Yes 🗆 No 🗆
(ii)	Whether hooters are audible from all places within the facility ?	Yes 🗆 No 🗆

The functional performance of safety interlocks for following emergency situation satisfactory

S.No.	Safety Interlocks	Action Anticipated	Action observed/ anticipated
(i)	Actuation of Pressure Plate	(i) Source returns to shielded condition with audio visual alarm(ii) Cancels search operation	Yes 🗆 No 🗆
(ii)	Trip Wire Pulling	(i) Sounds audio/visual alarms(ii) Cancels search operation	Yes 🗆 No 🗆
(iii)	Search Operation Push buttons depressed in improper sequence	(i) Not possible to raise the source	Yes 🗆 No 🗆
(iv)	Service Keys not in position	(i) Prevents source raising operation	Yes 🗆 No 🗆
(v)	Power supply failure	 (i) Auto start up of UPS (ii) Important indicators show the status of the facility (iii) Source returns to shielded condition 	Yes 🗆 No 🗆

(vi)	Emergency Push Buttons Actuation at various location	(i) Cancels search operation(ii) Source returns to shielded condition with audio visual alarm	Yes 🗆 No 🗆
(vii)	Jamming of Product Box	 (i) Cancels search operation (ii) Source returns to shielded condition with audio visual alarm (iii) Conveyor stops automatically 	Yes 🗆 No 🗆
(viii)	Failure of PLC	(i) Source returns to the shielded condition(ii) Prevents the source raising operation	Yes 🗆 No 🗆
(ix)	Roof Plug not in position	(i) Prevents the source raising operation	Yes □ No □ NA □
(x)	Actuation of Seismic Detector	(i) Source returns to the shielded condition	Yes 🗆 No 🗆

Comment:

9. Schedule for Servicing and Maintenance:

(i)	Whether maintenance and repair work is performed	
	accordance with manufacturer's recommendations?	Yes 🗆 No 🗆

Yes \Box No \Box

(ii) Whether servicing/ maintenance procedures developed and followed ?

System/Components	Frequency of functional check/maintenance	Records Maintained
Radiation Survey Meter (RSM)	Daily	Yes 🗆 No 🗆
Area monitor inside the cell	Daily	Yes 🗆 No 🗆
Source movement	Weekly	Yes 🗆 No 🗆
Product movement	Weekly	Yes 🗆 No 🗆
Source lifting wires and guide wires	Weekly	Yes 🗆 No 🗆
Area monitor (other locations)	Monthly	Yes 🗆 No 🗆
Components of source and product movement system	Monthly	Yes 🗆 No 🗆
Heat/smoke detector	Monthly	Yes 🗆 No 🗆
Ventilation system	Monthly	Yes 🗆 No 🗆
Water level controls and emergency water supply tank	Monthly	Yes 🗆 No 🗆
Emergency safety systems	Quarterly	Yes 🗆 No 🗆
Power failure	Quarterly	Yes 🗆 No 🗆
Contamination check	Quarterly	Yes 🗆 No 🗆
Comment:		

10. Unusual Occurrences/Accidents

11.

(a)	Any unusual occurrence /accident encountered after the last RI ?	Yes 🗆 No 🗆 NA 🗆
	If yes, then details:	
(b)	AERB was informed about the incident/accident	Yes 🗆 No 🗆
(c)	Actions taken to prevent recurrence	Yes 🗆 No 🗆
Γ	Comment	
Availa	ability of Documents/Records:	_
(i)	Minutes of Local Safety Committee (LSC):	Yes 🗆 No 🗆
(ii)	Operating procedures:	Yes 🗆 No 🗆
(iii)	Operation logbook:	Yes 🗆 No 🗆
(iv)	Display of proper emergency procedures:	Yes 🗆 No 🗆
(v)	Preventive servicing maintenance records:	Yes 🗆 No 🗆
(vi)	Radiation protection survey records:	Yes 🗆 No 🗆
(vii)	PMS records:	Yes 🗆 No 🗆
(viii)	Special medical records:	Yes 🗆 No 🗆

(ix) Emergency plan and preparedness procedures: Yes □ No □
 Comment:

12. Any other Observations:

(Attach extra sheet if required)

(Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed about the above observations.

(Signature of Co-ordinator of the Institution) (Signature of Licensee/Head of the Institution)

Name:

Designation:

Name:

Designation:

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF INDUSTRIAL ACCELERATOR RADIATION PROCESSING FACILITY

					Date of inspection:		
					Type of inspection:		
					Pre-commissioning		
					Routine		
					Special		
					Surprise		
1.1	Details	s of the Radiation	n Facility (R	F):	Sulpilse		
1.1.1	Institution number:						
	Name and address of the RF:						
	Telephone No. Fax No.		(0):				
1.2	Туре о	f the Facility:	Govt./Semi-Govt./Autonomous/Private/Joint venture/Others				
1.3 1.4	Emplo (a) (b) Licens (a) (b)	yer : Name: Designation: Telephone No. Mobile No. E-mail ee: Name: Designation: Telephone No. Mobile No. E-mail	(O): (O):		(R) (R)		
1.5	Facilit (a) (b)	y in Charge: Name: Designation: Telephone No. Mobile No. E-mail	(0):		(R)		
1.6	RSO: (a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):		(R)		
1.7	Inspe	Inspection Coordinator from Institution:					
-----	-------	---	------------	--	--	--	--
	(a)	Name:					
	(D)	Telephone No. (O): (R)					
		Mobile No.					
		E-mail					
2.	Com	pliance of recommendation based on Last Inspection					
	(i)	Date of last inspection, if any:					
	(ii)	Whether all the recommendations are already complied ?	Yes 🗆 No 🗆				
	(iii)	Particulars of pending recommendation, if any:					
3.	On- S	Site Verification of Consents/Approvals issued					
	(i)	Whether licence for operation is valid ?	Yes 🗆 No 🗆				
	(ii)	Layout approval available:	Yes 🗆 No 🗆				
	(iii)	Construction approval available:	Yes 🗆 No 🗆				
	(iv)	Whether RSO certificate is valid ?	Yes 🗆 No 🗆				
	(v)	Whether Licensee is the same as mentioned in the licence ?	Yes 🗆 No 🗆				
		If no, whether any amendment of licence was sought and obtained ?	Yes 🗆 No 🗆				
	Γ	Comments:					

4.1 Particulars of Accelerator:

- (i) Type of Accelerator: Electron beam/X-ray/Both
- (ii) Make, Model, S. No. :
- (iii) Maximum beam rating (voltage, beam current and power):
- (iv) Maximum X-ray energy:
- (v) Scan width:
- (vi) Number of hours the accelerator is in 'ON' condition during the quarter
- (vii) The vacuum system pressure:
- (viii) Maximum beam dimensions:

4.2 Details of Check/ Reference Sources Available

- (i) Name of the source : _____
- (ii) Activity of source: —— MBq (——— mCi) as on date: ——
- (iii) Whether reference source installed properly near personnel access door ? Yes \Box No \Box

Comments:

5. Availability of Operating Personnel

- (i) Number of RSO(s) available:
- (ii) Number of qualified operators available:
- (iii) Number of Quality Control Officer (QCO) available (as applicable) :
 Comments:

6. Personnel Monitoring

1 61 50	June Montoring	
Instit	ute personnel monitoring service (PMS) number :	
Num	ber of personnel monitoring devices (PMD) in the RF:	
State	whether;	
(a)	PMD is provided to all radiation workers ?	Yes 🗆 No 🗆
(b)	PMD is provided to the trainees (if any)?	Yes \Box No \Box NA \Box
(c)	PMD are being worn by workers appropriately ?	Yes 🗆 No 🗆
(d)	Proper storage of PMD is available ?	Yes 🗆 No 🗆
(e)	Dose records available ?	Yes 🗆 No 🗆
(f)	Radiation workers have access to their personnel monitoring records ?	Yes 🗆 No 🗆
(g)	PMS was suspended any time during last three years ?	Yes 🗆 No 🗆
(h)	Any over-exposure is reported during last three years ?	Yes 🗆 No 🗆
	If yes, whether dose recorded was found to be genuine ?	Yes 🗆 No 🗆
(i)	Adequate measures have been taken to avoid recurrence of over-exposure ?	Yes 🗆 No 🗆
Whet	her pocket dosimeters are available ?	Yes 🗆 No 🗆
If yes	s, whether used by radiation workers any time?	Yes 🗆 No 🗆
If yes	s, whether dose records are maintained ?	Yes 🗆 No 🗆
[Comments:	
	I ers Instit Num ¹ State (a) (b) (c) (d) (c) (d) (e) (f) (g) (h) (i) Whet If yes	 Institute personnel monitoring service (PMS) number : Number of personnel monitoring devices (PMD) in the RF: State whether; (a) PMD is provided to all radiation workers ? (b) PMD is provided to the trainees (if any) ? (c) PMD are being worn by workers appropriately ? (d) Proper storage of PMD is available ? (e) Dose records available ? (f) Radiation workers have access to their personnel monitoring records ? (g) PMS was suspended any time during last three years ? (h) Any over-exposure is reported during last three years ? (i) Adequate measures have been taken to avoid recurrence of over-exposure ? Whether pocket dosimeters are available ? If yes, whether dose records are maintained ? Comments:

7. Radiation Measuring/Protection Level Equipment

(a) Whether periodic radiation protection survey carried out and records maintained ?

Type of Equipment	Available (Yes/No)	Working (Yes/No)	Calibration valid (Yes/No)
Gamma zone monitors (Location of Installation) - Personnel Access Door - Product Exit Locations - Any other Locations, please specify			
Radiation Survey Instruments			
Any other radiation measuring device			

8. Functional Performance of Safety Systems/Components/Interlocks

8.1 Beam ON/OFF Indication

(i) Whether functional performance of following beam ON/OFF indicator is satisfactory:

(a) Audio: Yes \Box No \Box

(b) Visual: Yes \Box No \Box

8.2 Personnel Access Door (PAD)

(i)	Avai	Availability of warning light indicators:Yes \Box No \Box			
(ii)	Radi	Radiation warning placards displayed on PAD:Yes \Box No \Box			
(iii)	Whe Safet	ther functional performance of following PAD ty interlocks satisfactory ?			
	(a)	Main door closure limit switch :	Yes 🗆 No 🗆 NA 🗆		
	(b)	Multipurpose key/PSI lock :	Yes 🗆 No 🗆 NA 🗆		
	(c)	Any other interlock :	Yes 🗆 No 🗆 NA 🗆		
(iv)	Whe Door	ther functional performance of Personnel Access (PAD) to cell roof safety interlock is satisfactory ?			
	(a)	Door closure limit switch:	Yes 🗆 No 🗆 NA 🗆		
	(b)	Any other interlock :	Yes \Box No \Box NA \Box		
[Comm	ent			

8.3 Cell Ventilation

(i)	Whe vent		
	-	Exhaust fan put off:	Yes 🗆 No 🗆
	-	Non-functioning of exhaust fan:	Yes 🗆 No 🗆
	Comm	ent	

8.4 Fire Safety

(i)	When in the	ther required number of fire extinguishers are available plant?	Yes 🗆 No 🗆	
(ii)	Whe	ther plant personnel trained for fire fighting ?	Yes 🗆 No 🗆	
(iii)	Whe	Whether functional performance of following safety interlock satisfactory		
	(a)	Smoke detector detects the smoke:	Yes 🗆 No 🗆	
	(b)	Heat detector actuates at set temperature:	Yes 🗆 No 🗆	
	Comme	ent		

8.5 Emergency Safety Systems

(i)	Whether all hooters for dif	erent purposes are distinguishable	? Yes \Box No \Box
(1)	in mether an mooters for an	erent purposes are distinguishable	

(ii) Whether hooters are audible from all places within the facility ? Yes \Box No \Box

The functional performance of safety interlocks for following emergency situations satisfactory:

S.No.	Safety Interlocks	Action Anticipated	Action observed/ anticipated
(i)	Power supply failure	 (i) Auto start up of UPS (ii) Important indicators show the status of the facility (iii) Turns "OFF" the beam 	Yes 🗆 No 🗆 Yes 🗆 No 🗆 Yes 🗆 No 🗆 NA 🗆
(ii)	Emergency Push Buttons Actuation at various locations	(i) Cancel search operation(ii) Turns "OFF" the beam with audio visual alarm	Yes 🗆 No 🗆 NA 🗆 Yes 🗆 No 🗆
(iii)	Jamming of Product Movement	(i) Turns "OFF" the beam with audio visual alarm	Yes 🗆 No 🗆 NA 🗆
(iv)	Actuation of Pressure Plate/ Similar System	(i) Cancel search operation(ii) Turns "OFF" the beam with audio visual alarm	Yes 🗆 No 🗆 NA 🗆 Yes 🗆 No 🗆
(v)	Search Operation Push buttons depressed in improper sequence	(i) Not possible to beam turn "ON"	Yes 🗆 No 🗆
(vi)	Trip Wire Pulling	(i) Cancels Search Operation(ii) Sounds audio/visual alarms	Yes 🗆 No 🗆 NA 🗆 Yes 🗆 No 🗆 NA 🗆
(vii)	Service Keys not in position	(i) Prevents the beam turn "ON"	Yes 🗆 No 🗆
(viii)	Failure of PLC	(i) Turns "OFF" the beam(ii) Prevents the beam to turn "ON"	Yes No Yes No
(ix)	Failure of Cooling system	(i) Turns 'OFF' the beam(ii) Prevents the beam turn "ON"	Yes 🗆 No 🗆 NA 🗆 Yes 🗆 No 🗆

9. Schedule for Servicing and Maintenance:

(i)	Whether maintenance and repair work is performed accordance with manufacturer's recommendations ?	Yes 🗆 No 🗆
(ii)	Whether servicing/maintenance procedures developed and followed ?	Yes 🗆 No 🗆

System/Components	Frequency of functional check/maintenance	Records Maintained
Radiation Survey meter functionality check	Daily	Yes 🗆 No 🗆
Ozone monitor	Daily	Yes 🗆 No 🗆
Components of Product Movement system	Monthly	Yes 🗆 No 🗆
Smoke detector	Monthly	Yes 🗆 No 🗆
Ventilation System	Monthly	Yes 🗆 No 🗆
SF ₆ detector	Quarterly	Yes 🗆 No 🗆
Emergency Safety systems	Quarterly	Yes 🗆 No 🗆
Power failure	Quarterly	Yes 🗆 No 🗆

Comment:			

10. Unusual Occurrences/Accidents

11.

(i)	Any unusual occurrence /accident encountered after the last RI ? If yes, then details:	Yes 🗆 No 🗆 NA 🗆
(ii)	AERB was informed about the incident/accident	Yes 🗆 No 🗆
(iii)	Actions taken to prevent recurrence	Yes 🗆 No 🗆
[Comment:]
Avai	lability of Documents/Records:	
(i)	Minutes of Local Safety Committee (LSC):	Yes 🗆 No 🗆
(ii)	Operating procedures:	Yes 🗆 No 🗆
(iii)	Operation logbook:	Yes 🗆 No 🗆
(iv)	Display of proper emergency handling procedures:	Yes 🗆 No 🗆
(v)	Preventive servicing maintenance records:	Yes 🗆 No 🗆
(vi)	Radiation protection survey records:	Yes 🗆 No 🗆
(vii)	PMS records:	Yes 🗆 No 🗆
(viii)	Special medical records:	Yes 🗆 No 🗆
(ix)	Emergency plan and preparedness procedures:	Yes 🗆 No 🗆
		1

Comment:

12. Any other Observations:

(Attach extra sheet, if requires)

Signature of inspector(s) with date)	
Name of Inspector(s):	
I/we was/were informed the above observations.	
(Signature of Coordinator of the Institution)	(Signature of the Licensee/Head Institution)
Name :	Name:
Designation:	Designation:

of the

ANNEXURE-22

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF INDUSTRIAL RADIOGRAPHY FACILITY

Date of inspection: Type of inspection: Pre-commissioning Routine Special Surprise

Surprise 1.1 **Details of the Radiation Facility (RF):** 1.1.1 Institution number: Name and address of the RF: Telephone No. (O): Fax No. 1.1.2 Name and address of the Radiography Site for Inspection: 1.2 Type of the Facility: Govt. /Semi-Govt./Autonomous/Private/Joint venture/Others 1.3 **Employer:** (a) Name: (b) Designation: Telephone No. (O): (R) Mobile No. E-mail 1.4 Licensee: Name: (a) Designation: (b) Telephone No. (0): (R) Mobile No. E-mail 1.5 **RSO:** (a) Name: Designation: (b) Telephone No. (O): (R) Mobile No. E-mail **Inspection Coordinator at the Radiography Site:** 1.6 Name: (a)

(b) Designation:

		Telephone No. Mobile No. E-mail	(0):	(R)	
1.7.1	Name	and Address of C	Contract Awardi	ng Agency:	
1.7.2	Respon (a) (b)	nsible Person from Name: Designation: Telephone No. Mobile No. E-mail	m Contract Awa (O):	arding Agency for Radiograp (R)	hy Work:
2.	Comp	liance of recomm	endation based (on Last Inspection	
	(i)	Date of last insp	ection, if any:		
	(ii)	Whether all the	recommendation	s are already complied ?	Yes 🗆 No 🗆
	(iii)	Particulars of pe	nding recommen	dation, if any:	
3.	On-Sit	te Verification of	Consents/Appro	ovals issued:	
	(i)	Whether licence	for operation is	valid?	Yes 🗆 No 🗆 NA 🗆
	(ii)	Whether radiogr	aphy site approv	al is obtained and valid?	Yes 🗆 No 🗆 NA 🗆
	(iii)	Whether RSO aj	oproval is valid?		Yes 🗆 No 🗆 NA 🗆
	(iv)	Whether approv is available ?	al(s) for radiogra	pher(s)/site-in-charge(s)	Yes 🗆 No 🗆 NA 🗆
	(v)	Whether NOC(s of radiography c)/authorisation(s) levice(s) availabl) iss procurement	Yes 🗆 No 🗆 NA 🗆
	(vi)	Whether license	e is the same as r	nentioned in the licence ?	Yes 🗆 No 🗆
		If no, whether an and obtained ?	ny amendment of	licence was sought	Yes 🗆 No 🗆
	(vii)	Duly filled in &	signed logbook i	s available:	Yes 🗆 No 🗆
	(viii)	Emergency plan	and preparednes	s is available:	Yes 🗆 No 🗆
	(ix)	Documents on se	ecurity plan is av	ailable:	Yes 🗆 No 🗆
		Comments:			

4. Type of Radiography Facility

- (i) Field radiography
- (ii) Enclosed radiography
- (iii) Radiography source storage facility

4.1 Field Radiography

(i)	Whether valid site approval/movement permission is available ?	Yes 🗆 No 🗆
(ii)	Whether valid source storage room approval is available ?	Yes 🗆 No 🗆 NA 🗆

Enclosed Radiography 4.2

(i)	Whether layout & construction approval is available ?	Yes 🗆 No 🗆
(ii)	Whether constructed as per approved layout?	Yes 🗆 No 🗆
(iii)	Whether commissioning approval of the enclosure is available ?	Yes 🗆 No 🗆
(iv)	Periodic radiation survey report of the enclosure is available:	Yes 🗆 No 🗆
Γ	Comments:	
Availa	ability of Radiography Personnel	
(i)	Number of approved Radiographers available:	
(ii)		
	Number of approved Site In-Charge (SIC)/ RSOs available:	
Γ	Number of approved Site In-Charge (SIC)/ RSOs available: Comments:	

5.

6.	Perso	onnel Monitoring	
6.1	Instit	ute personnel monitoring service (PMS) number :	
6.2	Numl	ber of personnel monitoring devices (PMD) in the RF:	
6.3	State	whether;	
	(a)	PMD is provided to all radiation workers ?	Yes 🗆 No 🗆
	(b)	PMD is provided to the trainees (if any)?	Yes 🗆 No 🗆 NA 🗆
	(c)	PMD are being worn by workers appropriately ?	Yes 🗆 No 🗆
	(d)	Proper storage of PMD is available ?	Yes 🗆 No 🗆
	(e)	Dose records available ?	Yes 🗆 No 🗆
	(f)	Radiation workers have access to their personnel monitoring records ?	Yes 🗆 No 🗆
	(g)	PMS was suspended any time during last three years ?	Yes 🗆 No 🗆
	(h)	Any over-exposure is reported during last three years ?	Yes 🗆 No 🗆
		If yes, whether dose recorded was found to be genuine ?	Yes 🗆 No 🗆
	(i)	Adequate measures have been taken to avoid recurrence of over-exposure ?	Yes 🗆 No 🗆
6.4	Whet	her pocket dosimeters are available ?	Yes 🗆 No 🗆
	If yes	, whether used by radiation workers any time?	Yes 🗆 No 🗆
	If yes	s, whether dose records are maintained ?	Yes 🗆 No 🗆
	[Comments:	

7. Radiation Measuring/Protection Level Equipment

Equipment	Adequate no. (Yes/No)	Working (Yes/No)	Calibration valid (Yes/No)
Radiation Survey Meter (RSM)			
Gamma zone monitor(s) (enclosed radiography)			
Adequate no. of direct reading dosimeters (Pocket dosimeter)			
Whether above instruments are appropriate for radiation type and energy ?	Yes □ No □ If 'No' then de	tails:	

Comments (s):

8. **Radiography Device(s)/Source(s) available** (attach extra sheet, if necessary)

- (i) No. of gamma radiography exposure devices/X-ray devices available:
- (ii) Whether exposure device inventory is as per safety status report ? Yes \Box No \Box

8.1 Industrial Gamma Radiography Exposure Devices (IGREDs):

S. No.	Make	Model and S.No.	Radionuclide	Activity as on date TBq(Ci)	Whether leakage Radiation level around the IGRED is within permissible limit ? (Yes/No)	Remarks, if any

8.2 Industrial X-ray/Accelerator(s):

S. No.	Make	Model and S.No	Max kV/mA in case X-ray	Energy (MeV) in case accelerator	Whether machines are in operation ? (Yes/No)	Remarks, if any

8.3 Discrete source(s):

S. No.	Radionuclide	Activity as on date TBq (Ci)	Purpose(s)	Whether in use ? (Yes/No)	Remarks, if any

8.4 Details of Disused Sources:

(i)	Any decommissioning/disposal carried out during	
	last three year ?	Yes L NO L NA L
(ii)	Whether permission taken for disposal/decommissioning?	Yes 🗆 No 🗆 NA 🗆

()	Any disused source available for disposal	
	If yes, type of radionuclide, Activity:	— (MBq) ——— (mCi)
(iv)	In case of disused sources, whether the institute has plan of action for disposal/decommissioning the same:	Yes 🗆 No 🗆 NA 🗆
	Comments:	
Detail	ls of Emergency Handling Accessories Available at Site:	
(i)	Lead pot :	Yes 🗆 No 🗆
(ii)	Remote handling tongs :	Yes 🗆 No 🗆
(ii) (iii)	Remote handling tongs : Adequate temporary shielding available : (lead sheets/concrete blocks/sand bags etc.)	$Yes \square No \square$ $Yes \square No \square$
(ii) (iii) (iv)	Remote handling tongs : Adequate temporary shielding available : (lead sheets/concrete blocks/sand bags etc.) Radiation warning placards:	Yes □ No □ Yes □ No □ Yes □ No □
(ii) (iii) (iv) (v)	Remote handling tongs : Adequate temporary shielding available : (lead sheets/concrete blocks/sand bags etc.) Radiation warning placards: Cordoning off ropes:	Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □

10. Details of Source Storage Facility at Site:

9.

(i)	Type of storage (If other, please specify)	:	Exclusive room/room with pit/other
(ii)	Fencing around storage	:	Available \Box Not available \Box
(iii)	Occupancies around storage	:	Full/Partial/Occasional
(iv)	Radiation warning placards (Wherever applicable)	:	Exhibited/Not exhibited
(v)	Locking arrangement	:	Satisfactory/Not satisfactory
(vi)	Proper storage of sources	:	Verified daily/Not verified inside the storage room
(vii)	Whether source storage facilit	y is safe and se	cure ? Yes \Box No \Box
	Comments:		

11. Functionality Check of Operational Parameters of Radiography Facility:

11.1 Enclosed Installation:

(a) Type of installation: Enclosed/Open Top/Pit Type

S. No.	Parameters	Available Yes/No/N.A	Working Yes/No/N.A
(i)	Interlocking switches for enclosure access doors		
(ii)	Red warning lights		
(iii)	Area zone monitor		
(iv)	Proper position of the monitor		
(v)	Radiation warning sign boards are exhibited		
(vi)	Emergency switches working		
(vii)	Emergency procedures displayed		

11.2 Field Radiography Installation:

12.

13.

14.

(i)	Type of radiography site : W	orkshop/Erection/ Isolated areas
(ii)	Radiography work done during :	hrs tohrs
(iii)	Whether effective cordoning of facilities available ?	Yes 🗆 No 🗆
(iv)	Nature of occupancies outside the cordon during exposur	res: Full/Partial/Occasional/Nil
(v)	Whether contract awarding agency issues clearance prior radiography work ?	∙to Yes □ No □
Unu	sual Occurrences/Accidents	
(a)	Any unusual occurrence/accident encountered after the last RI ?	Yes 🗆 No 🗆 NA 🗆
	If yes, then details :	
(b)	AERB was informed about the incident/accident	Yes 🗆 No 🗆
(c)	Actions taken to prevent recurrence	Yes 🗆 No 🗆
	Comments:	
Deta	nils Enforcement Actions Taken:	
(a)	Any enforcement actions taken against the institution dur last three years:	ing Yes □ No □
(b)	Reasons for enforcement actions :	
(c)	Corrective measures initiated after enforcement actions:	Yes 🗆 No 🗆
Any	other observations:	

(Attach extra sheet, if required)

Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed the above observations.

(Signature of Co-ordinator of the Institution)	(Signature of the Licensee/Head of the institution)
Name:	Name:
Designation:	Designation:

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ANNEXURE-23

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF GAMMA IRRADIATION CHAMBER (GIC) FACILITY (CATEGORY-I IRRADIATOR)

				Date	of inspection:	
				Туре	of inspection:	
				Rout	ine	
				Spec	ial	
				Surp	rise	
1.1	Detai	ls of the Radiation Fa	cility (RF)			
1.1.1	Instit	ution number:				
	Name Telep Fax N	e and address of the RF: hone No. No.	: (0):			
1.1.2	Name	e and address of Department	ment possessin	g Gamma Irradia	tion Chamber (GIC) Uni	t:
1.2	Туре	of the Facility:	Govt./Semi-0	Govt./Autonomou	us/Private/Joint venture/C	Others
1.3	Empl (a) (b)	loyer : Name: Designation: Telephone No. Mobile No. E-mail	(O):		(R)	
1.4	Licer (a) (b)	isee : Name: Designation: Telephone No. Mobile No. E-mail	(O):		(R)	
1.5	RSO (a) (b)	: Name: Designation: Telephone No. Mobile No. E-mail	(O):		(R)	
1.6	Inspe	ection Coordinator fro	m Institution:	:		
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):		(R)	

2.	2. Compliance of recommendation based on Last Inspection			
	(i) Date of last inspection, if any:			
	(ii)	Whether all the recommendations are already complied ?	Yes 🗆 No 🗆	
	(iii)	Particulars of pending recommendation:		
3. On-Site Verification of Consents/Approvals issued:				
	(i)	Whether Authorisation for commissioning /operation is valid?	Yes 🗆 No 🗆	
	(ii)	Layout approval available:	Yes 🗆 No 🗆	
	(iii)	Whether RSO certificate is valid ?	Yes 🗆 No 🗆	
	(iv)	Whether licensee is the same as mentioned in the licence ?	Yes 🗆 No 🗆	
		If no, whether any amendment of licence was sought and obtained ?	Yes 🗆 No 🗆	
4.	Source	s/Facilities Available:		

No. of GIC units available: (a)

Whether GIC inventory is as per safety status report ? Yes 🗆 No 🗆 (b)

If no, provide details,	which are not	in the inventory:
-------------------------	---------------	-------------------

S. No	Particulars of GIC	Unit 1	Unit 2
(i)	Type of unit :(GIC/Blood Irradiator)		
(ii)	Make, Model and S. No.		
(iii)	Type of radionuclide		
(iv)	Max. initial activity loaded in TBq (kCi)		
(v)	Year of installation		
(vi)	Present activity : TBq (kCi)		
(vii)	Status of GIC : In Operation/Not in Operation (Since When)		
(viii)	Purpose of GIC		
(ix)	Number of hours operated per month		
(x)	Type of samples irradiated		

(c)	Whether any disused GIC unit is available for disposal ?	Yes 🗆 No 🗆
(d)	Whether permission taken for disposal/decommissioning?	Yes 🗆 No 🗆
(e)	In case of disused sources, whether the institute has plan of action for disposal/decommissioning the same ?	Yes 🗆 No 🗆
	Comments:	

Availability of Operating Personnel: 5.

Whether person trained on "Radiation Safety and Regulatory Aspects" available ? (i)

Yes \Box No \Box

	~ /		1			
		S. No.	Name	Training on Radiation Safety	Year of Passing	
	(iii)	No. of	personnel/users involved	d in handling of GIC :		
	(iv)	Whether servicin	er the institution personr ng and maintenance of C	nel are trained on operation, GIC unit by supplier ?	Yes 🗆 No	, 🗆
6.	Perso	nnel Mor	nitoring			
6.1	Institu	ite person	nel monitoring service (PMS) number :		
6.2	Numb	er of pers	onnel monitoring device	es (PMD) in the RF:	_	
6.3	State v	whether;				
	(a)	PMD is	s provided to all radiatio	n workers ?	Yes 🗆 No	, 🗆
	(b)	PMD is	s provided to the trainee	s (if any) ?	Yes 🗆 No 🗆 NA	
	(c)	PMD a	re being worn by worker	rs appropriately ?	Yes 🗆 No	, 🗆
	(d)	Proper	storage of PMD is avail	able ?	Yes 🗆 No	, 🗆
	(e)	Dose re	ecords available?		Yes 🗆 No	, 🗆
	(f)	Radiati monito	on workers have access ring records ?	to their personnel	Yes 🗆 No	
	(g)	PMS w	as suspended any time d	luring last three years ?	Yes 🗆 No	
	(h)	Any ov	ver-exposure is reported	during last three years ?	Yes 🗆 No	
		If yes,	whether dose recorded w	vas found to be genuine ?	Yes 🗆 No	
	(i)	Adequa over-ex	ate measures have been t xposure ?	taken to avoid recurrence of	Yes 🗆 No) 🗌
6.4	Wheth	ner pocket	t dosimeters are availabl	e ?	Yes 🗆 No	
	If yes,	whether	used by radiation worke	rs any time:	Yes 🗆 No	
	If yes,	whether	dose records are maintai	ned:	Yes 🗆 No	

7.1 Radiation Measurement/Protection Level Equipment

Equipment	Available (Yes/No)	Working (Yes/No)	Calibration valid (Yes/No)
Radiation Survey Meter (RSM)			
Area monitor, as applicable			
Whether above instruments are appropriate for radiation type and energy ?	Yes □ No □ If no, then details:		

7.2 Particulars of the radiation measuring equipment in case not available in status report:

S. No.	Make	Model and S. No.	Range	Working (Yes/No)	Date of recent calibration

7.3 Radiation protection surveillance around GIC installation:

(i)	Whether periodic radiation protection survey performed ?	Yes 🗆 No 🗆
(ii)	Whether survey records maintained ?	Yes 🗆 No 🗆
(iii)	Whether radiation levels around GIC installations is within the prescribed limit ?	Yes 🗆 No 🗆

Particulars of protection survey

	Radiation level from external surface	Unit 1 ìSv/h (mR/h)	Unit 2 ìSv/h (mR/h)	
At 5	cm			
At 10	00 cm			
Near dista prepa	est Accessible location, with approximate nce from unit (eg. Entrance door, Sample aration table ——)			
(iv)	Whether installation room is safe and secured f	?	Yes 🗆 N	lo □
(v)	Whether the wall thickness/shielding for install room is adequate ?	ation	Yes 🗆 N	lo 🗆
	Comments:			

8. Practice Specific Requirements

(i)	Whether exclusive room provided for GIC ?	Yes 🗆 No 🗆
(ii)	Radiation warning board in English, Hindi and regional language displayed at entrance door of GIC unit installation room :	Yes 🗆 No 🗆
(iii)	Radiation warning symbol pasted/painted/engraved on the on GIC housing:	Yes 🗆 No 🗆
(iv)	Whether emergency response procedures with contact details displayed at institution and GIC room ?	Yes 🗆 No 🗆
(v)	Whether physical security measures provided for GIC room are adequate ?	Yes 🗆 No 🗆
(vi)	Security arrangement for the GIC are same as institutions security:	Yes 🗆 No 🗆
(vii)	General housekeeping of the GIC room: $Good \square$ Full of u	inwanted material \Box
	Comments:	

9. Unusual Occurrences/Accidents

(a)	Any unusual occurrence/accident encountered after the last RI ?	Yes \Box No \Box NA \Box
	If yes, then details:	
(b)	AERB was informed about the incident/accident	Yes 🗆 No 🗆
(c)	Actions taken to prevent recurrence	Yes 🗆 No 🗆
Γ	Comments:]
Avail	ability of Documents/Records:	-
(i)	Logbook on operation of GIC with up-to-date records:	Yes \Box No \Box
(ii)	Radiation protection survey report:	Yes 🗆 No 🗆
(iii)	Servicing/maintenance records:	Yes 🗆 No 🗆

(iv)Emergency plan and preparedness:Yes □ No □(v)Document on physical security aspects:Yes □ No □

11. Any other Observations:

10.

(attach extra sheet, if any)

Comments:

Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed the above observations.

(Signature of Co-ordinator of the Institution)	(Signature of the Licensee/Head of the Institution)
Name:	Name:
Designation:	Designation:

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ANNEXURE-24

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF IONISING RADIATION GAUGING DEVICES (IRGDs)/NUCLEONIC GAUGE INSTALLATION

Date of inspection: Type of inspection: Routine Special Surprise

1.1 Details of the Radiation Facility (RF):

1.1.1 Institution number:

Name and address of the RF: Telephone No. (O): Fax No.

1.1.2 Name and address of Unit/Plant possessing IRGDs/NG:

1.2 Type of the Facility:

Govt./Semi-Govt./Autonomous/Private/Joint venture/Others

1.3	Emplo (a) (b)	yer: Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.4	Licens (a) (b)	ee: Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.5	Head o (a) (b)	of the Plant/Depa Name: Designation: Telephone No. Mobile No. E-mail	rtment (O):	(R)
1.6	RSO: (a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)

1.7 Inspection Coordinator from Institution:

2.

3.

5. 5.1

5.2 5.3

(a) (b)	Name: Designation: Telephone No. (O): Mobile No. E-mail	(R)	
Con	pliance of recommendation	n based on Last Inspection	
(i)	Date of last inspection, it	f any:	
(ii)	Whether all the recomme	endations are already complied ?	Yes 🗆 No 🗆
(iii)	Particulars of pending re	commendation :	
On-	Site Verification of Consent	ts/Approvals issued:	
(i)	Whether Registration for	r all IRGDs/Nucleonic gauges is obtained ?	Yes 🗆 No 🗆
(ii)	Whether Registration for	r operation is valid ?	Yes 🗆 No 🗆
(iii)	Whether RSO certificate	e is valid ?	Yes 🗆 No 🗆
(iv)	Whether Licensee is the	same as mentioned in the licence ?	Yes 🗆 No 🗆

If no, whether any amendment of licence was sought and obtained ?

Yes \Box No \Box

4. Availability of Operating Personnel:

 Whether person trained on "Radiation Safety and Regulatory Aspects" available ?
 Yes □ No □

Particulars of the trained person(s)

	S. No.	Name	Training on radiation safety	Year of Pa	assing	
(ii)	No. of	personnel/users involved	in handling of IRGDs/NG	:		
(iii)	Whether servicin	er the institution personn ng and maintenance of IF	el are trained on operation, RGDs/NG by supplier ?		Yes 🗆	No 🗆
Perso	nnel Mor	nitoring (PMS is not ma	ndatory for NG)			
Whet	her person	nnel monitoring services	(PMS) is availed:		Yes 🗆	No 🗆
If no,	whether F	PM service needs to be av	vailed:		Yes 🗆	No 🗆
If Yes	then,					
Numb	per of pers	onnel monitoring device	s (PMD) in the RF:			
State	whether;					
(a)	PMD is	s provided to all radiation	n workers ?		Yes 🗆	No 🗆
(b)	PMD is	s provided to the trainees	s (if any) ?	Yes 🗆	No 🗆 🛛	NA 🗆
(c)	PMD a	re being worn by worker	s appropriately ?		Yes 🗆	No 🗆
(d)	Proper	storage of PMD is availa	able ?		Yes 🗆	No 🗆
(e)	Dose re	ecords available?			Yes 🗆	No 🗆

(f)	Radiation workers have access to their personnel monitoring records ?	Yes 🗆 No 🗆
(g)	PMS was suspended any time during last three years ?	Yes 🗆 No 🗆
(h)	Any over-exposure is reported during last three years ?	Yes 🗆 No 🗆
	If yes, whether dose recorded was found to be genuine ?	Yes 🗆 No 🗆
(i)	Adequate measures have been taken to avoid recurrence of over-exposure ?	Yes 🗆 No 🗆
Whethe	er pocket dosimeters are available ?	Yes 🗆 No 🗆 NA 🗆
If yes,	whether used by radiation workers any time?	Yes 🗆 No 🗆 NA 🗆
If yes,	whether dose records are maintained ?	Yes 🗆 No 🗆 NA 🗆

6.1 Radiation Measurement /Protection Level Equipment

(i) Number of Radiation Survey Meter (RSM): -

Type of Equipment(s)	Available (Yes/No)	Working (Yes/No)	Calibration valid (Yes/No)
Radiation Survey Meter (RSM)	Yes/No	Yes/No	Yes/No
Whether above instruments are appropriate for radiation type and energy ?	Yes □ No□ If no, then details:		

6.2 Provide details of RSM in case not available in Status Report:

S. No.	Make	Model and S. No.	Range	Working (Yes / No)	Date of recent calibration

7.1 Sources/Facilities Available

5.4

- (i) No. of IRGD with radioisotope(s)/X-ray source available:
- (ii) Whether IRGD inventory is as per safety status report (SSR)? Yes \Box No \Box
- (iii) Inventory of radioactive sources: Updated \Box Incomplete \Box

If no, provide details, which are not in the inventory:

S. No.	Type of Gauge(s)	Make, Model & S. No.	Source & Activity with date	Number of Gauges	Location of gauges	Present status of gauges (In use/ yet to be installed /disused)

7.2 Particular of the IRGDs presently not in use or disused source for disposal:

(i) Any decommissioning/disposal carried out in past ?: Yes \Box No \Box NA \Box

(ii) No. of IRGDs not in use : _____

(iii) No. of disused sources to be disposed off : _____

Particulars of disused source/NG

	S. No.	Make, Model	Gauge S. No	Source Activity with date	Procurement/import Authorisation no with date				
(iv)	(iv) In case of disused sources, whether the institute has plan of action for disposal/decommissioning the same ? Yes \Box No \Box NA \Box								
(v)	Wł	nether permission	n taken for dispo	sal/decommissioning	g? Yes \Box No \Box NA \Box				
Sou	irce Sto	rage:							
(i)	Wł sou	nether safe and se arces not in use/d	ecured source sto isused source ?	orage facility availab	le for Yes □ No □				
(ii)	Wł	nether the wall th	ickness/shieldin	g for storage room is	s adequate ? Yes \Box No \Box				
(iii)	Wł	nether physical se	ecurity measures	provided for facility	$Y ? Yes \square No \square$				
Rae	diation 1	Protection Surv	eillance around	IRGD/NG Installa	tion:				
(i)	Wł	nether periodic ra	diation protection	on survey performed	?				
(ii)	Wł	nether survey rec	ords maintained	?	Yes 🗆 No 🗆				
(iii)	Wł	Whether periodic surveillance report satisfactory ?Yes \Box No \Box							
(iv)	Wł wit	nether radiation 1 hin the prescribe	evels around IR d limit ?	GD/NG installations	is Yes □ No □				
	Par	ticulars of protection	ction survey						

S.	Make,	Source &	Location	Height of	Radiation level from external surface				
No.	Model & S. No.	Activity with date	of gauges	Installation	At 5 cm	100 cm	Other specify	Accessible location, y distance	
(v)	(v) Whether installation location is safe and secured ? Yes \Box No \Box								
(vi)	(vi) Whether any protective cover/cage is provided around Yes \Box No \Box NA installation?						es 🗆 No 🗆 NA 🗆		
	Comme	ents:							

9. Practice Specific Requirements

7.3

8.

(i)	Fencing/barrier need to be provided around source housing:	Yes \Box No \Box NA \Box
(ii)	Radiation warning board in English, Hindi and regional language displayed at the fencing/at the access point to the source housing.	Yes 🗆 No 🗆
(iii)	Radiation warning symbol pasted/painted/engraved on the source housing:	Yes 🗆 No 🗆

	(iv) Source 'ON' and 'OFF' position clearly marked on the source housing:				l No□
	(v)	Insulation/asbestos lining to be provided on the source housing to protect it from fire.	Yes 🗆	No 🗆	NA \Box
	(vi)	Additional shielding of lead/steel is required to be provided on the source housing.	Yes 🗆	No 🗆	NA 🗆
		If yes, the approximate thickness of lead/steel is	m		
	(vii)	Source detector alignment needs to be rectified.	Yes 🗆	No 🗆	$NA \square$
	(viii)	Defective source housing to be replaced by new one.	Yes 🗆	No 🗆	$NA \square$
	(ix)	Display of proper safety procedures such as, source switched 'OFF' repair/maintenance work in the immediate vicinity of the installatio	during n.	Yes 🗆	No 🗆
	(x)	Emergency procedures with contact details displayed nearing IRGD/NG device and source storage room:		Yes 🗆	No 🗆
	Γ	Comments:	7		
10.	Unus	ual Occurrences/Accidents	_		
	(a)	Any unusual occurrence /accident encountered after the last RI ?	Yes 🗆	No 🗆	NA 🗆
		If yes, then details			
	(b)	AERB was informed about the incident /accident		Yes 🗆	No \square
	(c)	Actions taken to prevent recurrence		Yes 🗆	No \Box
11.	Avail	ability of Documents/Records			
	(i)	Updated inventory of IRGDs/NG :		Yes 🗆	No \Box
	(ii)	Copies of AERB consents/approvals:		Yes 🗆	No 🗆
	(iii)	Periodic radiation protection survey:		Yes 🗆	No \square
	(iv)	Servicing/maintenance records:		Yes 🗆	No \square
	(v)	Leak test/swipe test results of source capsule, if any:		Yes 🗆	No 🗆
	(vi)	Logbook on operation of IRGDs/NG with up-to-date records		Yes 🗆	No 🗆
	(vii)	Logbook for movement of portable gauges		Yes 🗆	No 🗆
	(viii)	Emergency response plan and preparedness for IRGD/NG:		Yes 🗆	No \square
12.	Any o	other Observations:			

(Attach extra sheet, if required)

Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed the above observations.

(Signature of Coordinator of the Institution)	(Signature of the Licensee/Head of the Institution)
Name:	Name:
Designation:	Designation:

ANNEXURE-25

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF WELL LOGGING FACILITIY

Date of inspection: Type of inspection: Routine Special Surprise

1.1 Details of the Radiation Facility (RF):

1.1.1 Institution number:

Name and address of the RF: Telephone No. (O): Fax No.

1.1.2 Name and address of logging site handling Radiation Sources:

1.2 Type of the Facility:

Govt./Semi-Govt./Autonomous/Private/Joint venture/Others

1.3 Employer:

	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.4	Licen	see:		
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.5	Head	of the Plant/Depa	rtment	
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.6	RSO:			
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)

1.7	Inspection Coordinator from Institution: (a) Name:							
	(b)	Designa Telepho Mobile E-mail	ttion: ne No. No.	(0):	(R)			
2.	Com	pliance of	recomm	endation based	l on Last Inspection			
	(i)	Date of	last insp	ection, if any:				
	(ii)	Whethe	r all the	recommendatio	ns are already complied ?		Yes 🗆	No 🗆
	(iii)	Particul	ars of pe	ending recomme	endation:			
3.	On-S	ite Verifica	ation of	Consents/App	rovals issued:			
	(i)	Whethe is obtain	r Authoi ned ?	risation for operation	ation of well logging source		Yes 🗆	No 🗆
	(ii)	Whethe	r Authoi	risation for well	logging operation is valid ?		Yes 🗆	No 🗆
	(iii)	Whethe	r RSO c	ertificate is vali	d ?		Yes 🗆	No 🗆
	(iv)	Whethe	r license	e is the same as	mentioned in the licence ?		Yes 🗆	No 🗆
		If no, w	hether a	ny amendment o	of licence was sought and obtained	1?	Yes 🗆	No 🗆
4.	Avail	ability of (Operati	ng Personnel :				
	(i)	Whethe Aspects	r person ' availal	trained on 'Rad	liation Safety and Regulatory		Yes 🗆	No 🗆
		Particul	ars of th	e trained person	1			
		S. No.		Name	Training on radiation safety	Year of I	Passing	
	(ii)	No. of p	ersonne	l/users involved	l in handling of radiation sources:			
5.	Perso	onnel Mon	itoring	(Gamma & neu	itron as applicable)			
5.1	Institu	ute personr	nel moni	toring service (I	PMS) number :			
5.2	Numb	per of perso	onnel mo	onitoring device	s (PMD) in the RF:	_		
5.3	State	whether;						
	(a)	PMD is	provide	d to all radiation	n workers ?		Yes 🗆	No 🗆
	(b) PMD is provided to the trainees (if any)? Yes \Box No \Box N					NA 🗆		
	(c)	PMD ar	e being	worn by worker	s appropriately ?		Yes 🗆	No 🗆
	(d)	Proper s	storage of	of PMD is availa	able ?		Yes 🗆	No 🗆
	(e)	Dose re	cords av	ailable?			Yes 🗆	No 🗆
	(f)	Radiation workers have access to their personnel monitoring records ?					Yes 🗆	No 🗆
(g) PMS was suspended any time during last three				uring last three years ?		Yes 🗆	No 🗆	

(h)	Any over-exposure is reported during last three years ?	Yes 🗆 No 🗆
	If yes, whether dose recorded was found to be genuine ?	Yes 🗆 No 🗆
(i)	Adequate measures have been taken to avoid recurrence of over-exposure ?	Yes 🗆 No 🗆
Wheth	Yes 🗆 No 🗆	
If yes,	Yes 🗆 No 🗆	

If yes, whether dose records are maintained

5.4

6.1 Radiation Measurement/Protection level Equipment

Equipment(s)	Adequate No. (Yes/No)	Working (Yes/No)	Calibration valid (Yes/No)
Gamma Radiation Survey Meter (RSM)			
Neutron Radiation Survey Meter (RSM)			
Gamma zone monitor			
Whether above instruments are appropriate for radiation type and energy ?	for Yes / No If no, then details:		

6.2 Provide details of Survey Instruments in case not available in Status Report:

S. No.	Make	Model and S. No.	Range	Working (Yes/No)	Date of recent calibration

7.1 Radiation Sources available

- (i) No. of radioisotope(s)/pulsed neutron generators available:
- (ii) Whether source inventory is as per safety status report ? Yes \Box No \Box

(iii) Inventory of radioactive sources: Satisfactory \Box Not Satisfactory \Box

If No, provide details of source, which are not in the inventory,

S. No.	Type of Source	Make, Model & S. No.	Source & Activity with date	Number of Devices	Present Location of Handling	Present status of source (In use/disused)	Radiation level on external surface of container

7.2 Decommissioning/Disposal:

- (i) Any decommissioning/disposal carried out in past ?: Yes \Box No \Box NA \Box
- (ii) No. of disused sources: —

Particulars of disused source/Pulsed Neutron generators (PNG) to be disposed off:

S. No.	Make, Model S. No.	Source /PNG with S. No	Activity with date	Procurement/import Authorisation no with date

(iii)	In case of disused sources, whether the institute has plan of action for disposal/decommissioning the same ? :	Yes 🗆	No 🗆	NA 🗆
(iv)	Whether permission taken for disposal/decommissioning ?	Yes 🗆	No 🗆	NA \Box
Radiati	on Protection Survey around Source Storage Area:			
(i)	Whether safe and secured source storage facility available ?		Yes 🗆	No 🗆
(ii)	Whether the wall thickness/shielding for storage room is adequate ?:		Yes 🗆	No 🗆
(iii)	Whether periodic radiation protection survey performed ?		Yes 🗆	No 🗆
(iv)	Whether radiation levels around storage room is within the prescribed limit ?		Yes 🗆	No 🗆

Particulars of radiation protection survey:

8.

9.

Location of storage	Distance from nearest occupied position	Radiation level at external surface of wall

(v) Occupancy around source storage room and calibration room:

		Full 🗆	Partial 🗆	Occasio	onal 🗆
(vi)	Whether physical security measures provided for storage facility ?	e		Yes 🗆	No 🗆
Practic	e Specific Requirements				
(i)	Fencing/barrier needs to be provided around source storage area:		Yes 🗆	No 🗆 🛛	NA 🗆
(ii)	Whether radiation warning board in English, Hindi and local language displayed at the entry of source storage room and at fencing of storage room ?			Yes 🗆	No 🗆
(iii)	Controlled areas at field sites have appropriate barriers a warning signs in the local language:	and		Yes 🗆	No 🗆
(iv)	Radiation warning symbol pasted/painted/engraved on containers of radioactive material:			Yes 🗆	No 🗆
(v)	Additional shielding of lead/steel is required to be provided on the transport package:	ded	Yes 🗆	No 🗆 1	NA 🗆
	If yes, the approximate thickness of lead/steel is		cm		

	(vi)	Proper safety procurers are followed during source transfer procedures from container to logging tool and vice-a-veras :	Yes 🗆	No 🗆
	(vii)	Emergency procedures with contact details displayed in source storage room:	Yes 🗆	No 🗆
	(viii)	Source probes were kept stored in vehicle when not in used:	Yes \Box	No 🗆
	(ix)	If yes, the vehicle is parked in a safe/secure area:	Yes 🗆 No 🗆	$NA \square$
10.	Unusu	al Occurrences/Accidents		
	(a)	Any unusual occurrence /accident encountered after the last RI ?	Yes \Box No \Box	$NA \square$
		If yes, then details		
	(b)	AERB was informed about the incident/accident	Yes \Box	No 🗆
	(c)	Actions taken to prevent recurrence		
11.	Availa	bility of Documents/Records		
	(i)	Inventory of radiation sources:	Yes 🗆	No 🗆
	(ii)	Copies of AERB consents/approvals for procurement/import/export	: Yes \square	No 🗆
	(iii)	Periodic radiation protection survey:	Yes \Box	No 🗆
	(iv)	Radiation protection manual:	Yes 🗆	No 🗆
	(v)	Servicing/maintenance records:	Yes 🗆	No 🗆
	(vi)	Leak test/swipe test results of source capsule, if any:	Yes 🗆	No 🗆
	(vii)	Logbook on operation of sources with up-to-date records	Yes 🗆	No 🗆
	(viii)	Logbook for movement of radiation sources:	Yes 🗆	No 🗆
	(ix)	Emergency response plan and preparedness:	Yes 🗆	No 🗆
12.	Any o	ther Observations:		

(Attach extra sheets, if any)

Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed the above observations.

(Signature of Coordinator of the Institution)	(Signature of the Licensee/Head of the Institution)
Name:	Name:
Designation:	Designation:

ANNEXURE-26

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF FACILITIES ENGAGED IN COMMERCIAL PRODUCTION OF DEVICES CONTAINING RADIATION SOURCES

Date of inspection:	
Type of inspection:	
Routine	
Special	
Surprise	

1.1 Details of the Radiation Facility (RF):

1.1.1 Institution number:

Name and address of the RF: Telephone No. (O): Fax No.

1.2 Type of the Facility: Govt./Semi-Govt./Autonomous/Private/Joint venture/Others

1.3 Employer:

	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):		(R)
1.4	Licens (a) (b)	see: Name: Designation: Telephone No. Mobile No. E-mail	(O):		(R)
1.5	RSO: (a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):		(R)
1.6	Inspec (a) (b)	tion coordinator Name: Designation: Telephone No. Mobile No. E-mail	from the Institu (O):	tion :	(R)

2.	Comj	pliance of recommendation based on Last Inspection			
	(a)	Date of last inspection, if any:			
	(b)	Whether all the recommendations are already complied ?		Yes 🗆	No 🗆
	(c)	Particulars of pending recommendation:			
3.	On-S	ite Verification of Consents/Approvals issued:			
	(a)	Layout approval available:		Yes 🗆	No 🗆
	(b)	Whether authorisation for commercial production of radiation devices is valid ?		Yes 🗆	No 🗆
	(c)	Whether type approval is obtained for radiation devices to be manufactured ?		Yes 🗆	No 🗆
	(d)	Whether RSO certificate is valid ?		Yes 🗆	No 🗆
	(e)	Whether licensee is the same as mentioned in the licence ?		Yes 🗆	No 🗆
		If no, whether any amendment of licence was sought and obtained ?		Yes 🗆	No 🗆
4.	Avail	ability of Operating Personnel			
	(i)	Number of qualified and trained persons on radiation safety :	-		
	(ii)	Number of personnel trained on servicing and maintenance :	-		
5.	Perso	onnel Monitoring			
5.1	Institu	ate personnel monitoring service (PMS) number :	-		
5.2	Numb	per of personnel monitoring devices (PMD) in the RF:	-		
5.3	State	whether;			
	(a)	PMD is provided to all radiation workers ?		Yes \square	No 🗆
	(b)	PMD is provided to the trainees (if any)?	Yes 🗆	No 🗆	$NA \square$
	(c)	PMD are being worn by workers appropriately ?		Yes \square	No 🗆
	(d)	Proper storage of PMD is available ?		Yes \square	No 🗆
	(e)	Dose records available ?		Yes 🗆	No 🗆
	(f)	Radiation workers have access to their personnel monitoring records ?		Yes 🗆	No 🗆
	(g)	PMS was suspended any time during last three years ?		Yes 🗆	No 🗆
	(h)	Any over-exposure is reported during last three years ?		Yes 🗆	No 🗆
		If yes, whether dose recorded was found to be genuine ?		Yes 🗆	No 🗆
	(i)	Adequate measures have been taken to avoid recurrence of overexposure ?		Yes 🗆	No 🗆
5.4	Whet	her pocket dosimeters are available ?		Yes 🗆	No 🗆
	If yes	, whether used by radiation workers any time ?		Yes 🗆	No 🗆
	If yes	, whether dose records are maintained ?		Yes 🗆	No 🗆

6.1 Radiation Measurement/Protection Level Equipment

Instruments(s)	Adequate No. (Yes/No)	Working (Yes/No)	Calibration valid (Yes/No)
Radiation Survey Meter (RSM)	Yes/No	Yes/No	Yes/No
Whether above instruments are appropriate for radiation type and energy ?	Yes □ No□ If no, then detai	ls:	

6.2 Provide details of RSM in case not available in Status Report :

Make and Model	S. No.	Range	Functional Status Working/not working	Date of latest calibration

7.1 Sources and Production Facilities:

7.2

(i) Whether inventory of radiation devices is as per safety status report ?

Yes \Box No \Box

If no, provide details:

S. No.	Type of Devices	Make, Model & S. No.	Source & Activity with date	Number of Devices	Status (To be supply/ received for disposal)

(ii)	Whether disused radiation source taken back for disposal ?	Yes 🗆 No 🗆
	If yes, whether inventory in respect of disposal is maintained:	Yes 🗆 No 🗆
(iii)	In case of disused sources, whether the institute has plan of action for disposal/decommissioning the same ?	Yes 🗆 No 🗆 NA 🗆
(iv)	Whether permission taken for disposal/decommissioning?	Yes \Box No \Box NA \Box
Produ	ction Facilities	
(a)	List the various types of radiation devices to be manufactured (Model no.)	
(b)	Radionuclides handled at the facility :	
(c)	Maximum activity of the source(s) being handled :	—— Bq (mCi)
(d)	No. of radiation devices to be manufactured per year :	
(e)	No. of radiation devices/X-ray source manufactured in last year :	
(f)	Whether leak test/swipe test performed to check integrity of sources ?	Yes 🗆 No 🗆

	(g)	Whet natio	ther test facilities available for type approval in accordational/international standards ?	nce with	Yes 🗆	No 🗆
	(h)	Whet	ther accessories/tools for handling radiation sources ava	ilable ?	Yes 🗆	No 🗆
	(i)	Whet	her emergency handling tool available ?		Yes 🗆	No 🗆
	(j)	Spare	e shielding container available:		Yes 🗆	No□
	(k)	Whet	ther auxiliary shielding material available ?		Yes 🗆	No□
	(1)	Avail	ability of following at source handling room:			
		(i)	Area monitor		Yes 🗆	No 🗆
		(ii)	Red warning light		Yes 🗆	No 🗆
		(iii)	Radiation caution symbol		Yes 🗆	No 🗆
		(iv)	Warning placards		Yes 🗆	No 🗆
	(m)	Whet	ther radiation devices calibration facility is available:		Yes 🗆	No 🗆
8.	Radia	tion pr	otection surveillance of source storage/calibration fa	cility:		
	(a)	Whet	ther safe and secured source storage facility available?		Yes 🗆	No 🗆
	(b)	Whet	ther the wall thickness/shielding for storage room is ade	quate ?	Yes 🗆	No 🗆
	(c)	Whet	ther periodic radiation protection survey performed?		Yes 🗆	No 🗆
	(d)	Whet	ther radiation level are within prescribed limit?		Yes □	No 🗆
	(e)	Occu calibi	pancy around source storage room and ration room: Full	\Box Partial \Box (Occasio	onal 🗆
	(f)	Whet	ther physical security measures provided for facility?		Yes 🗆	No 🗆
9.	Pract	ice Spe	cific Requirements			
	(a)	Fenci	ing/barrier needs to be provided around source storage f	facility:	Yes □	No 🗆
	(b)	Radia displa	ation warning board in English, Hindi and regional lang ayed at the fencing/at the access point to the source	uage	Vec 🗆	Na 🗆
	(c)	Radia	ge facinity nousing.	5		
		sourc	e housing:		Yes 🗆	No 🗆
	(d)	Emer	gency procedures with contact details displayed in insti	tution:	Yes 🗆	No 🗆
10.	Unus	ual Occ	urrences/Accidents			
	(a)	Any the la If ye	unusual occurrence /accident encountered after ast RI ? s, then details:	Yes 🗆	No 🗆	NA 🗆
	(b)	AER	B was informed about the incident/accident		Yes 🗆	No 🗆
	(c)	Actic	ons taken to prevent recurrence		Yes 🗆	No 🗆

11. Availability of Documents/Records:

(i)	Inventory of radiation sources:	Yes 🗆 No 🗆
(ii)	Copies of AERB consents/approvals (procurement/supply/ export/disposal):	Yes 🗆 No 🗆
(iii)	Radiation devices manufacturing procedures:	Yes 🗆 No 🗆
(iv)	Leak test/swipe test results of source capsule, if any:	Yes 🗆 No 🗆
(v)	Quality Assurance records:	Yes 🗆 No 🗆
(vi)	Servicing maintenance records:	Yes 🗆 No 🗆
(vii)	Radiation protection survey records	Yes 🗆 No 🗆
(viii)	Radiation protection Manual	Yes 🗆 No 🗆
(ix)	Logbook for radiation devices with up-to-date records:	Yes 🗆 No 🗆
(x)	Emergency response plan and preparedness:	Yes 🗆 No 🗆
(xi)	Inventory of supply of radiation devices to authorized user:	Yes 🗆 No 🗆
Any	other Observations:	

(Attach extra sheets, if required)

Signature of inspector(s) with date)

Name of Inspector(s):

12.

I/we was/were informed the above observations.

(Signature of Co-ordinator of the Institution)	(Signature of the Licensee/Head of the Institution)
Name :	Name:
Designation:	Designation:

ANNEXURE-27

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF SEALED RADIOACTIVE SOURCES IN RESEARCH APPLICATIONS

Date of inspection: Type of inspection: Routine Special Surprise

				Su	rprise
1.1	Details	of the Radiation	Facilities (Rl	F):	
1.1.1	Name a	and address of the	RF:		
	Telepho Fax No	one No.	(0):		
1.1.2	Name &	& Address of the D	epartment Pos	sessing Sources :	
1.2	Type of	f the Facility:	Govt./Semi	-Govt./Autonomou	s/Private/Joint venture/Others
1.3	Employ (a) (b)	yer: Name: Designation: Telephone No. Mobile No. E-mail	(0):		(R)
1.4	License (a) (b)	ee: Name: Designation: Telephone No. Mobile No. E-mail	(0):		(R)
1.5	RSO/I	n-charge for the S	afety & Secu	rity of the Source(s):
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):		(R)
1.6	Inspect	tion Coordinator	from Instituti	on:	
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):		(R)

2.	Com	Compliance of recommendation based on Last Inspection						
	(i)	Date of last inspection, if any:						
	(ii)	Whether all the recommendations are already complied ?	Yes 🗆 No 🗆					
	(iii)	Particulars of pending recommendation, if any:						
3.	On- S	Site Verification of Consents/Approvals issued						
	(i)	Whether Registration for operation obtained ?	Yes 🗆 No 🗆					
	(ii)	Layout and construction approval:	Yes 🗆 No 🗆					
	(iii)	Whether Registration for operation valid ?	Yes 🗆 No 🗆					
	(iv)	Whether RSO certificate is valid ?	Yes 🗆 No 🗆					
	(iv)	Whether NOC/authorisation for procurement of radiation sources is available ?	Yes 🗆 No 🗆					
	(v)	Whether commissioning approval of the lab is available (if applicable) ?	Yes 🗆 No 🗆					
	(vi)	Whether Licensee is the same as mentioned in the licence ?	Yes 🗆 No 🗆					
		If no, whether any amendment of licence was sought and obtained ?	Yes 🗆 No 🗆					
4.	Avail	ability of Operating Personnel:						
	(i)	Whether person trained on "Radiation Safety and Regulatory Aspects" available ?	Yes 🗆 No 🗆					

Particulars of the trained person

S. No.	Name	Training on Radiation Safety	Year of Passing

(ii) No. of personnel/users involved in handling of radiation sources:

Comments:		

5. Personnel Monitoring

5.1	If not	applicable, than go to next item:	
5.2	If app	licable than, provide details below:	
	(a)	Institute personnel monitoring services (PMS) number:	
	(b)	Number of personnel monitoring devices (PMD) in the RF:	
5.3	State v	whether;	
	(a)	PMD is provided to all radiation workers ?	Yes 🗆 No 🗆
	(b)	PMD is provided to the trainees (if any)?	Yes 🗆 No 🗆 NA 🗆
	(c)	PMD are being worn by workers appropriately ?	Yes 🗆 No 🗆
	(d)	Proper storage of PMD is available ?	Yes 🗆 No 🗆
	(e)	Dose records available ?	Yes 🗆 No 🗆

(f)	Radiation workers have access to their personnel monitoring records ?	Yes 🗆 No 🗆
(g)	PMS was suspended any time during last three years ?	Yes \Box No \Box
(i)	Any over-exposure is reported during last three years ?	Yes \square No \square
	If yes, whether dose recorded was found to be genuine ?	Yes 🗆 No 🗆
(j)	Adequate measures have been taken to avoid recurrence of over-exposure ?	Yes 🗆 No 🗆
Whethe	er pocket dosimeters are available ?	Yes \square No \square
If yes,	whether used by radiation workers any time?	Yes 🗆 No 🗆
If yes,	whether dose records are maintained ?	Yes 🗆 No 🗆

6.1 Radiation Measurement/Protection Level Equipment:

Instrument(s)	Available (Yes/No)	Working (Yes/No)	Calibration valid (Yes/No)
Radiation Survey Meter (RSM)			
Gamma zone monitor (if applicable)			
Whether above instruments are appropriate for radiation type and energy ?	Yes \square NoIf no, then deta		

6.2 Particulars of the RSM in case not available in status report:

S. No.	Make	Model and S. No.	Range	Working (Yes / No)	Date of recent calibration

7.1 Sources Available

5.4

- (a) Whether authorizations are available for all the sources ? Yes \Box No \Box
- (b) Whether inventory of radiation devices is as per safety status report ? Yes □ No □

If no, provide details:

S. No.	Radionuclide	Quantity	Activity as on date	S. Nos. (if applicable)	Manufacturer
1					
2					

7.2 Details of Disused Sources:

S. No.	Radionuclide	Quantity	Activity as on date	S. Nos. (if applicable)	Manufacturer
1					
2					
(a)	Any disposal carried out during last year ?	Yes 🗆 No 🗆			
-----	--	------------			
(b)	Whether permission taken for disposal ?	Yes 🗆 No 🗆			
(c)	In case of disused sources, whether the institute has plan of action for disposal/decommissioning the same ?	Yes 🗆 No 🗆			
	Comments:				

Details of Safe Storage & Handling Accessories Available 8.

(a)	Separate room with lock & key is available for storage:	Yes 🗆 No 🗆
(b)	Lead pot for storage is available (if applicable):	Yes 🗆 No 🗆
(c)	Remote handling tongs are available (if applicable) :	Yes 🗆 No 🗆
(d)	Radiation warning symbol is displayed in the storage:	Yes 🗆 No 🗆
(e)	Radiation warning board in English, Hindi and regional language is provided:	Yes 🗆 No 🗆
(f)	Whether periodic radiation protection survey performed (if applicable) ?	Yes 🗆 No 🗆
(g)	Whether physical security measures provided for facility ?	Yes 🗆 No 🗆
	Comments	

9. **Unusual Occurrences/Accidents**

10.

(a)	Any unusual occurrence /accident encountered after the last RI ?	Yes 🗆 No 🗆 NA 🗆
	If yes, then details:	
(b)	AERB was informed about the incident/accident	Yes 🗆 No 🗆
(c)	Actions taken to prevent recurrence	Yes 🗆 No 🗆
Availa	bility of Documents/Records:	
(i)	Updated inventory of radiation sources:	Yes 🗆 No 🗆
(ii)	Copies of AERB consents/approvals (procurement/export/ disposal):	Yes 🗆 No 🗆
(iii)	Leak test/swipe test results of source capsule, if any:	Yes 🗆 No 🗆
(iv)	Radiation protection survey records:	Yes 🗆 No 🗆
(v)	Radiation protection manual:	Yes 🗆 No 🗆
(vi)	Logbook for radiation devices with up-to-date records:	Yes 🗆 No 🗆
(vii)	Emergency response plan and preparedness:	Yes 🗆 No 🗆
Any o	ther Observations:	
(14400)	housing chooses if no quinced)	

11.

(Attach extra sheets, if required)

Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed the above observations.

(Signature of Co-ordinator of the Institution)	(Signature of the Licensee/Head of the Institution)
Name :	Name:
Designation:	Designation:

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF OPEN RADIOACTIVE SOURCES IN RESEARCH APPLICATIONS

Date of inspection: Type of inspection: Routine Special Surprise

1.1 Details of the Radiation Facilities (RF) :

1.1.1 Institution number:

Name and address of the RF: Telephone No. (O): Fax No.

1.1.2 Name and Address of Dept. possession Radiation Sources:

1.2 Type of the Facility: Govt./Semi-Govt./Autonomous/Private/Joint venture/Others

1.3	Emplo	yer:			
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):		(R)
1.4	Licens	ee:			
	(a) (b)	Name: Designation : Telephone No. Mobile No. E-mail	(0):		(R)
1.5	RSO:				
	(a) (b)	Name : Designation : Telephone No. Mobile No. E-mail	(0):		(R)
1.6	Inspec	tion Coordinator	r from Institution	:	
	(a) (b)	Name: Designation : Telephone No. Mobile No. E-mail	(0):		(R)

2. Compliance of recommendation based on Last Inspection

(i)	Date of last inspection, if any:	
(ii)	Whether all the recommendations are already complied ?	Yes \square No \square
(iii)	Particulars of pending recommendation, if any:	
On-Site	e Verification Consents/Approvals issued	
(a)	Whether Registration for operation has obtained ?	Yes \Box No \Box
(b)	Layout approval available:	Yes \Box No \Box
(c)	Whether NOC/authorization for procurement of radiation sources are available ?	Yes 🗆 No 🗆
(d)	Whether RSO certificate is valid ?:	Yes \square No \square
(e)	Whether licensee is the same as mentioned in the licence ?	Yes \Box No \Box
	If no, whether any amendment of licence was sought and obtained ?	Yes \Box No \Box
Availal	oility of Operating Personnel:	
(i)	Whether person trained on 'Radiation Safety and Regulatory	

4.

3.

(1)Regulatory ιy Aspects' available ? Yes \Box No \Box

Particulars of the trained person

S. No. Name		Training on Radiation Safety	Year of Passing

No. of personnel/users involved in handling of Radiation Sources: (ii)

Comments	:
----------	---

5. **Personnel Monitoring**

5.1	If not.	Applicable \Box than go to the next item:	
5.2	If app	licable than \Box provide the details below:	
	(a)	Institute personnel monitoring services (PMS) number:	
	(b)	Number of personnel monitoring devices (PMD) in the RF:	
5.3	State v	whether;	
	(a)	PMD is provided to all radiation workers ?	Yes 🗆 No 🗆
	(b)	PMD is provided to the trainees (if any)?	Yes 🗆 No 🗆 NA 🗆
	(c)	PMD are being worn by workers appropriately ?	Yes 🗆 No 🗆
	(d)	Proper storage of PMD is available ?	Yes 🗆 No 🗆
	(e)	Dose records available ?	Yes 🗆 No 🗆
	(f)	Radiation workers have access to their personnel monitoring records ?	Yes 🗆 No 🗆

(g)	(g) PMS was suspended any time during last three years ?	
(h)	Any over-exposure is reported during last three years ?	Yes \Box No \Box
	If yes, whether dose recorded was found to be genuine ?	Yes \Box No \Box
(i)	Adequate measures have been taken to avoid recurrence of over-exposure ?	Yes □ No□
Whethe	er pocket dosimeters are available ?	Yes \Box No \Box
If yes, v	whether used by radiation workers any time?	Yes \Box No \Box
If yes, whether dose records are maintained ?		Yes 🗆 No 🗆

6.1 Radiation Measurement/Protection Level Equipment:

Equipment	Available (Yes/No)	Working (Yes/No)	Calibration valid (Yes/No)
Radiation Survey Meter (RSM)			
Contamination monitor			
Air/Alarm monitor			
Foot, hand and clothing monitor			
Any other monitoring instrument, (Pl. specify)			
Whether above instruments are appropriate for radiation type and energy ?	Yes \Box No \Box If no, then det	tails:	

comments

5.4

6.2. Particulars of the measuring equipment in case not available in status report:

S. No.	Make	Model and S. No.	Range	Working (Yes/No)	Date of recent calibration

7.1 Details Pertaining to Radioisotopes being handled

Sl. No.	Isotope	Radio-toxicity Group	Max. Activity handled MBq (mCi)	Physical form	Type of operation with this isotope

7.2 Radioactive Waste Disposal :

- (a) Through sink:
- (b) Through pits:

Yes 🗆 No 🗆

Yes \Box No \Box

(c)	Delay tanks:	Yes 🗆 No 🗆
(d)	Any other mode (specify):	Yes 🗆 No 🗆

8. Details of Disused Sealed Sources in the Department

S. No.	Radionuclide	Quantity	Activity as on date	Status (used/disused)		
(a)	(a) Any disposal carried out during last year for sealed sources $?:$ Yes \Box No \Box					
(b)	Whether permission taken for disposal $?:$ Yes \Box No \Box					
(c)	Whether any so	Yes 🗆 No 🗆				
	If yes, method of disposal:					
(d)	In case of disused sources, whether the institute has plan of : Yes \Box No \Box action for disposal/decommissioning the same ?					
Comme	Comments:					

9. Details of Safe Storage & Handling Accessories Available

9.1 Handling :

9.2

9.3

(i)	Remote handling tongs:	Yes 🗆	No 🗆
(ii)	Foot-operated dustbins:	Yes 🗆	No 🗆
(iii)	Pro-pipettes/Remote pipettes:	Yes 🗆	No 🗆
(iv)	Stainless steel sink:	Yes 🗆	No 🗆
(v)	Fume hood:	Yes 🗆	No 🗆
(vi)	Fume hood with filter:	Yes 🗆	No 🗆
(vii)	Glove box:	Yes 🗆	No 🗆
(viii)	Dual type glove box :	Yes 🗆	No 🗆
(ix)	Face mask:	Yes 🗆	No 🗆
(x)	Surgical gloves:	Yes 🗆	No 🗆
Faciliti	es for High Activity handling (wherever applicable):		
(i)	Shoe barrier:	Yes 🗆	No 🗆
(ii)	Shower for decontamination:	Yes 🗆	No 🗆
(iii)	Master slave manipulator:	Yes 🗆	No 🗆
(iv)	Bioassay:	Yes 🗆	No 🗆
(v)	Whole body counting:	Yes 🗆	No 🗆
Type of	f Storage:		
(i)	Steel storage cupboard:	Yes 🗆	No 🗆

	(ii)	Lead storage:	Yes 🗆 No 🗆
	(iii)	Concrete storage:	Yes 🗆 No 🗆
	(iv)	Storage safe:	Yes 🗆 No 🗆
9.4	Sour	ce Storage	
	(i)	Separate room with lock and key is available for storage:	Yes 🗆 No 🗆
	(ii)	Radiation warning symbol is displayed in the storage:	Yes 🗆 No 🗆
	(iii)	Radiation warning board in English, Hindi and regional language is provided:	Yes 🗆 No 🗆
	(iv)	Whether physical security measures provided for storage facility ?	Yes 🗆 No 🗆
		Comments]
10.	Unus	ual Occurrences/Accidents	
	(a)	Any unusual occurrence /accident encountered after the last RI ?	Yes 🗆 No 🗆 NA 🗆
		If "Yes" then details:	
	(b)	AERB was informed about the incident/accident	Yes 🗆 No 🗆
	(c)	Actions taken to prevent recurrence	Yes 🗆 No 🗆
11.	Avail	ability of Documents/Records:	
	(i)	Inventory of radiation sources:	Yes 🗆 No 🗆
	(ii)	Copies of AERB consents/approvals (procurement/export/disposal):	Yes 🗆 No 🗆
	(iii)	Radiation protection survey records:	Yes 🗆 No 🗆
	(iv)	Radiation protection manual:	Yes 🗆 No 🗆
	(v)	Disposal of radioactive waste records:	Yes 🗆 No 🗆

12. Any other Observations:

(vi)

(vii)

(Attach extra sheets, if required)

Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed the above observations.

Logbook for radiation devices with up-to-date records:

Emergency response plan and preparedness:

(Signature of Coordinator of the Institution) (Signature of the Licensee/Head of the Institution)
Name:	Name:
Designation:	Designation:

Yes \Box No \Box

Yes \Box No \Box

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF FACILITIES ENGAGED IN COMMERCIAL PRODUCTION OF RADIATION GENERATING EQUIPMENT (DIAGNOSTIC X-RAY EQUIPMENT)

				Date of inspection:
				Type of inspection:
				Routine
				Special
				Surprise
1.1	Detail	s of the Radiatio	n Facilities (R	F):
1.1.1	Institu	tion Number:		
	Name Teleph Fax Ne	and address of the none No. o.	e RF: (O):	
1.2	Туре о	of the Facility:	Govt./Semi-C	Govt./Autonomous/Private/Joint venture/Others
1.3	Emplo (a) (b)	yer: Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.4	Licens (a) (b)	see : Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.5	RSO: (a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.6	Inspec (a) (b)	ction Coordinato Name: Designation: Telephone No. Mobile No. E-mail	r from Institut (O):	tion: (R)

2. Compliance of recommendation based on Last Inspection

(i)	Date of last inspection, if any:	
(ii)	Whether all the recommendations are already complied ?	Yes 🗆 No 🗆
(iii)	Particulars of pending recommendation:	
On-Site	e Verification of Consents/Approvals issued:	
(a)	Whether licence for operation is obtained ?	Yes 🗆 No 🗆
(b)	Whether licence for operation is valid ?	Yes 🗆 No 🗆
(c)	Layout approval available:	Yes 🗆 No 🗆
(d)	Whether RSO certificate is valid ?	Yes 🗆 No 🗆
(e)	Whether licensee is the same as mentioned in the licence ?	Yes 🗆 No 🗆
	If no, whether any amendment of licence was sought and obtained ?	Yes 🗆 No 🗆
(f)	Whether periodic status report on production/supply of X–ray equipment is submitted to AERB ?	Yes 🗆 No 🗆
Availal	oility of Operating Personnel:	
(i)	Whether person trained on "Radiation Safety and Regulatory	

Particulars of the person trained on

Aspects" available ?

S. No.	Name	Training on Radiation Safety	Year of Passing

Yes \Box No \Box

4.2 Staff Details (Persons involved in handling of X-ray equipment):

Name	Designation	Academic/ Professional Qualification	Experience in the field	Personnel Monitoring (PMS) No.	Full-time/Part-time

(i) Whether the institution personnel are trained on operation, servicing and maintenance of equipment ?
 Yes □ No □

5. Particulars of Production Facilities:

5.1 For Manufacturers:

3.

4.1

S. No.	Type of Equipment	Model Name	AERB Type Approval No.	No. of Production/ Year
1				
2				

5.2 For Suppliers:

S. No.	Type of Equipment	Model Name	AERB NOC/Type Approval No.	No. of units supplied/Year
1				
2				

6. Personnel Monitoring:

6.1	Institu	te personnel monitoring service (PMS) number :	
6.2	Numbe	er of personnel monitoring devices (PMD) in the RF:	
6.3	State w	vhether;	
	(a)	PMD is provided to all radiation workers ?	Yes 🗆 No 🗆
	(b)	PMD is provided to the trainees (if any)?	Yes 🗆 No 🗆 NA 🗆
	(c)	PMD are being worn by workers appropriately ?	Yes 🗆 No 🗆
	(d)	Proper storage of PMD is available ?	Yes 🗆 No 🗆
	(e)	Dose records available ?	Yes 🗆 No 🗆
	(f)	Radiation workers have access to their personnel monitoring records ?	Yes 🗆 No 🗆
	(g)	PMS was suspended any time during last three years ?	Yes 🗆 No 🗆
	(h)	Any over-exposure is reported during last three years ?	Yes 🗆 No 🗆
		If yes, whether dose recorded was found to be genuine ?	Yes 🗆 No 🗆
	(i)	Adequate measures have been taken to avoid recurrence of over-exposure?	Yes 🗆 No 🗆
6.4	Wheth	er pocket dosimeters are available ?	Yes 🗆 No 🗆
	If yes,	whether used by radiation workers any time?	Yes 🗆 No 🗆
	If yes,	whether dose records are maintained ?	Yes 🗆 No 🗆
	[Comments:	

7. Details regarding QA Test tools/ Radiation Dosimeter/Survey Meter:

Make	Model	Type of detector	Month and Year of Procurement	Working (yes/no)	Date of last calibration

8. Operational, Functionality of Testing Facility:

(i)	Whether X-ray room shielding is proper/ as per AERB layout	
	approval ?	$Yes \square No \square$
(ii)	Any modifications done to the existing approved installations:	Yes 🗆 No 🗆

	If yes, whether permission obtained for the same ?	Yes 🗆 No 🗆
(iii)	Availability of mobile protective barriers with lead glass and lead aprons:	Yes 🗆 No 🗆
(iv)	Availability of lead equivalent rubber glove, thyroid shield and gonad shield:	Yes 🗆 No 🗆
(v)	Whether proper storage is available for Lead aprons ?	Yes 🗆 No 🗆
(vi)	Availability of red light, X-ray caution symbol, warning placards:	Yes 🗆 No 🗆
(vii)	Whether periodic radiation safety status report(s) are maintained ?	Yes 🗆 No 🗆
(viii)	Whether equipment inventory is maintained ?	Yes 🗆 No 🗆
(ix)	Whether door(s) are lead lined/ lead equivalent material ?	Yes 🗆 No 🗆
(x)	Whether emergency response plan and preparedness is available ?	Yes 🗆 No 🗆
	Comments:	

Yes \Box No \Box NA \Box

9. Unusual Occurrences/Accidents (a) Any unusual occurrence /accident encountered after the last RI ? If "Yes" then details:

	(b)	AERB was informed about the incident/accident	Yes 🗆 No 🗆
	(c)	Actions taken to prevent recurrence	Yes 🗆 No 🗆
10.	Availa	bility of Documents/Records:	
	(i)	Copies of AERB consents/approvals:	Yes 🗆 No 🗆
	(ii)	Radiation devices manufacturing procedures:	Yes 🗆 No 🗆
	(iii)	Quality Assurance records:	Yes 🗆 No 🗆
	(vi)	Servicing maintenance records:	Yes 🗆 No 🗆
	(v)	Radiation protection survey records	Yes 🗆 No 🗆
	(vi)	Periodic radiation safety status reports:	Yes 🗆 No 🗆
	(vii)	Radiation protection manual:	Yes 🗆 No 🗆
	(viii)	Logbook for radiation devices with up-to-date records:	Yes 🗆 No 🗆
	(ix)	Emergency response plan and preparedness:	Yes 🗆 No 🗆
	(x)	Inventory of supply of radiation equipment to authorized user:	Yes 🗆 No 🗆
11.	Any o	ther Observations:	
	(Attao	h suture also set if us arrived)	

(Attach extra sheet, if required)

Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed the above observations.

(Signature of Co-ordinator of the Institution)	(Signature of the Licensee/Head of the Institution)
Name :	Name:
Designation:	Designation:

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF FACILITIES ENGAGED IN COMMERCIAL PRODUCTION OF RADIOACTIVE MATERIAL (SEALED RADIOACTIVE SOURCES)

				Date of inspection:
				Type of inspection:
				Routine
				Special
				Surprise
1.1	Deta	ils of the Radiatio	n Facility (RF)	:
1.1.1	Instit	tution number:		
	Nam Telej Fax l	e and address of the phone No. No.	e RF: (O):	
1.2	Туре	e of the Facility:	Govt./Sem	i-Govt./Autonomous/Private/Joint venture/Others
1.3	Emp (a) (b)	loyer : Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.4	Lice (a) (b)	nsee : Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.5	RSO):		
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.6	Insp	ection Coordinato	r from Institut	ion:
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)

2.	Comp	pliance of recommendation based on Last Inspection				
	(a)	Date of	last inspection, if any	7:		
	(b)	Whether	r all the recommenda	tions are already complied ?	Yes 🗆 No 🗆	
	(c)	Particula	ars of pending recom	mendation:		
3.	On-Si	te Verifica	ation of Consents/Aj	pprovals issued:		
	(a)	Whether sources	r licence for commerce is valid ?	cial production of sealed	Yes 🗆 No 🗆	
	(b)	Layout	approval available :		Yes 🗆 No 🗆	
	(c)	Whether are avai	r type approvals for s lable ?	ealed sources to be manufactured	Yes 🗆 No 🗆	
	(d)	Whethe	r RSO approval is val	lid ?	Yes 🗆 No 🗆	
	(e)	Whether	r licensee is the same	as mentioned in the licence ?	Yes 🗆 No 🗆	
		If no, w	hether any amendmen	nt of licence was sought and obtained	ed? Yes \Box No \Box	
4.	Availa	ability of (Operating Personnel	l:		
	(i)	Whether Aspects	r person trained on "F " available ?	Radiation Safety and Regulatory	Yes 🗆 No 🗆	
		Particul	ars of the trained pers	son		
		S. No.	Name	Training on Radiation Safety	Year of Passing	

	(ii)	No. of p	personnel/users involv	ved in handling of Radiation sources	:		
	(iii)	Number	r of personnel trained	on emergency handling are available	: .		
5.	Person	nnel Mon	itoring				
5.1	Institu	te personi	nel monitoring service	e (PMS) number :			
5.2	Numbe	er of perso	onnel monitoring dev	ices (PMD) in the RF:			
5.3	State w	whether;					
	(a)	PMD is	provided to all radia	tion workers ?		Yes 🗆	No 🗆
	(b)	PMD is	provided to the train	ees (if any)?	Yes 🗆	No 🗆	$NA \square$
	(c)	PMD at	re being worn by wor	kers appropriately ?		Yes 🗆	No 🗆
	(d)	Proper	storage of PMD is av	ailable ?		Yes 🗆	No 🗆
	(e)	Dose re	cords available?			Yes 🗆	No 🗆
	(f)	Radiation monitor	on workers have acce ring records ?	ss to their personnel		Yes 🗆	No 🗆
	(g)	PMS w	as suspended any tim	e during last three years ?		Yes 🗆	No 🗆
	(h)	Any ov	er-exposure is reporte	ed during last three years ?		Yes 🗆	No 🗆
		If yes, v	whether dose recorded	d was found to be genuine ?		Yes 🗆	No 🗆

	(i)	Adequate measures have been taken to avoid recurrence of over-exposure ?	Yes 🗆	No 🗆
5.4	Whethe	er pocket dosimeters are available ?	Yes 🗆	No 🗆
	If yes,	whether used by radiation workers any time?	Yes 🗆	No 🗆
	If yes,	whether dose records are maintained ?	Yes \square	No 🗆

6.1 Radiation Measurement/Protection Level Equipment

Equipment	Available (Yes/No)	Working (Yes/No)	Calibration valid (Yes/No)
Radiation Survey Meter (RSM)			
Contamination monitor (s)			
Gamma zone monitor (s)			
Direct reading dosimeteters			
Calibrated instruments for activity measurement			
Whether above instruments are appropriate for radiation type and energy ?	Yes □ No□ If no, then details:		

6.2. Provide details of measuring equipment if not available in status report:

S. No.	Make	Model and S. No.	Range	Working (Yes/No)	Date of recent calibration

7. Particulars of Production Facilities:

7.1 Type of sealed source encapsulations to be manufactured:

S. No.	Manufacturers identification	Radioisotope & Max Activity GBq (Ci)	Sealed source Classification	Intended Use	No. of source production/year

7.2 Availability of adequate Source handling Facilities

Type of Facility	Availability (Yes/No)	Working (Yes/No/NA)
Hot cell with separate exhaust system		
Master slave manipulator		
Viewing window with adequate shielding		
Remote handling tongs with detachable head		
Fume hood		

	Glove	e box	
	Face	mask	
	Surgi	cal gloves	
	Anyo	other, pl. specify	
7.3	Wheth	her the decontamination facility as identified in emergency nse manual is available ?	Yes 🗆 No 🗆
7.4	Whet	Yes 🗆 No 🗆	
7.5	Whet	her emergency handling tools are available ?	Yes 🗆 No 🗆
7.6	Whet	her adequate waste storage facilities are available ?	Yes 🗆 No 🗆
7.7	Whet sealed	Yes 🗆 No 🗆	
	If yes	, specify	
7.8	Whet	her facilities for leak test of the sealed sources are available ?	Yes 🗆 No 🗆
	If yes	, specify	
7.9	Whet encap	her test facilities are available for type approval of sealed source sulation in accordance with national/international standards?	Yes 🗆 No 🗆
7.10	Sourc	e storage facility	
	(i)	Whether safe and secured source storage facility available ?	Yes 🗆 No 🗆
	(ii)	Whether the wall thickness/shielding for storage room is adequate	? Yes \Box No \Box
	(iii)	Whether physical security measures provided for facility ?	Yes 🗆 No 🗆
	(iv)	Radiation warning boards in English, Hindi and regional language displayed at the fencing/at the access point to the source storage facility.	Yes 🗆 No 🗆
8.	Unus	ual Occurrences/Accidents	
	(a)	Any unusual occurrence/accident encountered after the last RI ?	Yes 🗆 No 🗆 NA 🗆
		If yes, then details:	
	(b)	AERB was informed about the incident/accident	Yes 🗆 No 🗆
	(c)	Actions taken to prevent recurrence	Yes 🗆 No 🗆
9.	Avail	ability of Documents/Records	
	(a)	Inventory of source manufactured:	Yes 🗆 No 🗆
	(b)	Leak test/contamination check results of source capsules manufactured:	Yes 🗆 No 🗆
	(c)	Radiation source manufacturing procedures:	Yes 🗆 No 🗆
	(d)	Ouality Assurance (OA) records:	Yes 🗆 No 🗆

(e)	Procedures to demonstrate that the manufactured sources are				
	identical to the prototype:				
(f)	Isodose distribution chart for single source, where applicable:	Yes \Box No \Box			
(g)	Periodic radiation protection survey records:	Yes 🗆 No 🗆			
(h)	Radiation protection manual:	Yes \Box No \Box			
(i)	Emergency response plan and preparedness:	Yes \Box No \Box			
(j)	Records of sources received for disposal:	Yes \Box No \Box			
(k)	Source supply inventory with source serial nos. to authorised users :	Yes \Box No \Box			
(1)	Documents on security aspects of the facility:	Yes \Box No \Box			
Any other Observations:					

(Attach extra sheets, if required)

Signature of inspector(s) with date)

Name of Inspector(s):

10.

I/we was/were informed the above observations.

(Signature of Co-ordinator of the Institution)	(Signature of the Licensee/Head of the Institution)
Name:	Name:
Designation:	Designation:

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF RECOGNISED LABORATORY FOR CALIBRATION OF RADIATION MONITORING INSTRUMENTS (RMI)

Date of inspection: Type of inspection: Pre-recognition Routine Special Surprise

1.1 Details of the Radiation Facility (RF):

- 1.1.1 Institution number:
- 1.1.2 Name and address of the RF: Telephone No. (O): Fax No.

1.2 Type of the Facility: Govt. /Semi-Govt./Autonomous/Private/Joint venture/Others

1.3 Employer:

	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):		(R)
1.4	Licens	see:			
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):		(R)
1.5	RSO:				
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):		(R)
1.6	Inspec	ction Coordinator	from the Institu	tion:	
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):		(R)

2. Compliance of recommendation based on Last Inspection

3.

((i)	Date of last inspection, if any:	
((ii)	Whether all the recommendations are already complied ?	Yes 🗆 No 🗆
((iii)	Particulars of pending recommendation, if any:	
	On S	ite Verification of Consents/Approvals issued:	
((i)	Whether the facility has been constructed as per the approved plan?	Yes 🗆 No 🗆
((ii)	Layout approval available:	Yes 🗆 No 🗆
((iii)	Whether certificate of Recognition for operation is valid ?	Yes 🗆 No 🗆
((iv)	Whether RSO certificate is valid ?	Yes 🗆 No 🗆
((v)	Whether licensee is the same as mentioned in the certificate of recognition ?	Yes 🗆 No 🗆
		If no, whether any amendment to certificate of recognition was sought and obtained ?	Yes 🗆 No 🗆
	Γ	Comments:	

4. Calibration Exposure Device(s)/Source(s) available (attach extra sheet, if necessary)

S No.	Make	Model and S.No.	Radionuclide	Activity as on date TBq (Ci)	Whether leakage Radiation level around the device is within permi- permissible limit ?	Remarks, if any
					Yes 🗆 No 🗆	
					Yes 🗆 No 🗆	

5.	Availability of Operating Personnel			
4.5	Participation in quality audit programmes conducted by national laboratory in last two years:		Yes □	No 🗆
4.4	Standard Calibration Practice (SCP) has been established:		Yes 🗆	No 🗆
4.3	Physical security arrangements provided for radiation sources by the institut	te:	Yes 🗆	No 🗆
4.2	Emergency response plan with contact nos. has been conspicuously displayed	ed:	Yes 🗆	No 🗆
4.1	Calibration exposure device is approved by AERB:	Yes 🗆	No 🗆	$NA \square$

5. Availability of Operating Personner

(i) Whether person trained on "Radiation Safety, Regulatory Aspects and calibration of RMIs available ?

Yes \Box No \Box

Particulars of the trained person

S. No.	Name	Training on calibration of RMIs & radiation safety	Year of Passing	

	(ii)	No. of personnel/users involved in calibration of RMIs:	
	(iii)	Whether the institution personnels are trained on operation, servicing and maintenance of calibration exposure device by supplier ?	Yes 🗆 No 🗆
6.	Perso	onnel Monitoring	
6.1	Institu	te personnel monitoring service (PMS) number :	
6.2	Numb	per of personnel monitoring devices (PMD) in the RF:	
6.3	State	whether;	
	(a)	PMD is provided to all radiation workers?	Yes 🗆 No 🗆
	(b)	PMD is provided to the trainees (if any)?	Yes \Box No \Box NA \Box
	(c)	PMD is being worn by workers appropriately ?	Yes 🗆 No 🗆
	(d)	Proper storage of PMD is available ?	Yes 🗆 No 🗆
	(e)	Dose records available ?	Yes 🗆 No 🗆
	(f)	Radiation workers have access to their personnel monitoring records ?	Yes 🗆 No 🗆
	(g)	PMS was suspended any time during last three years ?	Yes 🗆 No 🗆
	(h)	Any over-exposure is reported during last three years ?	Yes 🗆 No 🗆
		If yes, whether dose recorded was found to be genuine ?	Yes 🗆 No 🗆
	(i)	Adequate measures have been taken to avoid recurrence of overexposure ?	Yes 🗆 No 🗆
6.4	Whet	her pocket dosimeters are available ?	Yes 🗆 No 🗆
	If yes	, whether used by radiation workers any time ?	Yes 🗆 No 🗆
	If yes	, whether dose records are maintained ?	Yes 🗆 No 🗆
		Comments:	

7. Radiation Measuring/Protection Level Equipment

Equipment	Available Yes □ No □	Working Yes □ No □	Calibration valid Yes □ No □
Ion Chamber			
Radiation Survey Meter (working standard):			
Radiation Survey Meter (work place monitoring)			
Gamma Zone monitor(s) (calibration enclosure)			
Adequate no. of direct reading dosimeters			
Whether above Instruments are appropriate for radiation type and energy ?	Yes \Box No \Box If no, then detain	ils:	

Comments:

8. Associated Equipment

Equipment	Working Yes □ No □	Calibration valid Yes □ No □ NA □
Electometer		
Appropriate device for distance measurement		
Appropriate alignment device		
Appropriate phantom for calibration of pocket dosimeters		
Appropriate thermometer		
Appropriate barometer		

Comments :

9. Details of Disused Sources:

(i)	Any decommissioning/disposal carried out during last three year ?	Yes 🗆 No 🗆 NA 🗆
(ii)	Whether permission taken for disposal/decommissioning?	Yes \Box No \Box NA \Box
(iii)	Any disused source available for disposal:	Yes 🗆 No 🗆
	If yes, Source: —— Activity: —— MBq (—— mCi)	
(iv)	In case of disused sources, whether the institute has plan of action for disposal/decommissioning of the same ?	Yes 🗆 No 🗆 NA 🗆
	Comments :	

10. Details of Emergency handling accessories available at site:

(i)	Lead pot :	Yes 🗆 No 🗆
(ii)	Remote handling tongs :	Yes 🗆 No 🗆
(iii)	Adequate temporary shielding available : (lead sheets/concrete blocks/sand bags etc.)	Yes 🗆 No 🗆
(iv)	Radiation warning placards:	Yes 🗆 No 🗆
(v)	Red warning lamps:	Yes 🗆 No 🗆
	Comments:]

11. Unusual Occurrences/Accidents

(a)	Any unusual occurrence/accident encountered after the last RI ?	Yes 🗆 No 🗆 NA 🗆
	If yes, then details	
(b)	AERB was informed about the incident/accident	Yes 🗆 No 🗆

	(c)	Actions taken to prevent recurrence	Yes 🗆 No 🗆
		Comments:	
12.	Detai	ls Enforcement Actions Taken:	
	(i)	Any enforcement actions taken against the institution during last three years ?	Yes 🗆 No 🗆
	(ii)	Reasons for enforcement actions :	
	(iii)	Corrective measures initiated after enforcement actions:	Yes 🗆 No 🗆
13.	Avail	ability of Documents/Records	
	(i)	Copies of AERB consents/approvals:	Yes 🗆 No 🗆
	(ii)	Periodic radiation protection survey:	Yes 🗆 No 🗆
	(iii)	Servicing/ maintenance records:	Yes 🗆 No 🗆
	(iv)	Logbook on calibration of RMIs:	Yes 🗆 No 🗆
	(v)	On site source standardization report:	Yes 🗆 No 🗆
	(vi)	Report on quality audit conducted by National laboratory (RP&AD, BARC):	Yes 🗆 No 🗆
14.	Any o	other Observations:	

(Attach extra sheet, if required)

Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed the above observations.

(Signature of Coordinator of the Institution) (Signature of the Licensee/Head of the Institution)

Name:	Name:
Designation:	Designation:

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF FACILITIES ENGAGED IN COMMERCIAL PRODUCTION OF CONSUMER PRODUCTS CONTAINING RADIOACTIVE MATERIAL (THORIUM NITRATE BASED GAS MANTLES MANUFACTURING)

Date of inspection:

Type of inspection:

Routine	
Special	
Surprise	

				Routine
				Special
				Surprise
1.1	Detail	s of the Radiation	n Facility (RF):	
1.1.1	Institu	tion number:		
	Name Teleph Fax Ne	and address of the tone No. o.	RF: (O):	
1.2	Туре о	of the Facility:	Govt./Semi-Govt./	/Autonomous/Private/Joint venture/Others
1.3	Emplo (a) (b)	Oyer: Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.4	Licens (a) (b)	see: Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)
1.5	RSO: (a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)
1.6	Inspec (a) (b)	ction Coordinator Name: Designation: Telephone No. Mobile No. E-mail	r from Institution: (O):	(R)

2.	Comj	Compliance of recommendation based on Last Inspection			
	(i)	Date of last inspection, if any:			
	(ii)	Whether all the recommendations are already complied ?	Yes 🗆 No 🗆		
	(iii)	Particulars of pending recommendation, if any:			
3.	On-S	ite Verification of Consents/Approvals issued:			
	(i)	Whether licence for handling of radioactive material has been obtained ?	Yes 🗆 No 🗆		
	(ii)	Whether licence for handling is valid ?	Yes 🗆 No 🗆		
	(iii)	Layout approval available:	Yes 🗆 No 🗆		
	(iv)	Whether RSO certificate is valid ?	Yes 🗆 No 🗆 NA 🗆		
	(v)	Whether licensee is the same as mentioned in the licence ?	Yes 🗆 No 🗆		
		If no, whether any amendment of licence was sought and obtained ?	Yes 🗆 No 🗆		
4.1	Avail	Availability of Operating Personnel:			
	(i)	Whether person trained on 'Radiation Safety and Regulatory Aspects' available ?	Yes 🗆 No 🗆 NA 🗆		

Particulars of the trained persons

S. No.	Name	Training on Radiation Safety	Year of Passing

(ii) No. of personnel/users involved in handling of radiation sources:

Particulars of the personnel:

S. No.	Particulars of the workers	Range of Age
1	Male	
2	Female	

(iii) Whether the personnel are aware about the safe handling of radiation sources ? Yes □ No □
 (iv) Whether procedures for safe handling of radioactive material

Yes 🗆 No 🗆

5.1 Radiation Measurement/Protection Level Equipment:

in local language displayed in working area ?

Equipment	Available (Yes/No/NA)	Working (Yes/No)	Calibration valid (Yes/No)
Radiation survey meter (RSM)			
Area monitor			
Contamination monitor			
Whether above instruments are appropriate for radiation type and energy ?	Yes/No If 'No' then de	tails:	

5.2 Provide details of measuring equipment if not available in Status Report:

Make and Model	S. No.	Range	Functional Status Working/not working	Date of last calibration

6. Observations at Storage Room

7.

8.

9.

10.

11.

(i)	Thorium nitrate is stored in an exclusive room:	Yes 🗆 No 🗆
	If yes; exclusive room is made of:	Concrete/Brick/Steel/Wooden partition
(ii)	Radiation level on the door/walls of the storage	room(µsv):
(iii)	No. of Thorium Nitrate drums available:	
Obsei	rvations at Thorium Nitrate Solution Making A	rea
(i)	Type and Condition of the floor:	
(ii)	Method of solution making:	Manual/Motorized
(iii)	Availability of PPE:	gas mask/cloth/gloves/gum boots
(iv)	Radiation level on the drum:	
(v)	PPE that are used during inspection:	
Obsei	rvations at Squeezing Area.	
(i)	Type and condition of the floor:	
(ii)	Squeezing of the hose after soaking in Thorium	Nitrate Solution/Ammonia:
		Manual \Box / Mechanical \Box
(iii)	Radiation level on the squeezer:	
(iv)	PPE that are used during inspection:	
Obsei	rvations at Ammonia Treatment and Washing A	rea
(i)	Type and condition of the floor:	
(ii)	Method of washing the hoses:	Manual \Box / Motorized \Box
(iii)	Radiation level in the area:	
(iv)	PPE used during inspection:	
Obsei	rvations at Drying Area:	
(i)	No of exhaust fans installed:	
(ii)	No of exhaust fans in working condition:	
(iii)	Radiation level in the area:	
Obsei	rvations at Cutting Area:	
(i)	Cutting operations are carried out in the premise	es of the plant: Yes \Box No \Box
(ii)	Whether masks are used while cutting:	Yes 🗆 No 🗆

- (iii) Radiation level in the area:
- (iv) PPE used during inspection

12. Observations at Coloring/Stamping

- (i) Coloring operations are carried out in the premises of the plant: Yes \Box No \Box
- (ii) Radiation level in the area:
- (iii) PPE used during inspection

13. Observations at Stitching

- (i) Stitching operations are carried out in the premises of the plant: Yes \Box No \Box
- (ii) Radiation level in the area:
- (iii) PPE used during inspection

14. Observations at Ironing Area

- (i) Ironing operations are carried out in the premise: Yes \Box No \Box
- (ii) Radiation level in the area:

15. Observations at Packing Area

- (i) Packing operations are carried out in the premises of the plant: Yes \Box No \Box
- (ii) Radiation level in the area:
- (iii) PPE used during inspection:

16. Observations at Office Area

- (i) Radiation level in the area:
- (ii) Background level in other area:

17. Thorium Accounting

- (i) Authorized quantity of Thorium Nitrate per month:
- (ii) Procurement per month:
- **18.** Lay-Out Plan of the Production Unit/ Factory: (*Attached Sketch*)

19. Availability of Documents/Records

(i)	Inventory of radioactive material:	Yes \Box No \Box
(ii)	Radiation device manufacturing procedures:	Yes 🗆 No 🗆
(iii)	Radioactive material, safe handling procedures:	Yes 🗆 No 🗆
(iv)	Periodic radiation protection survey records, as applicable:	Yes 🗆 No 🗆
(v)	Emergency response plan and preparedness:	Yes 🗆 No 🗆
(vi)	Records of disposal of radioactive material:	Yes \Box No \Box
(vii)	Radiation device manufacturing and supply inventory:	Yes 🗆 No 🗆
(viii)	Procedures for un-labeling of radioactive material empty container and its disposal:	Yes 🗆 No 🗆

(ix) Document on security aspects for the facility:

20. Any other Observations:

(Attach extra sheets, if required)

Signature of inspector(s) with date)	
Name of Inspector(s):	
I/we was/were informed the above observations	s.
(Signature of Coordinator of the Institution)	(Signature of the Licensee/Head of the Institution)
Name:	Name:
Designation:	Designation:

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF FACILITIES ENGAGED IN COMMERCIAL PRODUCTION OF X-RAY BAGGAGE INSPECTION SYSTEM

Date of inspection:

Type of inspection:				
Routine				
Special				
Surprise				

1.1 Details of the Radiation Facility (RF):

1.1.1 Institution number.	1.1	.1	Institution number:	
---------------------------	-----	----	---------------------	--

Name and address of the RF: Telephone No. (O): Fax No.

1.2	Type of the Facility:	Govt/Semi-Govt/Autonomous/Private/Joint venture/Others

1.3 Employer:

1.4	(b) Licens	Designation: Telephone No. Mobile No. E-mail	(O):	(R)
1.7	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)
1.5	RSO: (a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)
1.6	Inspec (a) (b)	tion Coordinator Name: Designation: Telephone No. Mobile No. E-mail	from Institution: (O):	(R)

2.	Comp	liance of recommendation based on Last Inspection	
	(i)	Date of last inspection, if any:	
	(ii)	Whether all the recommendations are already complied	1?
	(iii)	Particulars of pending recommendation, if any:	
3.	On-Si	te Verification of Consents/Approvals issued:	
	(a)	Whether licence for handling of X-ray devices has been obtained ?	Yes 🗆 No 🗆
	(b)	Whether licence for handling is valid ?	Yes 🗆 No 🗆
	(c)	Layout approval available:	Yes 🗆 No 🗆
	(d)	Whether RSO certificate is valid ?	Yes \Box No \Box NA \Box
	(e)	Whether licensee is the same as mentioned in the license	ce ? Yes \Box No \Box
		If no, whether an amendment of licence was sought and	d obtained ? Yes \Box No \Box
4.	Descri	ption of the Unit:	
	(a)	Model:	
	(b)	Serial No.:	
	(c)	Manufacturer:	
	(d)	Date and Place of manufacture of the device:	
	(e)	Purpose for which it is meant: cargo set	creening/parcel viewing/any other
	(f)	Location of installation:	
	(g)	Cabinet size:	
	(h)	Tunnel size:	
	(i)	Conveyor length:	
	(j)	Conveyor speed:	
	(k)	Resolution:	
5.	Maxin	num Rating of the Unit:	
	(a)	Operating Potential (kV):	
	(b)	Operating Current (mA):	
	(c)	Exposure time (in seconds) per scan:	
6.	No. of	X-ray Tubes:	
7.	Year a	nd Country of Manufacture of X-ray tube(s):	
8.	X-ray	Generator Details:	
	(a)	Operating Anode voltage:	
	(b)	Operating tube current:	

- (c) Beam divergence: ———— degrees
- (d) Beam slit size (width): ——— cm
- (e) Output of the X-ray beam at 1 m (at the maximum operating voltage and operating tube current):
- (f) Dose per scan:
- (g) Direction of X-rays: (i) Facing up (ii) Facing side

9. **Operational Safety:**

- (a) Draw the sketch of the cabinet of the unit showing the details of the shielding and mark the points from (i) to (xii).
- (b) Radiation levels at various locations on the outer surface of the baggage system including the curtains at entrance and exit (to be measured using the test kit that is used for demonstration of test parameters like penetration, resolution, etc):

S. No	Location of Measurement with Distance	Radiation Level µSv/h (mR/h)
1		
2		
3		
4		

10. Radiation Protection Survey:

(a) Particulars of radiation survey meter:

Make and Model	S. No.	Range	Functional Status (Working/not working)	Date of Latest Calibration

- (b) Energy range through which the radiation survey meter is suitable for use:
- (c) Whether the radiation survey meter can be used to measure back ground radiation levels ?
- (d) Whether the radiation survey meter can read radiation levels in steps of, at least, $10nSv/h(1\mu rem/h)$?

11. Practice Specific Information:

- (a) Safe operating guidelines to which the unit conforms to i.e. names of compliance standards to which the unit is designed including the standards pertaining to radiation safety:
- (b) Controls like movement of conveyor belt, emergency stop etc: Yes \Box No \Box
- (c) Shielding adequacy:
 - (i) Lead drapes on both sides of cabinet: present/absent
 - (ii) Lead equivalence of lead drapes: mm of Pb

	(d)	Safety interlocks:	Yes \square No \square
	(e)	Safety lock and key for the power supply:	Yes 🗆 No 🗆
	(f)	X-ray beam 'ON' indicator lights:	Yes 🗆 No 🗆
	(g)	Warning signs:	Yes \square No \square
12.	Estima	te of the Workload:	
	(a)	No. of baggages inspected in a shift:	
	(b)	No. of shifts in a day:	
	(c)	Average time taken to inspect one baggage:	
	(d)	No. of persons involved in handling the unit during a shift:	
13.	Availab	bility of Documents/Records	
	(a)	Radiation device manufacturing procedures:	Yes 🗆 No 🗆
	(b)	Periodic radiation protection survey records, as applicable:	Yes 🗆 No 🗆
	(c)	Emergency response plan and preparedness:	Yes 🗆 No 🗆
	(d)	Radiation device manufacturing and supply inventory:	Yes \square No \square
14.	Any ot	her Observations:	

(Attach extra sheets, if required)

Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed the above observations.

(Signature of Coordinator of the Institution) (Signature of the Licensee/Head of the Institution)

Name:	Name:
Designation:	Designation:

TYPICAL CHECKLIST FOR REGULATORY INSPECTION OF CARGO CONTAINER SCANNERS FACILITY

Date of inspection:

Type of inspection:

Routine	
Special	

Surprise

1.1 Details of the Radiation Facility (RF):

1.1.1 Institution number:

Name and address of the RF: Telephone No. (O): Fax No.

1.2 Type of the Facility: Govt./Semi-Govt./Autonomous/Private/Joint venture/others

1.3 Employer:

	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(0):	(R)
1.4	Licens	see:		
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)
1.5	RSO:			
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)
1.6	Inspec	ction Coordinato	from Institution:	
	(a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)

2. Compliance of recommendation based on Last Inspection

(i)	Date of last inspection, if any:			
(ii)	Whether all the recommendations are already complied ?		Yes 🗆 🛛	No 🗆
(iii)	Particulars of pending recommendation, if any:			
On-Site	Verification of Consents/Approvals issued:			
(a)	Whether licence for handling of radioactive material/X-ray device has been obtained ?		Yes 🗆 🗄	No 🗆
(b)	Whether licence for handling is valid ?		Yes 🗆 🗄	No 🗆
(c)	Layout approval available:		Yes 🗆	No 🗆
(d)	Whether RSO certificate is valid ?	Yes 🗆	No 🗆 1	NA 🗆
(e)	Whether licensee is the same as mentioned in the licence ?		Yes 🗆 🗄	No 🗆
	If no, whether any amendment of licence was sought and obtained ?		Yes 🗆 🗄	No 🗆

4. Details regarding Radiation Dosimeter/Survey Meter Availability:

Make	Model	Type of detector	Month and Year of Procurement	Working (yes/no)	Date of last calibration

5. Description of the Unit:

3.

Type of Unit: Fixed/Mobile/ Portable	Model	Serial No.:	Manufacturer	Date & Place of manufacture of the device	Working (Yes/No)	Location of installation/ operation

6. Radiation Source/Radiation Generating Device:

Туре	Radioisotope (Co-60)	Linac	Betatron	X-ray tube
ActivityMBq (—— mCi) as on date				
EnergyMV				
Max. PotentialkVmA				
Output (exposure rate at 1 m):				
Exposure time(in seconds) per scan:				
Beam divergence: ———— degrees				
Beam slit size (width): ———— cm				
Any other parameter				

- 7. Manufacturer of the Source of Radiation:
- 8. Reference of approval of the source of radiation:
- 9. Safe parameters of the scanner that were verified during inspection and observations:
- **10.** Cordon distance (for mobile/portable):

11. Details of radiation survey meter used:

(i) Particulars of radiation survey meter:

Make and Model	S. No.	Range	Functional Status Working/not working	Date of Latest Calibration

(ii) Energy range through which the radiation survey meter is suitable for use:

(iii)	Whether the radiation survey meter can be used to measure	
	back ground radiation levels?	Yes 🗆 No 🗆

Yes 🗆 No 🗆

(iv) Whether the radiation survey meter can read radiation levels in steps of, at least, 10 nSv/h (1µrem/h)?

12. Radiation Levels at various Locations:

S. No	Location of Measurement with Distance	Radiation Level µSv/h (mR/h)
1		
2		
3		
4		

13. Practice Specific Requirements;

(a)	Safety interlocks:	Yes 🗆 No 🗆
(b)	Safety lock and key for the power supply:	Yes 🗆 No 🗆
(c)	Exposure 'ON' indicator lights:	Yes 🗆 No 🗆
(d)	Warning signs:	Yes 🗆 No 🗆
(e)	Estimate of the workload:	
(f)	Dose for a single scan at the cordon/shielding wall:	
(g)	No. of scans per hour:	
(h)	Total dose in one hour at the cordon/shielding wall:	

14. Availability of Documents/Records

(a)	Copies of AERB consents/approvals regarding the scanner unit:	Yes 🗆 No 🗆		
(b)	Periodic radiation protection survey records :	Yes 🗆 No 🗆		
(c)	Logbook for radiation devices with up-to-date records	Yes 🗆 No 🗆		
(d)	Servicing/maintenance records:	Yes 🗆 No 🗆		
(e)	Radiation protection manual:	Yes 🗆 No 🗆		
(f)	Emergency response plan and preparedness:	Yes 🗆 No 🗆		
Any other Observations:				

(Attach extra sheets, if required)

Signature of inspector(s) with date)

Name of Inspector(s):

15.

I/we was/were informed the above observations.

(Signature of Coordinator of the Institution)	(Signature of the Licensee/Head of the Institution)
Name:	Name:
Designation:	Designation:

TYPICAL CHECKLIST FOR FIRE SAFETY ASPECTS FOR RADIATION FACILITY (DAE)

Date of inspection:

Type of inspection:

Routine	
Special	

				1 <u> </u>		
				Surprise		
1.1	Details of the Radiation Facility (RF):					
1.1.1	Institut	tion number:				
	Name and address of the RF:					
	Teleph	one No.	(O):			
	Fax No).				
1.2	Type o	of the Facility:	Govt./Semi-Govt./Autonomous	/Private/Joint venture/Others		
1.3	Emplo (a) (b)	yer: Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)		
1.4	Licens (a) (b)	eee: Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)		
1.5	RSO: (a) (b)	Name: Designation: Telephone No. Mobile No. E-mail	(O):	(R)		
1.6	Inspec (a) (b)	tion Coordinator Name: Designation: Telephone No. Mobile No. E-mail	from Institution: (O):	(R)		
2. Compliance of recommendation based on Last Inspection

- (i) Date of last inspection, if any:
- (ii) Whether all the recommendations are already complied ?

Yes 🗆 No 🗆

(iii) Particulars of pending recommendation, if any:

3. On-Site Verification of Safety Aspects

- (i) Check that personal access and escape routes are provided for each occupied area.
- (ii) Check that buildings and plants are so laid out and roads, passageways etc. so maintained as to permit unobstructed access for firefighting.
- (iii) Check the suitability and adequacy of fire extinguishers provided.
- (iv) For an irradiator facility, the radiation room shall have smoke and heat detection system with audible alarm.
- (v) Suitable fire detection system should be available in radiation facility.
- (vi) For irradiator facility, the radiation room shall have suitable automatic fire extinguishing system.
- (vii) Check that radiation room is having suitable ventilation system with damper to cut off it from other area.
- (viii) Check that trained persons are available for fire fighting.
- (ix) Check that adequate fire retardant barrier is provided to electric cables in radiation areas penetrating to other areas.
- (x) Standing fire order should be available and suitable fire drills should be conducted at least once in a year.
- (xi) Check that unwanted combustible and flammable material shall not be kept in radiation room.

4. Any other Observations:

(Attach extra sheets, if required)

Signature of inspector(s) with date)

Name of Inspector(s):

I/we was/were informed the above observations.

(Signature of Coordinator of the Institution)	(Signature of the Licensee/Head of the Institution)
Name:	Name:
Designation:	Designation:

ABBREVIATIONS

Atomic Energy Regulatory Board ANSI: American National Standards Institute ATR: Acceptance Test Report BIS: Bureau of India Standards BSS: **Basic Safety Standards** DAE: Department of Atomic Energy DBR: Design Basis Report DRS: Directorate of Radiation Safety EPP: **Emergency Plans and Preparedness** Final Safety Analysis Report FSAR: International Atomic Energy Agency IAEA: ICRP: International Commission on Radiation Protection IEC: International Electro technical Commission Institute of Electrical and Electronics Engineers IEEE: ISO: International Organization for Standardization LSC: Local Safety Committee NOC: No Objection Certificate PMS: Personnel Monitoring Services Preliminary Safety Analysis Report PSAR: QA: Quality Assurance Quality Control QC: RF: **Radiation Facility**

AERB:

RI:	Regulatory	Inspection
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RPM:	Radiation	Protection	Manual
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- RPP: Radiation Protection Programme
- RSM: Radiation Survey Meter
- RSO: Radiological Safety Officer
- SOP: Standard Operating Procedures
- SSC : Structures, System and Components
- TSO: Technical Support Organization

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Dates of meeting:

May 23, 2013 June 6, 12, 19 and 27, 2013 July 3, 19 & 26, 2013 August 2, 2013 April 2, 2014 June 26, 2014 August 13, 2014 November 11, 2014

Chairman and Members of ACCGORN:

Shri S.C. Hiremath (Chairman)	:	HWB (Former)
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Director, OPSD	:	AERB
Director, S&SED	:	AERB
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Shri S.K. Pradhan (Permanent Invitee)	:	AERB

LIST OF CODE, GUIDES AND MANUALS FOR REGULATION OF NUCLEAR AND RADIATION FACILITIES

Safety Series No.	Title
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
AERB/SG/G-4	Regulatory Inspection and Enforcement in Nuclear and Radiation Facilities.
AERB/SG/G-5	Role of AERB with respect to Emergency Response and Preparedness at Nuclear and Radiation Facilities
AERB/SG/G-6 (Rev. 1)	Development of Regulatory Safety Documents 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/SG/G-9	Format and Contents of Safety Analysis Report for Nuclear Power Plants (under development)
AERB/NPP/SG/G-10	Regulatory Review of Leval-I Probabilistic Safety Analysis for Nuclear Power Plants (under development)
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

AERB SAFETY MANUAL NO. AERB/RF/SM/G-3

Published by : Atomic Energy Regulatory Board Niyamak Bhavan, Anushaktinagar Mumbai - 400 094 INDIA.