GUIDE NO. AERB/RF/SG/G-3 (Vol. 1 of 4)

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GOVERNMENT OF INDIA

AERB SAFETY GUIDE

CONSENTING PROCESS FOR RADIATION FACILITIES

(VOLUME - 1)

ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY GUIDE NO. AERB/RF/SG/G-3 (Vol. 1 of 4)

CONSENTING PROCESS FOR RADIATION FACILITIES

(VOLUME - 1)

Atomic Energy Regulatory Board
Mumbai-400 094
India

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FOREWORD

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

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

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

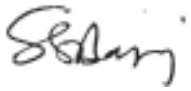
Consistent with the accepted practice, 'shall' and 'should' are used in the guide to distinguish between a firm requirement and a desirable option respectively. Appendices are an integral part of the document, whereas annexures, bibliography and list of participants are included to provide further information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

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

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

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

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



(S. S. Bajaj)
Chairman, AERB

DEFINITIONS

Acceptable Limits

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

Accelerator

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

Activity

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

$$A = dN/dt$$

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

Afterloading Applicator

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

Applicant

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

Approval

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

Atomic Energy Regulatory Board (AERB)

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

Authorisation

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

Becquerel

See 'Activity'

Betatron

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

Commissioning

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

Competent Authority

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

Computed Tomography

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

Consent

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

Consentee

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

Construction

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

Contamination

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

Cyclotron

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

Decommissioning

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

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

Decontamination

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

Disposal

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

Dose

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

Dosimeter

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

Dosimetry

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

Employer

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

Enclosed Installation

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

Ethical Review Committee

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

Fluoroscopy

The technique of imaging by using a fluorescent screen.

Handle

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

Industrial Gamma Radiography Exposure Device (IGRED)

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

Industrial radiography

Non-destructive testing of materials employing ionising radiation.

Ionisation

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

Irradiation

Exposure to ionising radiation.

Irradiators

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

Licence

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

Limit

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

Luminescence

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

Microtron

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

Monitoring

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

Nuclear Medicine

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

Package

The packaging with its radioactive contents as prescribed for transport.

Personnel Monitoring

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

Practice

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

Prescibed Limits

Limits established or accepted by the regulatory body.

Protective Barrier or Shielding (Radiation)

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

Protective Device

Device used for the purpose of radiological protection.

Quality Assurance

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

Radiation

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

Radiation Facility

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

Radioactive Waste

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

Radioactive Waste Management Facility

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

Radioactivity

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

Radiography (Medical)

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

Radiography Source

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

Radiography Technician/Radiography Technologist/Radiographer

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

Radiological Safety Officer (or Radiation Safety Officer)

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

Radiotherapy/Radiation Therapy

Medical treatment by ionising radiation.

Registration

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

Regulatory Body

See ‘Atomic Energy Regulatory Board’

Safety Assessment

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

Safety Site-in-charge

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

Sealed Source

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

Source

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

Source Changer

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

Source Housing

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

(i) define the useful beam; and

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

Synchrotron

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

Teletherapy

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

Tomography

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

Treatment Planning (Radiotherapy)

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

Treatment Simulation

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

Type Approval

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

Type A package

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

Type B(U) package

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

Unusual Occurrence

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

SPECIAL DEFINITIONS
(Specific for the Present Guide)

Consumer Product

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

Field Radiography

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

Person

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

Worker

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

X-ray Equipment

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

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1. INTRODUCTION

1.1 General

The safety code on 'Regulation of Nuclear and Radiation Facilities' AERB/SC/G, specified requirements for issue of consents for radiation facilities from the standpoint of safe operation of such facilities, and protection of the operating personnel, the general public and the environment from radiological and industrial hazards. The code has also outlined the role of atomic energy regulatory board (AERB), as well as the obligations of the Consentee in respect of safety of these facilities. This safety guide on 'Consenting Process for Radiation Facilities' provides explanatory details on information requirements, review and assessment related to consenting process, specified in the safety code.

The regulatory control on radiation sources and practices involving use of radiation for medical, industrial and research purposes is exercised by AERB through a system of consents. The consenting process is applied so as to allow use of sources only in practices, which are justified and for which radiation protection is to be ensured. The applicant is required to demonstrate:

(i) the justification and optimisation requirements have been met adequately, and

(ii) the security of sources shall be ensured at all times.

The consenting process involves several stages beginning with submission of an application by the user. Prescribed documents should accompany the application to demonstrate that safety has been achieved to the extent necessary. The information contained in these submissions will enable assessment of the safety implications of the activity to which the consent relates and evaluation whether the overall risk that would be posed by the activity will be acceptable to AERB. The bases for the review and assessment will be the compliance with the safety objectives and specific requirements as specified in the relevant safety codes and guides, and those stipulated by AERB.

1.2 Objectives

The objective of this Guide is to apprise the applicant on the details of the regulatory requirements in setting up the radiation facility. These include the regulatory consenting process, the relevant stages requiring consent, wherever applicable, documents to be submitted and the nature and extent of review. The guide also gives information on the methods of review and assessment adopted by AERB. It is intended to assist the applicant to be fully prepared for the regulatory scrutiny, and plan requisite actions accordingly in advance.

1.3 Scope

This guide explains in detail the regulatory consenting process at major stages, wherever applicable, in the setting up of a radiation facility. The review aspects for renewal of Consent are also covered in this Guide. Some sources and practices, use of which is exempted from the Consenting process, are indicated in this guide. There are some radiation facilities for which consenting procedures are not spelt out in this document. Such facilities are regulated by AERB on case by case basis. However, the information and requirements detailed in this document, may be found useful for other type of radiation facilities also. Security of sources and radiation facilities are not elaborated in this guide. However, the guidance on the same is given in AERB safety documents viz, 'Security of Radioactive Material during Transport' (AERB/NRF-TS/SG-10) and 'Security of Radioactive Sources in Radiation Facilities' (AERB/RF-RS/SG-1).

This guide deals with practices such as medical, industrial and research applications of radiation and radioisotopes for which the Consent is in the form of a Licence or an Authorisation. Other sources and practices for which Consent is in the form of a Registration/Approval are also covered in view of their widespread use. (e.g. diagnostic X-ray facilities).

2. CLASSIFICATION OF CONSENTS AND CONSENTING PROCESS

2.1 General

AERB grants Consent for handling radiation sources in accordance with the provision of Sections 16 and 17 of the Atomic Energy Act, 1962 and relevant Rules issued thereunder. A wide range of sources and devices requires regulatory review for Consent. The hazard potential in these sources is vastly different and the pre-requisites for Consent therefore widely differ. Accordingly, the consents are graded ranging from a 'Licence' for highest hazard sources to a 'Registration' for lowest hazard sources. These are detailed in the following sections:

2.2 Statutory Provisions for Regulatory Consents

The statutory bases for issuing regulatory Consents for the radiation facilities are the enabling provisions in the Atomic Energy Act, 1962 and the various Rules issued thereunder, which include:

(i) The Atomic Energy (Radiation Protection) Rules 2004, provide for the issuance of a licence, authorisation, registration and consent by the competent authority for handling of radioactive substances.

(ii) The Atomic Energy (Safe Disposal of Radioactive Wastes) Rules 1987, provide for the issuance of an Authorisation by the competent authority for disposal of radioactive waste, or transfer of radioactive waste, to an approved waste management agency.

(iii) The Atomic Energy (Control of Irradiation of Food) Rules, 1996, provide for the issuance of Certificate of Approval by the competent authority for an irradiation facility.

(iv) The Atomic Energy (Factories) Rules 1996, provide for administering the provisions of the Factories Act 1948 in the radiation facilities of Department of Atomic Energy, details of which are given in **Appendix-1**.

2.3 Stages of Consenting Process

The major stages at which Consents are required from AERB for radiation facilities are as follows**:**

(i) Siting

(ii) Layout plan and construction approval

(iii) Commissioning

(iv) Operation

(v) Decommissioning/Disposal

The Consenting process involves a continuous safety review/evaluation of the facility progressing through all the above stages. The inventory of the radioactive materials vary widely in different radiation facilities. Consequently, the potential hazards, in terms of radiation exposures within the facility and environmental effects from releases under normal and accidental conditions, are also vastly different in magnitude. In view of this, the AERB may combine two or more stages of Consent into a single Consent in case of low hazard potential facilities and carry out the safety assessment accordingly.

2.4 Regulatory Consenting Procedures

2.4.1 *General*

A Consent is an official document which:

(i) allows a specified activity or set of activities dealing with siting, construction, commissioning, operation or decommissioning of a radiation facility;

(ii) prescribes requirements and conditions governing the performance of these activities; and

(iii) where appropriate, specifies time limits on the validity of the Consent.

The applicant should submit an application for Consent at each stage in the prescribed format identified in the subsequent pages of the document.

2.4.2 *Consent for Siting*

The Consent at the first major stage, namely siting, involves the review of the safety aspects based on the conceptual design (or actual design, if available) of the facility and the site characteristics that have been considered for the location of the facility at the specified site. The applicant is required to submit to the AERB a site assessment report (SAR) which is applicable for only high hazard potential radiation facilities such as gamma radiation processing facilities, accelerator facilities with beam energy above 10 MeV, medical cyclotron facilities and integrated facilities for radiation technology.

The site assessment report should include:

(i) Salient features of the proposed site

(ii) Site characteristics affecting safety

(iii) Impact of the facility on the environment, if any

The scope and contents of site assessment report for a gamma radiation processing facility, accelerator facility above 10 MeV and integrated facility for radiation technology are indicated in **Appendix 2A**, **Appendix 4A**,

Appendix 6A respectively. Based on the assessment, regulatory Consent for locating the facility on the proposed site is issued.

2.4.3 *Consent for Construction/Layout Plan Approval*

The Consent at the second major stage viz, construction, involves review of the safety aspects as presented in the preliminary safety analysis report (PSAR) for the facility which is applicable to gamma radiation processing facility, accelerator facility above 10 MeV, medical cyclotron facility and integrated facility for radiation technology, that has to be submitted by the applicant. Typical format and contents of preliminary safety analysis report (PSAR) for gamma radiation processing facility, high energy particle accelerators used for research and industrial applications (above 10 MeV), medical cyclotron facility and integrated facility for radiation technology are given in **Appendix 2B**, **Appendix 3B-II** and **Appendix 5B**, **Appendix 6B** respectively. For certain facilities consent for construction may involve only layout plan approval.

2.4.4 *Consent for Commissioning*

The Consent at the third major stage, namely, commissioning of the radiation facility, may be issued in two or more interim stages, particularly for the high potential hazard facilities, as stated earlier. The interim stages of commissioning will vary widely depending on the type of the radiation facility. The applicant should submit to AERB for review the schedule for commissioning, for operation, radiation protection manual, emergency response and preparedness plans, and commissioning test results in the form of acceptance test report (ATR) on trial operation of the entire facility as per design intent. Based on the review of ATR, pre-commissioning inspection is carried out by AERB to verify compliance with ATR. If ATR is satisfactory, authorisation for the first source loading (about 10% of maximum designed strength) is issued in case of gamma radiation processing facility. The format for ATR for a gamma radiation processing facility (GRAPF) is given in **Appendix 2C**.

2.4.5 *Consent for Operation*

The Consent for the fourth major stage is for operation of the facility. The consent may initially be restricted to operation of the facility for a limited period with certain operational constraints, in order to gain operating experience during trial runs. This may also enable the consentee to rectify deficiencies, such as malfunctioning of equipment, radiation leakage and streaming etc. On establishing satisfactory safe trial operation of the entire facility as per design intent, the applicant should submit Commissioning Tests Results and final safety analysis report (FSAR) for the facility. FSAR includes the QA reports.

Applicant submits to AERB an application for obtaining the regulatory consent for routine operation along with final safety analysis report (FSAR) in a standard format given in Appendices which is applicable for facilities such as gamma radiation processing facility, high energy particle accelerators used for research and industrial applications (above 10 MeV), medical cyclotron facility and integrated facility for radiation technology.

Based on the review of an application for obtaining the Regulatory Consent for routine operation along with final safety analysis report (FSAR) in a standard format, the Consent for routine operation is issued specifying a validity period after which it may be renewed on the basis of a regulatory review of the facility for safe performance. The procedure for renewal of Consent for routine operation is given in subsection 2.10.

During regular operation of the facility, safety reviews are carried out by the AERB periodically to ensure that the facility is being operated in accordance with the stipulations made in the Consent and also the procedures outlined in the documents submitted to AERB. In addition the facility is required to submit periodic safety status reports to AERB.

Modification to the plant design and operating procedures, having a bearing on safety and relevant to the Consenting process, requires approval by AERB. Modification may also include augmentation, expansion, life extension, etc. Relevant documents on the modification, together with justification and safety implication, should be submitted to AERB for safety review and assessment.

2.4.6 *Consent for Decommissioning/Disposal*

At the end of the service-life of the radiation facility, it is obligatory on the part of the Licensee to undertake decommissioning and safe disposal of spent/ disused sources. A report on the decommissioning procedures should be submitted to AERB. After review of the safety aspects Consent may be issued for decommissioning of the radiation facility and safe disposal of the radioactive waste generated, if any, with certain stipulations to be fulfilled by the consentee.

2.4.7 *Renewal of Consent for Operation/Type Approval/RSO*

The application for renewal of regulatory Consent for operation of radiation facilities is processed on the basis of the review of the periodic safety status report and report on any unusual occurrence in the facility. Prior to renewal, inspection of the facility is carried out, if necessary based on the review of the safety status reports to ensure that the operation of the facility is in conformity to its intended manner. The application formats for renewal of regulatory Consent for operation of radiation facility or type approval of devices/ equipment or RSO approval are same as the application format used

for obtaining first respective regulatory Consent, as mentioned in section 3. The details about the review and assessment process are given in section 4.

2.4.8 *Review and Assessment Process*

Stagewise Regulatory clearances are issued depending on each successfully completed stage of the radiation facility wherever applicable. The AERB may carry out inspection at certain stages, to verify the information provided in the application. Three-tier, two-tier and one-tier review processes are followed by AERB depending upon the type of facility before licence is granted for radiation facilities.

The assessment process may require furnishing generally the following:

(i) Submission of a detailed safety analysis report covering the design of the source, equipment and facility, layout, wherever applicable

(ii) Proposed quality assurance (QA) programme

(iii) Commissioning/performance tests and results

(iv) Availability of trained and certified manpower such as radiological safety officer (RSO), operators

(v) Availability of personnel monitoring devices

(vi) Availability of radiation monitoring and measuring instruments

(vii) Provisions, including adequate financial arrangement, for safe disposal of spent/disused sources

(viii) Waste disposal measures

(ix) Preparedness of plans for likely radiation emergency.

2.5 Licence

2.5.1 *Consent for Operation*

The Consent for operation on a regular basis is in the form of a Licence for:

(i) land based high intensity gamma radiation processing facility (GRAPF) other than gamma irradiation chambers;

(ii) high energy particle accelerators used for research and industrial processing applications;

(iii) neutron generators;

(iv) facilities engaged in the commercial production of radioactive material or radiation generating equipment;

(v) telegamma and accelerators used in radiotherapy;

(vi) computed tomography (CT) unit

(vii) interventional radiological X-ray unit;

(viii) industrial radiography; and

(ix) such other source or practice as may be notified by the competent authority from time to time.

'Stages of Consenting Process' as defined in subsection 2.3 and 'Regulatory Consenting Procedures' as defined in 2.4, wherever applicable, and explained in section 3, for issuing consent in the form of an Authorisation for radiation facility as defined in subsection 2.5.1(i-viii) are illustrated in Table given in subsection 2.5.2.

2.5.2 *Consents, Review Process and Lead Time at Various Stages*

Consents, review process and lead time required at various stages of consenting process for radiation facilities as defined in subsection 2.5.1(i-viii) are as follows:

Radiation facility as defined in 2.5.1(i-viii)	**Consent for siting (a)**	**Consent for layout pan/ construction approval (b)**	**Consent for commi-ssioning (c)**	**Consent for operation (Licence) (d)**	**Consent for decommi-ssioning/ disposal (e)**	**Review[9] process**	**Lead time[11]**
(i) Land based high intensity gamma radiation processing facility other than gamma irradiation chambers;	Required	Required	---	Combined Consent (c) and (d)	Required	Three tier	90 days
(ii) High energy particle accelerators used for research and industrial processing applications;	Required	Required[1]	Required	Required[2]	Required	Three tier	90 days
(iii) Neutron generators;	Required	Required	Required	Required	Required	Three tier	90 days
(iv) Facilities engaged in the commercial production of radioactive material or ra-diation genera-ting quipment[7];	Required	Required/not required[3]	---	Combined Consent (c) and (d)	Required/ not required[4]	Three/ two tier[5]	90/60[6] days

Radiation facility as defined in 2.5.1(i-viii)	Consent for siting (a)	Consent for Layout pan/ construction approval (b)	Consent for commi-ssioning (c)	Consent for operation (Licence) (d)	Consent for decommi-ssioning/ disposal (e)	Review[9] process	Lead time[11]
(v) Telegamma and accelerators used in radiotherapy;	---	Combined Consent (a) and (b)	---	Combined Consent (c) and (d)	Required	Two tier	60 days
(vi) Computed tomography (CT) unit	---	Combined Consent (a) and (b)	---	Combined Consent (c) and (d)	Not required	One tier[10]	30 days
(vii) Interventional radiological X-ray unit;	---	Combined Consent (a) and (b)	---	Combined Consent (c) and (d)	Not required	One tier[10]	30 days
(viii) Industrial radiography;	---	Combined[8] Consent (a) and (b)	---	Combined Consent (c) and (d)	Required	One tier	30 days

Notes:

1, 2 In case of high energy particle accelerators used for research and industrial processing applications with beam energy ≤ 10 MeV, combined consents for siting and construction is issued. Also combined consent for commissioning and operation is issued.

3 For facilities engaged in the production of radiation generating equipment (Diagnostic X-ray unit) separate consent for construction is not required.

4 Consent for decommissioning is not required for radiation facility engaged in production of radiation generating equipment.

5 The review process followed for facilities engaged in the production of radiation generating equipment is two tier.

6 The lead time for submission for facilities engaged in the production of radiation generating equipment is 60 days.

7 Licence for facilities engaged in commercial production of Radiation Generating Equipment (for radiological safety only) should be obtained

8 In case of Industrial Accelerator facility also, combined consent for siting and construction is issued.

9 The review process may involve up to three tiers. First tier review is carried out by concerned division (RSD/IPSD) of AERB. Second tier review is carried out by relevant safety committee of experts. Third tier review is carried out by the apex committee, SARCAR. Details of review process are given in subsections 4.7 to 4.10

10 For such review of the facility only the type approved equipment/unit should be installed.

11. Lead times given in this document are typical indicative values and may vary depending on quality of submissions and adherance to standard requirements.

2.6 Authorisation

2.6.1 *Authorisation for Operation*

The Consent for operation on a regular basis is in the form of an Authorisation for:

(i) Brachytherapy facilities

(ii) Gamma irradiation chambers

(iii) Nuclear medicine facilities

(iv) Facilities engaged in the commercial production of nucleonic gauges and consumer products containing radioactive material

(v) Radioactive sources in well logging

(vi) Such other source or practice as may be notified by the competent authority from time to time.

'Stages of Consenting Process' as defined in subsection 2.3 and 'Regulatory Consenting Procedures' as defined in 2.4, wherever applicable, and explained in section 3, for issuing consent in the form of an Authorisation for radiation facility as defined in subsection 2.6.1(i-v) are illustrated in Table given in subsection 2.6.2.

2.6.2 *Consents, Review Process and Lead Time at Various Stages*

Consents, review process and lead time required at various stages of consenting process for radiation facilities as defined in subsection 2.6.1(i-v) are as follows:

Radiation facility as defined in 2.6.1(i-v)	**Consent for siting (a)**	**Consent for construction/ layout plan approval (b)**	**Consent for commi-ssioning (c)**	**Consent for operation (Authoris-ation) (d)**	**Consent for decommi-ssioning/ disposal (e)**	**Review process**	**Lead time for submi-ssion**
(i) Brachy-therapy facilities	---	Combined Consent (a) and (b)	---	Combined Consent (c) and (d)	Required	One tier	30 days
(ii) Gamma irradiation chambers;	---	Combined Consent (a) and (b)	---	Combined Consent (c) and (d)	Required	One tier	30 days
(iii) Nuclear medicine facilities;	---	Combined Consent (a) and (b)	---	Combined Consent (c) and (d)	Required	One tier	30 days

Radiation facility as defined in 2.6.1(i-v)	Consent for siting (a)	Consent for construction/ layout plan approval (b)	Consent for commi-ssioning (c)	Consent for operation (Authoris-ation) (d)	Consent for decommi-ssioning/ disposal (e)	Review process	Lead time for submi-ssion
(iv) Facilities engaged in the commercial production of nucleonic gauges and consumer products containing radioactive material	---	---	---	Combined Consent (a), (b), (c) and (d)	Required on case by case basis	One tier	30 days
(v) Radioactive sources in well logging	Not required	---	Not required	Combined Consent (b) and (d)	Required	One tier	30 days

2.6.3 *Authorisation for Waste Dsposal/Decommissioning*

The Consent is in the form of an Authorisation for:

(i) Disposal of radioactive material

(ii) Transfer of decayed/unused radioactive sources to a radioactive waste management facility/supplier

(iii) Decommissioning of a radiation facility.

2.7 Registration

2.7.1 *Registration of Equipment/Laboratories*

The Consent is in the form of registration for use of:

(i) medical diagnostic X-ray equipment including radiotherapy simulator;

(ii) nucleonic gauges

(iii) radio-immuno-assay (RIA) laboratories;

(iv) radioactive sources in tracer studies;

(v) biomedical research using radioactive material; and

(vi) such other source or practice as may be specified by the competent authority from time to time.

'Stages of Consenting Process' as defined in section 2.3 and 'Regulatory Consenting Procedures' as defined in section. 2.4, wherever applicable and

explained in section 3, for issuing Consent in the form of a Registration for radiation facility as defined in subsection 2.7.1(i-v) are illustrated in Table given in subsection 2.7.2.

2.7.2 *Consents, Review Process and Lead Time at Various Stages*

Consents, review process and lead time required at various stages of consenting process for radiation facilities defined in subsection 2.7.1(i-v).

Radiation facility as defined in sec. 2.7.1(i-v)	**Consent for siting/ (a)**	**Consent for construction /layout plan approval (b)**	**Consent for commi-ssioning (c)**	**Consent for operation (registration) (d)**	**Consent for decommi-ssioning/ disposal (e)**	**Review process**	**Lead time for submi-ssion**
(i) Medical diagnostic X-ray equip-ment including therapy simulator;	---	Combined Consent (a) and (b)	---	Combined Consent (c) and (d)	Not required	One tier	30 days
(ii) Nucleonic gauges	Not required	Not required	---	Combined Consent (c) and (d)	Required	One tier	30 days
(iii) Radio-immuno-assay (RIA) laboratories;	---	Required Combined consent (a) and (b)	---	Combined Consent (c) and (d)	Not required	One tier	30 days
(iv) Radio-active sources in tracer studies;	---	Required Combined consent (a) and (b)	---	Combined[1] Consent (c) and (d)	Not required	One tier	30 days
(v) Biomedical research using radioactive material;	---	Required[2] Combined consent (a) and (b)	---	Combined Consent (c) and (d)	Not required	One tier	30 days

Notes

1 For tracers in hydrology studies only consent for operation is required.

2 Biomedical studies are to be carried only in an already approved laboratory for handling open isotopes. As such no separate clearance for siting and layout plan approval is required.

2.8 Consent/Approval

2.8.1 *Type Approval for Source(s), Equipment, Devices and Packages*

A Consent in the form of type approval shall be necessary for:

(i) sealed sources, radiation generating equipment and equipment containing radioactive sources for the purposes of manufacture and supply;

(ii) package design for transport of radioactive material; and

(iii) such other source or practice as may be notified by the competent authority from time to time.

A consent in the form of approval shall be necessary for shipments of radioactive consignment.

'Stages of Consenting Process' as defined in subsection.2.3 and 'Regulatory Consenting Procedures' as defined in subsection 2.4, are not applicable for issuing consent in the form of type approval and shipment approval defined in subsection.2.8.1. However, review of safety in the design of these equipment and packages will be carried out by AERB before issuing type approval. Specified design safety documents should be submitted by the applicant for safety review as explained in section 3.

2.8.2 *Safety Manpower Approval*

The consent is in the form of Approval for qualified and trained radiological safety officer (RSO), designated by all radiation facilities, vide, Atomic Energy (Radiation Protection) Rules, 2004, as explained in section 3.

2.8.3 *Consents/Approval, Review Process and Lead Time*

Consents/Approval, review process and lead time for the design of sources, equipment, devices, packages and for shipments as defined in subsection 2.8.1; and safety manpower as defined in subsection 2.8.2 are illustrated in the Table given below:

Consent / Approval		**Review process**	**Lead time for submission**
Type Approval	Sealed source	Three[1] /two tier	90/60 days
	Equipment[2]	Three tier /Two tier[3]	90/60[4] days
	Devices[5]	Two tier	60 days
	Package[6]	Three tier	90 days
	Shipment	One tier	30 days
Approval	Safety manpower	One tier	30 days

Notes

1 Three tier review process is applicable for the sealed source designed to conform to the requirements proved as special form radioactive material.

2 Equipment includes industrial processing accelerators, medical and research accelerators, CT scans and diagnostic X-rays units including therapy simulator and X-ray baggage inspection systems.

3 Two tier review process applicable for Telegamma therapy units, NDT accelerators, CT scans, diagnostic X-rays units including therapy simulator and X-ray baggage inspection systems.

4 Lead time for submission applicable for Telegamma therapy units, NDT accelerators, CT scans diagnostic X-rays units including therapy simulator and X-ray baggage inspection systems.

5 Devices include telegamma therapy units, gamma irradiation chambers, nucleonic gauge, brachytherapy units and radiography devices

6 Package includes usual transport containers, gamma irradiation chamber designed indigenously.

2.9 Exemption

The use of the following consumer products is exempted from the regulatory control. However, the manufacturing and distribution of the products in bulk require Consent in the form of authorisation from AERB. The consumer products containing radioactivity above the exempt limits have to be assessed for safety and shall be type approved by AERB, as per section 3.

- ionisation chamber smoke detectors (ICSD);
- gaseous tritium luminescence sources (GTLS);
- gaseous tritium luminescence devices (GTLD);
- gas mantles;
- luminescent timepieces and watches;
- fluorescent lamp starters; or
- any other source, or device specified by AERB.

2.10 Renewal of Consent

The application for renewal of regulatory consent for operation of radiation facilities is processed on the basis of the review of the periodic safety status reports and report on any unusual occurrence in the facility. Prior to renewal, inspection of the facility is carried out, if necessary based on the review of the safety status reports, to ensure that the operation of the facility is in conformity to its intended manner. The application formats for renewal of regulatory consent for operation of radiation facility or type approval of devices, equipment etc. are same as the application format used for obtaining first respective regulatory consent, as mentioned in section 3.

3. INFORMATION REQUIREMENTS FOR CONSENTING

3.1 General

Information that is required to be submitted in support of the application for Consent should cover comprehensively all aspects of safety, wherever applicable, in siting, construction/layout plan approval, commissioning and operation of the radiation facility under all conditions, viz., normal operation, anticipated mal-operations and accident conditions. It should also address the security system envisaged in the facility. Additional information in respect of subsequent modifications having a bearing on safety should also be furnished to the AERB. Submission of various documents and the Consenting stage at which they are required for different types of radiation facilities are identified in this section. Guidance on the contents of these documents is also provided.

3.2 Land-Based High Intensity Radiation Processing Facilities (other than Gamma Irradiation Chambers)

3.2.1 *Gamma Radiation Processing Facility (GRAPF)*

3.2.1.1 General

Gamma irradiation facilities are in use for preservation of food products, sterilisation of health care products, polymerisation of wood, vulcanisation of rubber and such purposes for which high intensity irradiation is required. The high intensity gamma radiation processing facility considered here is of land-based stationary installation type. Land-based gamma radiation processing facilities are further categorised on the basis of type of source storage, either dry source storage or wet source storage. Several GBq of radioactive material (^{60}Co or ^{137}Cs) suitably encapsulated in extended source units provide the gamma source for radiation processing of the target material.

3.2.1.2 Site Assessment and Approval

The first stage of Consenting process is assessing the suitability of the site in accordance with the AERB safety standard on 'Land-based Stationary Gamma Irradiators', [AERB/RF-IRRAD/SS-6 (Rev.1), 2007]. For this purpose the applicant has to submit an application along with detailed site characteristics/ assessment report, the format of which is given in **Appendix 2A**. The SAR should include data on (a) seismicity, (b) history of earthquakes in the region, and (c) proximity to a capable fault.

Flooding potential, the ground water level and geo-hydrology are also considered for pool type irradiators. The geological and soil characteristics are important from the point of view of supporting heavy structures. Further,

presence of any ammunition dumps, and storage of inflammable in the vicinity, distance of civil or military runway, if any, are also considered. The applicant should also submit the authenticated documents issued by relevant Government agency showing the status of ownership/lease of the premises. The application format for obtaining consent for site approval is given in **Annexure 1**.

3.2.1.3 Layout and Construction Approval

The design of land-based gamma radiation processing facility should meet the requirements specified by AERB in the safety standard on 'Land-based Stationary Gamma Irradiator', [AERB/RF-IRRAD/SS-6, (Rev-1), 2007]

The general requirements for a GRAPF should cover:

(i) Layout of the facility

(ii) Integral source units (ISU);

(iii) Source-frame and suspension mechanism;

(iv) Source-drive mechanism and wire ropes;

(v) Water-pool and pool lining, permeability and seepage of water, evaporation rate and safe water level, system for purification and demineralisation of water, pH and conductivity control;

(vi) Provision for on-line pool water contamination and pH monitoring;

(vii) Ventilation system;

(viii) Biological shielding;

(ix) Access control;

(x) Safety systems such as personnel access door interlocks and search buttons;

(xi) Emergency systems including trip wire, pressure plate;

(xii) Product-movement system and operating controls; and

(xiii) Material handling facilities.

A preliminary safety analysis report (PSAR), as per **Appendix 2B**, covering the above aspects along with the application for obtaining Consent for construction/layout approval as given in **Annexure-2**, shall be submitted to AERB for review. PSAR should also contain information regarding provisions/commitment of applicant for safe disposal of spent/disused sources.

The PSAR is reviewed bearing in mind (a) 'defence in depth' principle by redundancy, diversity and independence in the design, (b) the fail-safe system in the event of any deviation from normal practice, (c) power failure, (d) access control, and (e) unauthorised entry through product box entry route.

Adequacy of biological shielding of the radiation cell should be reviewed based on acceptable radiation levels at occupied locations. Based on the detailed review of the PSAR submitted by the applicant, the AERB will issue regulatory consent for layout and construction approval, with relevant stipulations involving checkpoints and hold points as well as quality assurance (QA) requirements as mentioned in PSAR.

The facility should maintain and keep available the reports on quality assurance (QA) during construction of the facility. Inspections may be carried out by the AERB prior to installation of the irradiator system, for assessing the integrity and adequacy of biological shielding and verification of conformance with the stipulations. The associated QA guidelines are given in **Appendix-2F**.

3.2.1.4 Commissioning

When all the systems are in place, performance of each system should be verified independently and also in an integrated manner. It is important to check all interlocks, operational controls, and source-drive system prior to loading of the source. Acceptance test reports (ATR) containing the results of the tests and radiation protection manual (RPM) should be prepared and submitted to the AERB. These are to be submitted as per **Appendix 2C** and **Appendix 2E** respectively. When the test results are in compliance with the design intent, regulatory clearance for procurement and loading of the source up to a specified activity (10 % of maximum approved design source strength) will be issued stipulating availability of approved transport containers. The following safety personnel shall be available prior to the initial source loading:

(i) Radiological safety officer (RSO)

(ii) Certified operators, and

(iii) Trained servicing and maintenance personnel.

Monitoring of radiation level and dosimetry of the products to be processed should be carried out at this stage.

No separate consent for commissioning is required, as this is part of combined consent for commissioning and operation.

3.2.1.5 Operation

The applicant should submit the final safety analysis report (FSAR) along with quality assurance manual (QAM) of the design and systems installed in the facility, to the AERB for review. These should be in the formats given in **Appendix 2D** and **Appendix 2F**. Based on the review of information provided in the ATR, FSAR, and obtained from inspections by the AERB, and the trouble free performance of facility and radiation levels and dosimetry results

within the acceptable limits, the regulatory consent in the form of Licence is issued by AERB. The application format for obtaining the Licence for commissioning and operation is given in **Annexure 3**.

At each stage of replenishment/ addition to the source strength of the radiation facility, the Consentee shall submit a safety status report for review and obtain a Consent for resumption of routine operation. The safety status report shall include all safety related information, such as radiation protection survey results, personnel doses received during this operation, product dosimetry results and unusual incidents, if any.

The Consentee is required to submit to the AERB, periodic status reports. Unusual occurrences should be promptly reported within 24 hours and this should be followed by a detailed report within the prescribed period. The Consentee is also required to report on the availability of qualified and trained manpower approved by the AERB, at all times of operation of the facility, malfunctioning of radiation monitoring and measuring devices and malfunctioning of any of the safety systems and emergency systems. Various requirements including QA aspects for GRAPF during operation are spelt out in AERB Safety Code on 'Operation and Maintenance of Land-based Gamma Irradiators', (AERB/SC/IRRAD, 1993) and should be established by the institution. Radiation processing facilities are inspected annually by the AERB and also whenever there is an unusual incident.

If the irradiation facility is used for radiation processing of food products, additional review of dosimetry will be carried out to ensure that the food items receive radiation dose as stipulated in the Atomic Energy (Control of Irradiation of Food) Rules, 1996. The appointment of a quality control officer (QCO) to look after the microbiological quality of food is mandatory. The AERB grants Certificate of Approval in accordance with these Rules. Based on the Certificate of Approval and the application for Licence, the Licence for food irradiation is issued by the Department of Atomic Energy, Government of India. The application format for obtaining the certificate of approval is given in **Annexure 4**.

The Consentee shall arrange to constitute a local safety committee (LSC) with the facility in-charge as Chairman and RSO as member secretary, to periodically review the safety of the radiation facility as stipulated in the safety code on 'Operation and Maintenance of Land-based Gamma Irradiators', (AERB/SC/IRRAD, 1993). The Committee may also include an operator(s), service engineer(s) as members. The minutes of the LSC meetings and action taken reports shall be available for inspection by the AERB.

3.2.1.6 Decommissioning /Disposal

When the radiation processing facility is no longer to be used, the radioactive sources have to be removed into an approved transport container and the radiation processing facility has to be decontaminated if required. If no radioactivity is present in the radiation facility it can be decommissioned which may include dismantling and recycling/reuse of materials. The disused radioactive source(s) and any contaminated material need to be disposed off. For the above, the Consentee should obtain an Authorisation from the AERB for transfer/disposal of radioactive waste to the authorised waste management agency. The application format for obtaining the said Authorisation for safe disposal of radioactive waste is given in **Annexure 50**. The Consentee is required to submit a report to the AERB on completion of decommissioning, safe disposal of sources and personnel doses received during decommissioning operations.

3.2.1.7 Lead Time for Submission/Availability of Documents

The lead-time for submission of documents for any stage of Consenting process is 90 days before the desired date of consent and documents should be complete in all respects for review by the AERB.

3.2.2 *Industrial Accelerator Radiation Processing Facility (IARPF)*

3.2.2.1 General

Photon and electron beam produced from accelerator facility is used for radiation processing of food items, healthcare products and cross-linking of cables. The accelerator facility considered here is of land-based stationary installation type. This guide deals with only land-based installations.

3.2.2.2 Site Assessment and Approval

The first stage of Consenting process is assessing the suitability of the site. The general requirements for siting of the accelerator facility with beam energy not exceeding 10 MeV includes (i) the geological and soil characteristics from the point of view of supporting heavy structures, (ii) since high voltages are involved, the site should be free from flooding and high moisture content in air, (iii) dust load should be negligible to prevent electrical sparking, (iv) ventilation system should be taken care of and (v) availability of uninterrupted power supply for smooth operation of the accelerator. The applicant should also submit the authenticated documents issued by relevant Government agency showing the status of ownership/lease of the premises.

3.2.2.3 Layout and Construction Approval

The approval for layout and construction of IARPF shall meet the requirements specified by the AERB.

The general requirements for accelerator facilities should cover:

(i) layout of the facility;

(ii) seismic analysis of the facility and structure;

(iii) biological shielding including sky shine radiation aspects and radiation protection provisions;

(iv) safety systems such as control console beam ON/OFF indicator, personnel access door interlocks, search buttons etc.;

(v) emergency systems including trip wire, pressure plate, push buttons, audio visible alarms etc.;

(vi) product-movement system;

(vii) radioactive waste disposal, if any;

(viii) accelerator vessel/tank;

(ix) beam port;

(x) gas handling;

(xi) cooling system;

(xii) vacuum system; and

(xiii) ventilation system for noxious gases.

Detailed safety analysis report should be submitted in the form of preliminary safety analysis report (PSAR), the format of which is given in **Appendix 3B-I**. The design is reviewed bearing in mind, (a) the importance of multiplicity of safe shut down systems in the event of any deviation from normal practice, (b) power failure, (c) access control, and (d) unauthorised entry through product box route. The application format for getting combined consent for site, layout and construction of IARPF is given in **Annexure 5**.

The most important aspect is the biological shielding design of accelerator facility. Adequacy of shielding of the enclosures should be verified based on acceptable radiation levels at occupied locations.

Electrical safety, fire and industrial safety aspects should also be included in PSAR. Reference is invited to 'Safety Guidelines on Accelerators' [AERB/SG/IS-5 (2005)] and the requirements specified therein should be complied with in the design of the accelerator facility.

The facility should maintain and keep available the reports on quality assurance (QA) during construction of the facility. Inspections may be carried out by the AERB prior to installation of the accelerator system for assessing the biological shielding adequacy and verification of conformance with the stipulations. The associated QA aspects are given in the format of PSAR. The format for quality assurance manual should be submitted as per **Appendix 3F**.

3.2.2.4 Commissioning

When all the accelerators systems are in place, performance of each system should be verified independently and also in an integrated manner. It is important to check all safety systems/components and interlocks, beam-lines, performance of the accelerator systems and subsystems prior to trial operation of the accelerator facility at full rated capacity. Acceptance test reports (ATR) containing the results of the tests should be prepared and submitted for review as per the format given in **Appendix 3C**. When the test results are in compliance with the design intent, regulatory clearance for commissioning will be issued. The following safety personnel shall be available at the commissioning stage:

(i) RSO

(ii) Certified operators

(iii) Trained servicing and maintenance personnel.

Monitoring of radiation level and dosimetry of irradiation field should be carried out at this stage. No separate consent for commissioning is required, as this is part of combined consent for commissioning and operation.

3.2.2.5 Operation

For obtaining Consent for operation of the accelerator, acceptance test results (ATR) and the final safety analysis report (FSAR) should be submitted for review. The FSAR should incorporate all the recommendations of the review committees, including modifications in the design and safety systems and procedures. The format for FSAR of IARPF is given in **Appendix 3D-I and II**. The Radiation Protection Manual should also be submitted along with FSAR in the format given in **Appendix 3E**. The quality assurance aspects in commissioning and operation should be addressed as per **Appendix 3F**.

When the accelerator performance is trouble free and radiation levels are within the acceptable limits, regulatory clearance for full rated capacity is considered after a review of the performance of the facility as mentioned in subsection 3.2.2.5.

Based on the review of information provided in the FSAR and obtained from inspections by the AERB, the regulatory consent in the form of Licence for commissioning and operation is issued for IARPF. The application format for Licence for commissioning and operation is given in **Annexure 6**.

The Consentee is required to submit to the AERB quarterly, periodic reports on safety status. Unusual occurrences should be promptly reported within 24 hours and this should be followed by a detailed report within the prescribed

period. Qualified and trained manpower approved by the AERB, should be present at the facility at all times of operation of the facility. Malfunctioning of radiation monitoring and measuring devices and malfunctioning of any of the safety systems and emergency systems should be reported periodically to the AERB. Accelerator installations are inspected annually by the AERB and also whenever there is an unusual incident.

If the accelerator facility is used for irradiation of food, additional review of dosimetry should be carried out to ensure that the food items receive radiation dose as stipulated in the Atomic Energy (Control of Irradiation of Food) Rules, 1996. In addition, the appointment of a quality control officer to look after the microbiological quality of food is mandatory. The AERB grants certificate of approval in accordance with the rules. Based on the Certificate of approval and the application for Licence, the Licence is issued by the department of Atomic Energy, Government of India. The application format for getting the Certificate of Approval and License is given in **Annexure 4**.

The Consentee shall arrange to constitute a local safety committee with the facility in-charge as Chairman and RSO as Member Secretary, to periodically review the safety of the accelerator facility. The committee may also include an operator(s) and service engineer as members. The minutes of the meetings and action taken reports shall be available for inspection by the AERB.

3.2.2.6 Decommissioning/Disposal

When the accelerator is no longer to be used, AERB may authorise decommissioning which may include dismantling and recycling/reuse of materials and safe disposal of radioactive waste. The contaminated material, if any, need to be disposed off. For the above, the Consentee should obtain an Authorisation from the AERB for transfer/disposal of radioactive waste to the authorised waste management agency. The application format for obtaining the said Authorisation for safe disposal of radioactive waste is given in **Annexure 50**. The Consentee is required to submit a report to the AERB on completion of decommissioning, safe disposal of sources and personnel doses received during decommissioning operations.

3.2.2.7 Lead Time for Submission/Availability of Documents

The lead-time for submission of documents at any stage of Consenting process is 90 days before the desired date of Consent and the documents should be complete in all respects for review by the AERB.

3.3 Particle Accelerator Research Facilities (PARF)

3.3.1 *General*

Particle accelerators are of electro-static, linear or cyclic types. Cyclic accelerators are generally of radio frequency or microwave type. Further, the

accelerators are either electron accelerators or charged particle accelerators. Van de graff generators are example of electro-static accelerator and linear accelerators and microtrons are examples of electron accelerators. Pelletrons and cyclotrons are examples of particle ion accelerators. Electron accelerators are associated with photon generation either directly or as synchrotron radiation. Therefore shielding should take into consideration the substantial photon generation. Similarly charged particle accelerators are source of neutrons and secondary particles such as mesons and pions for which appropriate shielding is required. High energy particle accelerators may lead to materials and leave residual radioactivity. Although the radioactive species are generally of short half-lives, their accumulated activity should be considered while handling the shielding materials, experimental objects and collimators that are likely to get activated to significant levels. Activation of soil and groundwater should also be considered.

Particle accelerators are used for research in nuclear physics, material science, nuclear chemistry and biology and various other fields. For PARF with beam energy <10MeV, the consenting requirements are similar to IARPF as described in subsection 3.2.2 and all the Appendices / (except PSAR, which is as per **Appendix 3B-II**) applicable for IARPF can be used for PARF (<10MeV). The format for application for consent for siting, layout and construction of particle accelerator research facility (PARF) <10MeV is given in **Annexure 5** and Licence for commissioning and operation is given in **Annexure 6**.

The Consenting requirements of PARF with beam energy >10 MeV are described below:-

3.3.2 *Site Assessment and Approval*

The consent at siting, involves the review of the safety aspects based on the conceptual design (or actual design, if available) of the accelerator facility and the site characteristics that have been considered for the location of the facility at the specified site. The site for locating the PARF has to be chosen carefully to meet all aspects of operational requirements, safety and impact on the environment under the conditions of normal, off-normal and design basis accidents, and situations arising out of natural or man-made hazards.

The applicant is required to submit to the AERB a site evaluation report (SER). The format for SER is given in **Appendix 4A**. The SER, in general, should include salient features of the proposed site, site characteristics affecting safety, impact of the facility on the environment. Applicant is also required to submit map of the site covering region upto 2 km radius. The format for application for siting consent is given in **Annexure 7**.

3.3.3 *Layout and Constration Approval*

The consent for construction involves review of the safety aspects as presented in the preliminary safety analysis report (PSAR) for the facility. PSAR should contain identification of potential safety hazards to equipment and personnel and the manner in which potential hazards and risks will be minimised. Mitigation of hazards can be accomplished through design safety features, safe operating procedure and training and administrative controls. Analysis of design or postulated emergency conditions, including those due to natural or disruptive factors should be provided in the PSAR. PSAR should conclude with justification for adequacy of safety measures. In addition applicant is required to submit civil engineering drawings, shielding design, baseline data on radiological parameters, ventilation system and design features of access control system. The construction schedule and QA manual for design and construction should also be submitted. The format for QA manual should be as per **Appendix 4F**. Job hazard analysis report identifying the hazards and mitigation measures for major jobs having potential for accident should be made available at the facility for various construction activities.

The format for PSAR is given in **Appendix 4B** and **4D**. The format for application for construction consent is given in **Annexure 8**.

After the completion of construction of building structures, the facility should prepare construction completion certificate (CCC) documents covering asbuilt design features along with justification of modifications made from the intended design (if any). This should be available with the facility before start of commissioning.

3.3.4 *Commissioning*

The consent for commissioning may be issued in several interim stages and will vary widely depending on the type of the research facility. The applicant should submit for review, the specifications of all systems, design manual, facility layout with details of site and building features, schedule for commissioning and commissioning procedures (CPs). The acceptance test report (ATR) needs to be submitted as per **Appendix 4C**. Apart from this, emergency preparedness procedures (EPP) and radiation protection manual (RPM), which should be as per AERB radiation protection manual (no separate format is given here) should also be submitted. The applicant is required to submit operator training and authorisation report. Availability of qualified manpower including approved radiological safety officer (RSO) during commissioning should be ensured. The format for application of RSO is given in **Annexure 9**.

The applicant is also required to submit quality assurance manual for commissioning and operation and the format of the same is given in

Appendix 4F. The applicant shall also prepare technical specifications for operations, which should include safety limits, limiting safety system settings, limiting condition for operations, administrative control and surveillance requirement. Technical specifications will ensure that operation of accelerator is within safety envelope as specified in FSAR.

The applicant should arrange to constitute a local safety committee (LSC) with Head of the institution as Chairman and RSO as member secretary to review the safety status of the facility periodically. The minutes of meeting and action taken reports shall be available for inspection by AERB. During commissioning applicant in consultation with RSO should carry out radiological impact analysis to ensure adequacy of protective measures taken. The radiological impact analysis should also include dose to the public due to sky-shine.

The format for application for commissioning Consent is given in **Annexure 10**.

3.3.5 *Operation*

The consent for operation may initially be restricted for operations at limited beam current and energy or for certain accelerating species to gain operating experience.

On establishing satisfactory and safe operation of the entire plant as per design intent, the plant will be issued with consent for regular operation and extraction of beam at rated capacity. For this purpose, the applicant has to submit detailed reports on the commissioning tests and also the final safety analysis report (FSAR) (alternatively known as SAD) reflecting the as-built design, approved by the AERB. The format for the FSAR is given in **Appendix 4B** and **4D**. The detailed commissioning test report should include acceptance test report (ATR) and the format for ATR is given in **Appendix 4C**. The radiation survey report during test run should also be compiled and submitted to AERB.

The format for the application for consent for operation is given in **Annexure 11**. At this stage, the documents submitted during previous consenting stage should be available at the site, incorporating revisions, if any.

The consent for regular operation is issued specifying a validity period after which it may be renewed on the basis of a regulatory review of the plant for safe performance.

During regular operation of the facility, safety reviews are carried out by the AERB periodically, to ensure that the facility is being operated in accordance with the stipulations made in the consent and also the procedures outlined in the documents submitted to the AERB.

In case accelerator beamlines are used by different users, the user safety manual should be available for each beamline. The user manual should contain roles and responsibility of user and facility staff, review of experimental setup by the local safety committee including shielding aspect, controls of beamline equipment and components to users and facility operators, training of users and communication modes.

Modification to the process, plant design and operating procedures, having a bearing on safety and relevant to the consenting process, requires approval by the AERB. Modification may also include augmentation, expansion, life extension, etc. Relevant documents on the modification, together with justification and safety implication, should be submitted to the AERB for safety review and assessment.

3.3.6 *Renewal of Consent for Operation*

The review requirements for renewal will be as per subsection 2.4.7. In addition, documents related to the following aspects are to be submitted for review:

(i) Safety performance of the plant including radiological survey reports

(ii) Significant event reports

(iii) In-service inspections reports as applicable

(iv) Violation of technical specifications

(v) Personnel exposures

(vi) Environmental releases (if applicable)

The review requirements for renewal will be specified by AERB depending on the type of the plant.

3.3.7 *Decommissioning/Disposal*

When the accelerator is to be decommissioned, the licensee should apply for Consent for decommissioning. A detailed report on the decommissioning aspects including procedures, management and transport of radioactive waste and radiation exposure control should be submitted. The presence of radioactivity by activation should be considered either for disposal as waste or reuse after decay. If no radioactivity is present, the accelerator can be decommissioned which may include dismantling and recycling/reuse of materials. If residual activity still exists, then the activated material should be safely disposed off to an authorised waste management facility. The application format for obtaining the Authorisation for safe disposal of radioactive waste is given in **Annexure 50**. The Consentee is required to submit to the AERB on completion of decommissioning, a report on safe disposal of radioactive waste and personnel doses received during decommissioning operations.

3.3.8 *Lead Time for Submission/Availability of Documents*

The lead-time for submission of documents at any stage of Consenting process is 90 days before the desired date of Consent and the documents should be complete in all respects for review by the AERB.

3.4 Facilities Engaged in the Commercial Production of Radioactive Material and Radiation Generating Equipment

3.4.1 *Medical Cyclotron Facility*

3.4.1.1 General

A new era of nuclear medicine diagnosis has started with medical cyclotron technology. Medical cyclotron produces mainly positron emitters, which can be used in molecular imaging of the organs. In medical cyclotron, particles such as protons, deuterons etc. are accelerated and made to bombard with suitable target material to produce radioisotopes, which are positron emitters. The positron emitters are produced by the (p, α), (p, n) or (d, n) reactions. The neutron activation of the surrounding medium draws the major attention in radiation safety. The medical cyclotrons are classified on the basis of particle accelerated, energy and also with respect to shielding. The self-shielded medical cyclotrons are incorporated with heavy shielding around the cyclotron. Additional structural shielding needs to be provided for such installation. Non self-shielded medical cyclotron needs heavy structural shielding to reduce outside radiation levels to safe limits.

A chemical synthesis module is necessary to prepare radiopharmaceutical from the positron emitting radio isotopes produced in medical cyclotron.

The accelerated particles may lead to activation of materials and leave residual radioactivity. Although the radioactive isotopes produced due to neutron activation are generally of short half-lives, their accumulated activity should be considered while handling the shielding materials, experimental objects and collimators that are likely to get activated to significant levels.

3.4.1.2 Site Assessment and Approval

The medical cyclotrons are located either in hospital premises or in industrial area. The first stage of consenting process is assessing the suitability of the site in accordance with the seismic condition, history of earthquakes in the region, proximity to a capable fault, flooding potential, ground water level, geo-hydrology, approach road and on the basis of occupancy. It should be ensured that there are no residential (public) premises within a radius of 30 m from the cyclotron vault and the height of the stack should be atleast 1.5m above the nearest tallest building in the vicinity. The geological and soil characteristics are important from the point of view of induced soil activity

and supporting heavy structures. Further, presence of any ammunition dumps, and storage of inflammable and toxic substances in the vicinity are also considered.

Basement may be an ideal site for location since the earth provides natural and effective shielding. Alternatively, medical cyclotrons may be located ground level as well. The medical cyclotron installations for the purpose of commercial radioisotope production and distribution should be housed in industrial areas. The application format for obtaining regulatory clearance for site approval is given in **Annexure 12**.

3.4.1.3 Layout Plan, Design/Construction Approval

The medical cyclotron shall be housed in a room with adequate shielding. Radiation areas and electrical high voltage areas need adequate isolation and access control. The design should incorporate safe cable routing, segregation of power and signal cables and provision of barriers to prevent fire. Fire-propagating material should not be in the vicinity of electrical joints.

The layout of the medical cyclotron facility shall be approved by AERB. As part of construction/layout plan approval by AERB a preliminary safety analysis report (PSAR) for medical cyclotron facility should be submitted.

The PSAR for medical cyclotron facility should contain the details as per the **Appendix 5B.**

The regulatory clearance for construction is granted after design safety review and layout plan approval and safety analysis of the installation, stipulating the checkpoints, hold points and QA requirements. The AERB may inspect the facility while under construction to verify whether the construction is as per design. The consentee is required to submit periodic reports on quality assurance to AERB. Installation of equipment, and preliminary tests on various systems are to be carried out in a phased manner as per the checkpoints. The application for layout plan and construction approval of medical cyclotron facility is given in **Annexure 13**. The QA manual for construction should be prepared and maintained by the facility and should be as per the format given in **Appendix 5F**.

3.4.1.4 Commissioning and Operation

For granting licence for commissioning, the AERB evaluates the system performance and the shielding adequacy of the installation. Prior to seeking permission, the applicant should have

(i) Qualified and trained manpower-operators, radio pharmacist and RSO Level-III

(ii) Personnel monitoring devices for all radiation workers

(iii) Radiation protection instruments (gamma, neutron, teletector, contamination monitor)

(iv) Radiation zone monitor

(v) Safe handling tools and devices.

Commissioning and trial operations are permitted to evaluate the system performance and radiation level measurements are to be carried out at all occupied locations and the results are to be submitted to the AERB.

The final safety analysis report (FSAR), the format of which is given in **Appendix 5D**, incorporating the results of commissioning, trial operations, and QA reports are prepared by the Consentee and submitted to the AERB. The application for license for commissioning and operation of medical cyclotron facility is given in **Annexure 14**. The QA manual for commissioning and operation should be prepared as per format given in **Appendix 5F**.

Based on a technical review of all safety aspects and inspection by AERB, licence is granted to operate the unit with a validity period.

The Consentee is required to submit periodic reports on safety status. Unusual occurrences, if any, should be promptly reported within 24 hours and this should be followed by a detailed report within the prescribed period. AERB may conduct inspection for the radiation facility as when required from time to time.

The Consentee shall arrange to constitute a local safety committee with the Head of the Institution and the RSO as Members to review the safety status of the facility. This committee may also include service engineer as a member. The minutes of the meetings and action taken reports shall be available for inspection by AERB.

3.4.1.5 Decommissioning

Approval from AERB should be obtained for decommissioning when the medical cyclotron is no longer to be used. The induced radioactivity in the cyclotron components and the structures have to be considered for disposal as a radioactive waste or it may be allowed for decay. If no radioactivity is present in the medical cyclotron components, it can be decommissioned which may include dismantling and recycling/reuse of materials. The Consentee is required to submit to AERB on completion of decommissioning a report on safe disposal of sources and personnel doses received during decommissioning operations.

3.4.1.6 Lead Time for Submission/Availability of Documents

The lead time for submission of documents at any stage of consenting process is 90 days before the desired date of consent and the documents should be complete in all respects for review by AERB.

3.4.2 *Facilities Engaged in the Commercial Production of Radiation Generating Equipment*

3.4.2.1 General

Manufacturing/Assembling of X-ray machines (maximum rating 150 kV, 1200mA) including mobile X-ray unit, ortho-pan-tomography (OPG), dental, C-Arm, mammography, interventional radiology, computed tomography unit and X-ray tubes, involves its testing for quality control measurements. This is an area of potential radiation exposure to the associated personnel.

3.4.2.2 Layout Plan Approval (of Testing Laboratory)

The layout of testing laboratory should be approved by AERB. The testing laboratory should be located at one corner of the facility where there should be access control for the workers not directly involved in the testing of the X-ray machines. Proper cooling arrangements (AC/cooling fan) should be provided for fast cooling of X-ray tubes while testing.

All protective accessories such as mobile protective barriers, lead apron should be available as stipulated by AERB in safety code titled 'Medical Diagnostic X-Ray Equipment and Installations', [AERB/SC/MED-2 (Rev.1), 2001]. These are essentially in the nature of access control and radiation shielding to minimise the radiation exposure to the workers.

Dark room should be available in the near vicinity of X-ray testing room for developing films.

The application format for layout plan approval of testing facility for facilities engaged in commercial production of radiation generating equipment is given in **Annexure 15**.

3.4.2.3 Construction

The construction of the facility can be started after obtaining layout plan approval from AERB and no separate regulatory clearance is required for construction.

However AERB may inspect the facility while under construction to verify whether the construction is in conformity with approved layout plan.

3.4.2.4 Licence for Commercial Production/Manufacturing

Prior to obtaining Licence for commercial production of radiation generating equipment the applicant should have:

(i) Qualified and trained manpower - RSO, service engineers

(ii) Personnel monitoring devices

(iii) QA kit, phantom etc.

(iv) Radiation monitoring instruments

(v) Radiation protection accessories.

AERB may inspect the facility before granting license for commercial production of radiation generating equipment. The application format for obtaining license for facility engaged in commercial production of radiation generating equipment is given in **Annexure 16**.

The consentee/licensee is required to submit to the AERB the periodic list of addresses of installations of X-ray units supplied by them along with QA report for each installation.

3.4.2.5 Lead Time for Submission/Availability of Documents

The lead time for submission of documents for any stage of Consenting process is 60 days before the desired date of Consent and documents should be complete in all respects for review by regulatory body.

3.4.3 *Integrated Facility for Radiation Technology (IFRT)*

3.4.3.1 General

Integrated facility for radiation technology (IFRT) is used for handling and storage of sealed radioactive sources for radiation equipment and high intensity sources. As per the hazard potential, IFRT facilities are classified into high bay area and low bay area. The high bay area includes a hot cell and water pool. This area is assigned for works like fabrication of sealed radioactive sources, their handling, transfer and storage to water pool or in approved packages.

The low bay area is used for maintenance and testing purpose. The facility is used for replenishment of sources, servicing of radiation equipment. The IFRT is a land-based stationary installation type.

3.4.3.2 Site Assessment and Approval

The first stage of consenting process is assessing the suitability of the site in accordance with the applicable safety standards such as AERB safety standard on 'Land-based Stationary Gamma Irradiators', [AERB/RF-IRRAD/SS-6 (Rev-1), 2007].

For this purpose the applicant has to submit an application along with detailed site assessment report (SAR), the format of which is given in **Appendix 6A**. The SAR should include data on (a) seismicity, (b) history of earthquakes in the region, and (c) proximity to a capable fault. The flooding potential, the ground water level and geo-hydrology are also considered, if

demineralised water pool is used for source storage. The geological and soil characteristics are important from the point of view of supporting heavy structures. Further, presence of any ammunition dumps, storage of inflammable in the vicinity, distance of civil or military runway, if any, are also considered. The application format for obtaining consent for site is given in **Annexure 17**.

3.4.3.3 Layout and Construction Approval

The design of the IFRT shall meet the applicable requirements of AERB safety standards such as those prescribed for Land-based Stationary Gamma Irradiators.

The general design requirements of IFRT should cover:

(i) Layout of the facility

(ii) Source handling equipment

(iii) Biological shielding

(iv) Water-pool and pool lining, permeability and seepage of water, evaporation rate and safe water level, system for purification and demineralisation of water, pH control and conductivity

(v) Provision for on-line pool water contamination, conductivity and pH monitoring

(vi) Air handling unit, ventilation system

(vii) Safety systems and safety interlocks

(viii) Emergency systems

(ix) Master slave manipulators (MSM)

(x) External transfer drawer (ETD)

(xi) Electric overhead transport (EOT) crane

(xii) Access control; and

(xiii) Management of radioactive waste disposal, if any.

A preliminary safety analysis report (PSAR), the format of which is given in **Appendix 6B**, covering the above aspects along with application for obtaining consent for layout/construction approval as given in **Annexure -18** should be submitted to AERB for review. The PSAR is reviewed bearing in mind (a) 'defence in depth' principle by redundancy, diversity and independence in the design, (b) the importance of fail-safe-system in the event of any deviation from normal practice, (c) power failure, (d) access control and (e) design basis report for civil structural design.

Adequacy of biological shielding of the hot cell is verified based on acceptable radiation levels at occupied locations. Based on the detailed review of the PSAR submitted by the applicant, the AERB may issue a regulatory consent for layout/construction approval, with relevant stipulations involving checkpoints and hold points as well as QA requirements as mentioned in PSAR.

The facility should maintain and keep available the reports on quality assurance (QA) during construction of the facility. Inspections may be carried out by AERB prior to installation of safety systems for assessing the integrity and adequacy of biological shielding and verification of conformance with the stipulations. The associated QA guidelines are given in **Appendix 6F**.

3.4.3.4 Commissioning and Operation

When all the systems are in place, performance of each system should be verified independently and also in an integrated manner. It is important to check all interlocks and operational controls prior to handling of sources. Acceptance test reports (ATR) containing the results of the tests should be prepared and submitted to the AERB. When the test results are in compliance with the design intent, regulatory Consent for handling of the sources in IFRT facility will be issued.

The following safety personnel shall be available prior to commissioning:

(i) Radiological safety officer

(ii) Certified operators and source handling personnel

(iii) Trained servicing and maintenance personnel.

Monitoring of radiation level around the IFRT and in all accessible locations should be carried out at this stage with specific source strength kept in the hot cell.

The applicant should submit the final safety analysis report (FSAR), the format of which is given in **Appendix 6D**, Radiation protection manual (RPM) as per **Appendix 6E** and quality assurance manual (QAM),as per **Appendix 6F**, to AERB for review.

When the functional performance of the important systems such as master-slave manipulator, external transfer drawer, cask handling cranes and other safety systems/interlocks are satisfactory and stray radiation levels around the biological shielding are within the acceptable limits and based on the review of information provided in ATR, FSAR and obtained from inspections by the AERB, the regulatory Consent in the form of Licence for operation is issued by AERB. The application format for obtaining the License is given in **Annexure 19**.

The Consentee is required to submit to AERB, the periodic safety status reports. Unusual occurrences should be promptly reported within 24 hours and this should be followed by a detailed report within the prescribed period. The Consentee is also required to report on the availability of qualified and trained manpower approved by AERB, at all times of operation of the facility, malfunctioning of radiation monitoring and measuring devices and malfunctioning of any of the safety systems and emergency systems. IFRT installations are inspected routinely by AERB and also whenever there is an unusual incident.

The Consentee shall arrange to constitute a local safety committee(LSC) with facility-in-charge as Chairman and RSO as Member Secretary, to periodically review the safety status of the IFRT. The Committee may also include the operator(s) and service engineer(s) as members. The minutes of the LSC meetings and action taken reports shall be available for inspection by AERB.

3.4.3.5 Decommissioning/Disposal

When the integrated facility for radiation technology is no longer to be used, the decommissioning proposal should be submitted to AERB. The facility has to be checked for presence of any radioactivity, before it can be decommissioned which may include dismantling and recycling/reuse of materials. For the above, the consentee should obtain an Authorisation from AERB for transfer/disposal of radioactive waste to the authorised waste management agency. The application format for obtaining the said authorisation for safe disposal of radioactive waste is given in **Annexure 50**. The consentee is required to submit a report to AERB on completion of decommissioning, safe disposal of sources and personnel doses received during decommissioning operations.

3.4.3.6 Lead Time for Submission/Availability of Documents

The lead time for submission of documents for any stage of Consenting process is 90 days before the desired date of Consent and documents should be complete in all respects for review by AERB.

3.5 Telegamma and Accelerator Facilities used in Radiation Therapy

3.5.1 *Telegamma Radiation Therapy Facility*

3.5.1.1 General

Radiation therapy is beneficial in treating cancers and certain non-malignant lesions. Deep-seated tumours, not otherwise accessible, are best treated by external beams of gamma rays or high energy X-rays. Shallow tumours are treated by high energy electrons or low energy gamma/ X-rays. The aim is to

deliver specified radiation dose to the malignant tissues in order to arrest further growth and achieve regression, at the same time sparing normal healthy tissues. Proper planning in terms of beam size, beam direction and other parameters is necessary to achieve the objective in an optimum manner. Such a procedure is called teletherapy.

High activity ^{60}Co or ^{137}Cs source is used in suitable devices to obtain well defined gamma ray beams from a distance directed to the region under treatment. Such a device is called telegamma therapy unit. The gamma-knife system (GKS) is another type of telegamma therapy unit in which radiation from a number of ^{60}Co sources are focused at a single point. This is used for radio surgery where the high radiation doses are delivered precisely to a small lesion. All the regulatory procedures (as given in subsection 3.5.1) for telegamma radiation therapy units will be followed for GKS and similar equipment using radioisotopes.

Check sources are used in radiotherapy facility for checking the functionality of the radiation measuring equipment such as secondary standard dosimeters. The regulatory procedure to be followed for procurement of these sources is same as that for discrete brachytherapy sources (see subsection 3.8.4).

3.5.1.2 Site and Layout Plan Approval

The room housing the telegamma unit should be located at one end of a hospital and contiguous with other radiation therapy facilities. Basement is desirable for location of telegamma facilities since the earth can form a cheap and effective shielding. However, it should be ensured that site should be free from flooding and high moisture in air. It shall be also ensured that the floor can take the heavy shielding load of the telegamma unit. The telegamma unit shall be housed in a room with adequate shielding and access control. The layout of the telegamma room has to be approved by AERB prior to its construction. The applicant should also submit the authenticated documents issued by relevant Government agency showing the status of ownership/lease of the premises.

The format of the application for obtaining site and layout approval for the facility is given in **Annexure 20**.

3.5.1.3 Construction

The construction of the telegamma therapy facility can be started after obtaining site and layout plan approval (see subsection 3.5.1.2) and no separate regulatory approval is required for construction. QA manual for construction should be prepared and implemented so that the requirements as per approved layout plan by AERB shall be ensured during construction with respect to material, density and thicknesses.

3.5.1.4 Procurement of Source/ Equipment

In order to carry out telegamma radiation therapy procedures using sealed radioisotopes, the applicant should first submit an application to obtain consent for procurement of source or the equipment with source. The applicant should ensure before procurement that the telegamma equipment is type approved. In case the equipment is not type approved, the local manufacturer/local supplier should submit the documents to AERB demonstrating the compliance with the applicable national/international standards and the type approval procedures as per subsection .3.18.1 shall be followed.

Prior to the procurement of the source or equipment with source the applicant should have the following:

(i) Radiological safety officer (RSO)

(ii) Personnel monitoring devices

(iii) Protection level dosimeters

(iv) Radiation protection manual/emergency preparedness plans and procedures (EPP)

(v) Room constructed as per AERB approved layout plan.

(vi) Provisions/commitment for safe disposal of spent/ disused sources.

The radiation protection manual should be as per **Appendix 7E**.

Based on review of the Application, AERB may issue Consent for the procurement of source or equipment with source.

The Application format for obtaining Consent for procurement/import of source or telegamma therapy equipment with source is given in **Annexure 21**.

In case of telegamma therapy units containing depleted Uranium, details regarding the same also need to be furnished as given in **Annexure 21**.

3.5.1.5 Commissioning and Operation

Before the grant of commissioning and operation licence, the Applicant is required to

(i) Evaluate the performance of the type-approved telegamma unit and prepare acceptance test report and submit to AERB.

(ii) Prepare and implement the quality assurance programme.

(iii) Prepare and implement the Radiation Protection Manual as per **Appendix 7E**.

These documents would be reviewed by AERB prior to grant of Licence for commissioning and operation.

The application format for getting Licence for commissioning and operation of the telegamma therapy unit is given in **Annexure 22**.

In case the unit is not type approved, AERB considers separately for type approval of the telegamma therapy unit as explained in subsection 3.18.1.

Prior to seeking regulatory clearance for commissioning and operation, the Consentee should have:

(i) Qualified and trained manpower - radiation oncologist, medical physicist, RSO Level-III, and radiation therapy technologist

(ii) Personnel monitoring devices for all workers

(iii) Protection level and therapy level dosimeters

(iv) Dosimetry accessories

(v) Radiation zone monitor.

It is also advisable that a treatment planning system and a treatment simulator are available for proper treatment planning and for treatment simulation. Also, the Consentee shall obtain a regulatory clearance for the procurement of radiation sources for radiation therapy for which the application format is given in **Annexure 21**.

The Consentee should ensure that:

(i) calibration of radiation beam output for all field sizes, dosimetry for all field sizes and depths, and

(ii) radiation level measurements at all occupied locations

are carried out at the time of commissioning. They are further carried out periodically or whenever repairs which are likely to affect the dosimetric and radiation safety performance of the unit are carried out. The QA aspects to be carried out during operation are spelt out in detail in AERB safety code titled 'Radiation Therapy Sources, Equipment and Installations', [AERB/RF-MED/SC-1 (Rev. 1), 2011].

The Consentee is required to submit annual safety status report to AERB. Unusual occurrences should be promptly reported within 24 hours and this should be followed by a detailed investigation report. AERB may conduct inspection for the radiation facility as and when required.

The Consentee shall arrange to constitute a Local Safety Committee with the Head of the institution as Chairman and the RSO as Member Secretary, to review the safety status of all the radiation facilities in the institution. The Committee may also include the service engineer as a member. The minutes of the meetings and the action taken reports shall be available for inspection by AERB.

3.5.1.6 Decommissioning/Disposal

Consent from AERB should be obtained for decommissioning when the telegamma unit is no longer to be used. The Consentee should arrange to remove the radioactive source and depleted Uranium, if present, and return them to the supplier for safe disposal. For the above, the Consentee should obtain an Authorisation from AERB for transfer/disposal of radioactive waste to the authorised waste management agency. The application format for obtaining the said Authorisation for safe disposal of radioactive waste is given in **Annexure 50**. The consentee is required to submit a report to AERB on completion of decommissioning, safe disposal of sources and personnel doses received during decommissioning operations.

3.5.1.7 Lead Time for Submission/Availability of Documents

The lead time for submission of documents at any stage of consenting process is 60 days before the desired date of consent provided the application is complete in all respects for review by AERB.

3.5.2 *Medical Linear Accelerator Facility*

3.5.2.1 General

Linear accelerators, betatrons and microtrons are capable of providing electron beams in the range of 6 MeV to 42 MeV and/or photon beams in the range of 4 MV to 25 MV for treatment of deep/shallow tumours. In betatrons and microtrons, the electron beams get accelerated in several orbits by a magnetic field. The regulatory procedures for units based on Medical Accelerator such as tomotherapy, cyberknife, intraoperative unit or any other similar unit is same as those of medical linear accelerator (MLA) facility.

Check sources are used in Radiotherapy facility for checking the functionality of the radiation measuring equipment such as secondary standard dosimeters. The regulatory procedure to be followed for procurement of these sources is same as that for discrete brachytherapy sources (see subsection 3.8.4).

3.5.2.2 Site and Layout Plan Approval

The room housing the accelerator should preferably be located at one end of the hospital and contiguous with other radiation therapy facilities. Basement is desirable site for location of accelerator facilities since the earth can form a cheap and effective shielding. Since high voltages are involved, the site should be free from flooding and high moisture in air. Dust load should be negligible to prevent electrical sparking. In addition, ventilation should be taken care of. It shall be ensured that the site can take the heavy shielding load of the accelerator unit.

The accelerator shall be housed in a room with adequate shielding and access control. The Site and Layout Plan of the therapy room should be approved by AERB prior to its construction.

The format for application for site and layout plan approval for medical linear accelerator is given in **Annexure 20**.

3.5.2.3 Construction

The construction of the medical linear accelerator facility can be started after obtaining layout plan approval and no separate regulatory approval is required for construction. QA manual for construction should be prepared and implemented so that the requirements as per approved layout plan by AERB shall be ensured during construction with respect to material, density and thicknesses.

3.5.2.4 Procurement of Medical Linear Accelerator

In order to carry out radiation therapy procedures using medical linear accelerator, the applicant should first submit an application to obtain consent for procurement of Medical Linear Accelerator. The consentee should ensure before procurement that the Medical Linear Accelerator is type approved. In case the Medical Linear Accelerator is not type approved, the local manufacturer/local supplier should submit the documents to AERB demonstrating the compliance with the applicable national/international standards and the Type Approval procedures as per subsection 3.18.1 shall be followed.

Prior to the procurement of the source or equipment with source the applicant should have the following:

(i) Radiological safety officer (RSO)

(ii) Personnel monitoring devices

(iii) Protection level dosimeters

(iv) Radiation protection manual/Emergency preparedness plans and procedures (EPP)

(v) Room constructed as per AERB approved layout plan.

Based on review of the application, AERB may issue Consent for the procurement of Medical Linear Accelerator (radiation generating equipment).

The Application format for obtaining Consent for procurement/import of Medical Linear Accelerator is given in **Annexure 21**.

In case of medical linear accelerator containing depleted uranium, details regarding the same also need to be furnished as given in **Annexure 21**.

3.5.2.5 Commissioning and Operation

Before the grant of commissioning and operation licence, the Applicant is required to

(i) Evaluate the performance of the type-approved telegamma unit and prepare acceptance test report and submit to AERB.

(ii) Prepare and implement the quality assurance programme

(iii) Prepare and implement the Radiation Protection Manual as per **Appendix 7E**.

These documents would be reviewed by AERB prior to grant of Licence for commissioning and operation.

The application format for obtaining consent for commissioning and operation of the medical linear accelerator is given in **Annexure 22**

In case the medical linear accelerator is not type approved, AERB considers for type approval of the medical linear accelerator unit separately as explained in subsection 3.18.1.

Prior to seeking Regulatory approval for commissioning and operation, the Consentee should have:

(i) Qualified and trained manpower - radiation oncologist, medical physicist, RSO, and radiation therapy technologist;

(ii) Personnel monitoring devices for all workers

(iii) Protection level and therapy level dosimeters

(iv) Dosimetry accessories including radiation field analyser.

It is also advisable that a treatment planning system and a treatment simulator are available for proper treatment planning and for treatment simulation.

The Consentee should ensure that

(i) calibration of radiation beam output, dosimetry for all field sizes and depths for all beam energies, and

(ii) measurement of radiation levels at all occupied locations

are carried out at the time of commissioning and periodically or whenever repairs are carried out that is likely to affect the dosimetric and radiation safety performance of the unit.

The Consentee is required to submit annual safety status report to AERB at the end of each calendar year. Unusual occurrences should be promptly reported within 24 hours and this should be followed by a detailed report. AERB may conduct inspection for the radiation facility as and when required.

The Consentee shall arrange to constitute a Local Safety Committee with the Head of the institution as Chairman and the RSO as Member Secretary to review the safety status of all the radiation facilities in the institution. The Committee may also include the service engineer as a member. The minutes of the meetings and the action taken reports shall be available for inspection by AERB.

3.5.2.6 Decommissioning/Disposal

Consent from the AERB should be obtained for decommissioning when the accelerator is no longer to be used. The Consentee should arrange to check for any contamination/induced activity in the treatment head and remove depleted uranium, if any, for safe disposal. If no radioactive contamination is present in the treatment head and nearby accessible areas, it can be decommissioned which may include dismantling. If activity exists, the active components should be disposed off separately. For the above, the Consentee should obtain an Authorisation from AERB for transfer/disposal of radioactive waste to the authorised waste management agency. The application format for obtaining the said Authorisation for safe disposal of radioactive waste is given in **Annexure 50**. The consentee is required to submit a report to AERB on completion of decommissioning, safe disposal of sources and personnel doses received during decommissioning operations.

3.5.2.7 Lead Time for Submission/Availability of Documents

The lead time for submission of documents at any stage of consenting process is 60 days before the desired date of consent provided the application is complete in all respects for review by AERB.

3.6 Computed Tomography (CT)/Interventional Radiology (CATH LAB)

3.6.1 *General*

Diagnostic facilities such as computed tomography and interventional radiology are important requisites in hospitals now-a-days. Operation of these facilities may pose radiation hazard to the operators and even the patients, unless safety measures are regulated at the design, manufacture, installation and operation stages of these facilities. AERB's Consenting process ensures safety at all these stages.

Computed tomography (CT) units are basically diagnostic X-ray units. The dose received by patients in a typical CT imaging is many orders higher than that of conventional radiography. In interventional radiology (Cath Lab) also, as the procedure time is long and staff needs to be present in the near vicinity of patient the dose to the patient, doctor and staff is high.

3.6.2 *Site and Layout Plan Approval*

The room housing the CT/Cath Lab unit should be planned in accordance with the radiation safety requirements stipulated by AERB in safety code titled 'Medical Diagnostic X-ray Equipment and Installations', [AERB/SC/MED-2 (Rev.1), 2001]. These are essentially in the nature of access control, patient flow control and radiation shielding. Adequate distance from the CT unit/Cath Lab unit to walls and ceiling obviate the need for unnecessary shielding and lead lining.

The CT/Cath Lab unit should be installed after obtaining layout plan approval from the AERB. The application format for layout plan approval of the CT/Cath Lab unit is given in **Annexure 23**.

3.6.3 *Construction*

The construction of the facility can be started after obtaining layout plan approval from regulatory board and no separate regulatory clearance is required for construction.

3.6.4 *Procurement*

It is to be ensured that only AERB Type Approved CT/Cath Lab units should be installed and used for patient diagnosis in India. In case unit is not Type Approved, Supplier/manufacturer has to submit application for Type Approval and relevant documents to AERB for issuing Type Approval as referred in subsection 3.18.1.

3.6.5 *Commissioning and Operation*

The applicant shall submit an application for Licence for operation of the CT unit. `Prior to commissioning the Consentee should have a qualified and trained Radiologist, and a radiography technologist/radiographer. The radiographer or the radiologist, who is familiar with basic principles of radiation protection, should be made responsible for radiation safety of the patient and the medical staff. He may be designated as RSO Level-I with the approval of the AERB. In response to the Licence application, AERB, as necessary, will inspect the installation before granting the Licence for operation of the CT/Cath Lab unit.

QA Test report as per format given in **Appendix 8C-I** OR **8C-II** (as appropriate) should be prepared and submitted along with application for Licence. Radiation protection manual (RPM) should be prepared as per the guidelines in **Appendix 8E** and updated from time to time. It should be made available to AERB officials whenever asked during inspection.

The Consentee should submit to AERB periodic reports on the radiation safety status of the installation. Any unusual occurrences should be promptly reported

within 24 hours and this should be followed by a detailed investigation report within the prescribed period.

The Application format for obtaining the license of the CT/Cath Lab unit is given in **Annexure 24**. For applicants seeking renewal of Licence, the requisite details need to be filled in the same License application format as per **Annexure 24**.

3.6.6 *Lead Time for Submission/Availability of Documents*

The lead time for submission of documents for any stage of Consenting process is 60 days before the desired date of Consent and the documents should be complete in all respects for review by AERB.

3.7 Radiography

3.7.1 *Industrial Radiography*

3.7.1.1 General

The industrial radiography is an indispensable, versatile and well-established non destructive testing/examination (NDT or NDE). This NDT technique is used to 'see' inside the manufactured products such as metal castings or welded pipelines whether the product contains flaws. Industrial radiography technique is a powerful industrial tool, but it involves some radiological risk if not practiced as per stipulated safe work procedures. The widespread use of radiography sources calls for meticulous regulatory programme for ensuring radiological safety of radiography personnel, members of the public and environment. In industrial radiography, sealed radioisotopes such as ^{60}Co, ^{137}Cs, ^{192}Ir, ^{75}Se, ^{170}Tm and industrial X-ray machines are used. Industrial radiography is carried out by using radiography devices such as industrial gamma radiography exposure device (IGRED)/industrial X-ray machine. Radioactive sources are housed in IGRED, which is an assembly of components to make radiographic exposures and it includes the source housing, mechanism for securing the source assembly, exposure mechanism, and including the source drive associated system, positioning devices and guide tube. Such industrial radiography exposure devices are used in enclosed installations and open field radiography. The radiography work need to be carried out by authorised radiography personnel by adhering to prescribed operating procedures so that there is no radiological risk to the workers, public and environment.

3.7.1.2 Procurement of Source/Device for Radiography

In order to carry out industrial radiography operations either using device with sealed radioisotopes (IGRED) or by industrial X-ray machine, the applicant should submit an Application to obtain consent for procurement of

the device with source (IGRED) or X-ray machine. In case of IGRED, layout details of the storage facility are also required to be submitted for approval by AERB. The IGRED/X-ray machine should also be type approved before procurement. In case IGREDs/X-ray machine is not type approved, the applicant should submit the documents to the AERB demonstrating the compliance with the applicable national/international standards and the Type Approval/NOC procedures as per subsection .3.18.1 shall be followed.

Prior to the procurement of the radiography device(s) /source, applicant should meet the provisions given in **Annexure-25**. These include the following:

(i) Radiological safety officer (RSO)

(ii) Certified radiographer

(iii) Personnel monitoring devices

(iv) Protection level dosimeters

(v) Radiation protection manual/emergency preparedness plans and procedures (EPP)

(vi) Provisions/commitment for safe disposal of spent/ disused sources.

Based on review of the Application, AERB may issue Consent for the procurement of IGRED/X-ray machine and loading of the source(s) in IGRED.

After obtaining the IGRED with source/X-ray machine the applicant needs to obtain License for commissioning and operation of radiography facility using IGREDs/X-ray machine, either in the approved enclosure or open field radiography. The approval for the same should be obtained as per the procedures given in subsections 3.7.2 and 3.7.3 respectively.

The Application format for obtaining Consent for Procurement of new* IGREDs/industrial X-ray machine is given in **Annexure 25**.

3.7.2 *Enclosed Radiography Installations*

3.7.2.1 General

Industrial radiography installations in which radiography operations are carried out in an enclosure which has walls providing adequate protection to persons working outside the enclosure, and which prevents unauthorised entry of person into the enclosure during radiography operation are called enclosed

* For existing devices already licenced by AERB, subsection 3.7.3 will not be applicable, however before commencement of radiography work with such devices, the applicant should obtain enclosure or site/ movement approval from AERB as per the guidance given in subsections 3.7.2 and 3.7.3.

installations. Such installation may be open top. The use of correctly designed and constructed enclosure for radiography work is a major factor in keeping radiation dose as low as reasonably achievable (ALARA). Radiography work is carried out in enclosures of enclosed type (with ceiling at the top) or open top. The open top enclosures are provided with audio-visual indication on the top. In such a case, audio-visual indication of radiography work should be displayed on top to prevent crane operators passing over the radiation area. Placard as well as red lamp, displayed outside the enclosure to prevent unauthorised access. The radiography enclosure should be in industrial premises and should have secured storage of the radiation sources. Radiography enclosures are constructed in shop floors to carry out NDT of heavy objects, which may be brought by overhead crane or in a truck. It is necessary to control unauthorised access into the radiation area by warning lights and/or alarms and also by interlocks for ground level doors. Furthermore, radiography work may be restricted to prevent unnecessary exposure to workers.

The radiography enclosure shall have adequate shielding and access control. The layout of the enclosed radiography installation requires approval of AERB prior to its construction.

3.7.2.2 Site, Layout Plan and Construction

AERB may carry out the inspection of the site proposed for construction of an enclosure. Based on the review of application and information obtained from inspection, if any, AERB may issue the Consent of approval for the layout plan/construction of enclosure. The construction of the enclosure shall be started after obtaining layout plan approval and no separate regulatory clearance will be issued for construction of the enclosure. AERB may inspect the facility while under construction to verify whether the construction is as per the approved layout plan.

The applicant should also submit the authenticated documents issued by relevant Government agency showing the status of ownership/lease of the premises. The Application format for obtaining the Consent for Layout Plan and Construction of the enclosed radiography facility is given in **Annexure 26**.

3.7.3 *Open Field Radiography*

In case of open field radiography, the site for open field radiography may be at the industrial premises or in open areas. Prior to the commencement of radiography work in open field, thorough assessment of the working environment shall be carried out by the applicant to identify any site-specific issues that will need to be addressed from radiation safety and security point of view.

The applicant should submit the Application for obtaining Site and movement Approval of the source to the proposed Site, for conducting radiography operation. The Application format for the Site and Movement Approval is given in **Annexure 27**.

AERB may carry out the inspection of the proposed site. Based on the review of application and information obtained from inspection, if any, AERB may issue approval to the proposed site for radiography operations.

3.7.3.1 Commissioning/Operation

Prior to carrying out radiography work, at either enclosed installations or at open field, the applicant should obtain License for commissioning and operation of the radiography facility using IGRED(s)/X-ray machine. The application should include the radiation protection manual as per **Appendix 9E**. The Application format for obtaining the Licence for commissioning and operation of radiography facility is given in **Annexure 28**.

The AERB may carry out the inspection of the IGREDs/X-ray machine, radiography site, source storage facility or radiography enclosure as and when required. Based on the review of application for Licence for commissioning and operation and information, if any, from the inspection, AERB may issue the Licence for Commissioning and Operation of radiography facility.

The Consentee is required to submit the periodic safety status reports to AERB. The Consentee should not transfer IGREDs/X-ray machine from one approved radiography site/enclosure to another radiography site/enclosure without the prior permission of the AERB. The Consentee should obtain a fresh approval from AERB, for procurement of new radiography exposure device/new radiography site/transfer of the IGRED to another site.

Any unusual occurrence or loss of radioactive source or radiography exposure device shall be promptly reported within 24 hours and this should be followed by a detailed investigation report.

The Consentee shall arrange to constitute a Local Safety Committee with the Head of the institution as Chairman and the RSO as Member Secretary, to review the safety status of all radiation facilities in the radiography institution. The Committee may also include a certified radiographer(s) as a member(s). The minutes of the meetings and the action taken reports shall be available for inspection by AERB.

3.7.3.2 Decommissioning/Disposal

Consent for decommissioning should be obtained from the AERB when the radiography exposure device is no longer to be used. The Consentee should arrange to remove the radioactive source and return it to the source supplier

for safe disposal. If the exposure device contains depleted uranium, the entire device has to be returned to the supplier for safe disposal or transferred to an authorised waste management agency for safe disposal. For this purpose, the Consentee should obtain an Authorisation from the AERB, in the prescribed format given in **Annexure 50**. If the radiography exposure device does not contain depleted uranium, the device should be checked for contamination. If no radioactive contamination is present in the source housing/guide tube the same can be decommissioned. If contamination is present, the contaminated components should be disposed off as radioactive waste. For this purpose, the Consentee should obtain an authorisation from AERB for transfer/disposal of radioactive waste to authorised waste management agency. The Consentee is required to submit to AERB a report on completion of decommissioning, detailing, of safe disposal of the devices or the source and other active components and personnel doses received during the decommissioning operation.

3.7.3.3 Lead Time for Submission/Availability of Documents

The lead time for submission of documents at any stage of consenting process is 30 days before the desired date of Consent and the documents should be completed in all respects for review by AERB.

3.7.4 *Industrial Accelerator Facility (IAF) for NDT*

3.7.4.1 General

The radiography work for non destructive examination (NDE) purpose is also carried out by industrial accelerator. The industrial accelerator is capable of providing electron beams in the order of tens of MeV and photon beams in the order of tens of MV for NDE of welds of thick objects.

3.7.4.2 Site, Layout Plan and Construction Approval

The room housing the accelerator should be located preferably at one end of the industrial workshop and contiguous with other radiography facilities. Basement is a desirable site for location of accelerator facilities since the earth can form a cheap and effective shielding. Since high voltages are involved, the site should be free from flooding and high moisture in air. Dust load should be negligible to prevent electrical sparking. In addition, ventilation should be taken care of. It shall be ensured that the site can take the heavy shielding load of the accelerator unit.

Requirements are specified in the AERB safety code on 'Industrial Radiography' (AERB/SC/IR-1, 2001) and relevant guidelines issued by the Competent Authority. Seismic characteristics of the site should be taken into consideration and its suitability for the location of the accelerator should be assessed. Industrial safety, particularly electrical and fire safety should be considered in the design.

The accelerator shall be housed in a room with adequate shielding and access control. Prior to its construction, the site layout of the accelerator room should be approved by AERB. The applicant should also submit the authenticated documents issued by relevant Government agency showing the status of ownership/lease of the premises. The Application format for obtaining regulatory consent for Site, Layout and Construction is given in **Annexure 29**. Detailed safety analysis report should be submitted in the form of preliminary safety analysis report (PSAR), the format of which is given in **Appendix 3B-III**. AERB issues no separate Consent for construction. However, AERB may inspect the facility while under construction to verify whether the construction is as per design approved. Installation of accelerator and preliminary tests on various systems is to be carried out in a phased manner as per the checkpoints. The quality assurance aspects should be addressed as per **Appendix 3F**.

3.7.4.3 Commissioning and Operation

After installation of the industrial accelerator and detailed performance verification of the accelerator systems, the Consentee should submit to the AERB the Application for obtaining the Consent for commissioning/operation of industrial accelerator facility as per the format given in the Annexure 30 along with the FSAR (to be submitted as per **Appendix 3D-III**). The quality assurance aspects in the commissioning and operation of the NDT accelerator should be as per **APPENDIX 3F**.

AERB may carryout inspection of the industrial accelerator facility if required prior to commissioning and operation.

Prior to seeing the permission for commissioning/operation Consentee should have:

(i) Qualified and trained manpower - RSO, certified operator(s)

(ii) Personnel monitoring devices

(iii) Protection level dosimeters/Radiation zone monitor

(iv) Emergency response plan and preparedness.

Based on the review of the application, the Acceptance Test Report (to be submitted as per **Appendix 3B**) and radiation protection manual (RPM) (to be in the format given as per **Appendix 3E**) and information obtained from inspection, if any, AERB may issue the Consent for commissioning/operation of the industrial accelerator. The Consentee is required to submit periodic status report to the AERB. Unusual occurrences should be promptly reported within 24 hours and this should be followed by a detailed investigation report.

The Consentee shall arrange to constitute a Local Safety Committee with the Head of the institution as Chairman and the RSO as Member Secretary, to review the safety status of all accelerator facility. The Committee may also include a certified operator(s) as a member(s). The minutes of the meetings and the action taken reports shall be available for inspection by AERB.

3.7.4.4 Decommissioning/Disposal

When the accelerator is no longer to be used, the Consentee should obtain Consent for decommissioning from the AERB and a detailed report on decommissioning procedures, management of radioactive waste and likely radiation exposures to personnel at the facility should be submitted. The Consentee should check for any contamination and if no radioactive contamination is present in the accelerator facility and nearby accessible areas, it can be decommissioned. If activity exists, the active components should be disposed off separately. For the above, the Consentee should obtain an Authorisation from the AERB for transfer/disposal of radioactive waste to the authorised waste management agency. The application format for obtaining the said Authorisation for safe disposal of radioactive waste is given in **Annexure 50**. The Consentee is required to submit a report to the AERB, on completion of decommissioning, detailing safe disposal of waste and personnel doses received during decommissioning operation.

3.7.4.5 Lead Time for Submission/Availability of Documents

The lead-time for submission of documents at any stage of Consenting process is 30 days before the desired date of Consent and the documents should be complete in all respects for review by the AERB.

3.8 Brachytherapy Facilities

3.8.1 *General*

Discrete sources in the form of pellets, wires, needles, seeds and tubes are inserted into body cavities or implanted into tissues to treat malignant diseases. Surface applicators are used for treating disease of skin and eye. Pre-loaded brachytherapy in which sources are applied in operation theatre gives more radiation exposure to the radiation oncologist and assisting staff. Hence, it is preferred to use Afterloading technique, in which the applicator is inserted in the patient body in the operation theatre and the sources are loaded into the applicator manually or remotely. The manual procedure of loading the sources into the applicators is known as manual-afterloading technique (MAL). Whereas for loading the source remotely, a computer controlled unit is used, which is known as remote afterloading brachytherapy unit (RAL). The sources used in brachytherapy are categorised as low dose rate (LDR) sources, medium dose rate (MDR) sources and high dose rate (HDR) sources based on the

dose rates. Pre-loaded and manual afterloading brachytherapy may result in loss or misplacement of sources and unavoidable dose to operating and nursing staff. Remote afterloading (RAL) brachytherapy unit reduces the dose to medical and paramedical staff and other patients.

Check sources are used in radiotherapy facility for checking the functionality of the radiation measuring equipment such as survey meter. The regulatory procedure for procurement of these sources is same as that for discrete brachytherapy sources (see subsection 3.8.4).

3.8.2 *Site and Layout Plan Approval*

The brachytherapy facility should be located at one end of a hospital and contiguous with other radiotherapy facilities. Basement is desirable for location of brachytherapy facilities since the earth can form a cheap and effective shielding. However, it should be ensured that site should be free from flooding and high moisture in air.

The brachytherapy facility requires adequate shielding and access control. The brachytherapy rooms, including wards in case of manual procedures, have to be planned. Access control and containment of source in case of loss of control are paramount. The Site and Layout of the brachytherapy facility has to be approved by AERB prior to its construction. The technical parameters as applicable for Site and Layout Plan approval are to be submitted by the applicant.

The format for Application for Site and Layout Plan Approval for Brachytherapy Facility is given in **Annexure 20**.

3.8.3 *Construction*

The construction of the brachytherapy facility can be started after obtaining layout plan approval and no separate regulatory clearance is required for construction.

3.8.4 *Procurement of Sources*

In order to carry out brachytherapy procedures using sealed radioisotopes, the applicant should first submit an application to obtain consent for procurement of source or the equipment with source. For manual afterloading (MAL) technique no equipment is used. However, for remote afterloading (RAL) technique computer controlled equipment is required and hence the consentee needs to ensure that the equipment is type approved before procurement. In case the equipment is not type approved, the local manufacturer/local supplier should submit the documents to AERB demonstrating the compliance with the applicable national/international standards and the Type Approval procedures as per subsection 3.18.1 shall be followed.

Prior to the procurement of the source or equipment with source the applicant should have the following:

(i) Radiological safety officer (RSO)

(ii) Personnel monitoring devices

(iii) Protection level dosimeters

(iv) Radiation protection manual/emergency preparedness plans and procedures (EPP)

(v) Room constructed as per AERB approved layout plan

The radiation protection manual should be as per **Appendix 7E**.

Based on review of the Application, AERB may issue Consent for the procurement of source or equipment with source.

The Application format for obtaining Consent for procurement/import of source or brachytherapy equipment with source is given in **Annexure 21**. In case of brachytherapy units containing depleted uranium, details regarding the same also need to be furnished as given in **Annexure 21**.

3.8.5 *Commissioning and Operation*

As no equipment is involved for manual afterloading (MAL) technique, after procurement of brachytherapy sources, consent needs to be obtained prior to their use for treatment. However, in case of remote afterloading (RAL) brachytherapy, before the grant of commissioning and operation licence, the Applicant is required to

(i) Evaluate the performance of the type-approved telegamma unit and prepare acceptance test report and submit to AERB

(ii) Prepare and implement the quality assurance programme

(iii) Prepare and implement the radiation protection manual as per **Appendix 7E**.

These documents would be reviewed by AERB prior to grant of Licence for commissioning and operation. The application format for obtaining consent for commissioning and operation of the brachytherapy facility is given in **Annexure 22**.

In case the remote afterloading (RAL) brachytherapy unit is not type approved, AERB considers for type approval of the remote afterloading (RAL) brachytherapy unit separately as explained in subsection 3.18.1.

Prior to seeking regulatory consent for commissioning and operation, the Consentee should have:

(i) Qualified and trained manpower - radiation oncologist, medical physicist, RSO and radiation therapy technologist

(ii) Personnel monitoring devices for all workers

(iii) Protection level and therapy level dosimeters

(iv) Dosimetry accessories

(v) Radiation zone monitor.

It is also advisable that a treatment planning system and a treatment simulator are available for proper treatment planning and for treatment simulation.

The Consentee should ensure that:

(i) calibration of radiation beam output and

(ii) measurement of radiation levels at all occupied locations

are carried out at the time of commissioning and periodically or whenever repairs are carried out that is likely to affect the dosimetric and radiation safety performance of the unit.

The Consentee is required to submit annual safety status report to AERB at the end of each calendar year. Unusual occurrences should be promptly reported within 24 hours and this should be followed by a detailed investigation report. AERB may conduct inspection for the radiation facility as and when required.

The Consentee shall arrange to constitute a Local Safety Committee with the Head of the institution as Chairman and the RSO as Member Secretary to review the safety status of all the radiation facilities in the institution. The Committee may also include the service engineer as a member. The minutes of the meetings and the action taken reports shall be available for inspection by AERB.

3.8.6 *Decommissioning/Disposal*

Consent from AERB for decommissioning of remote afterloading (RAL) brachytherapy unit if no longer to be used. In case of decommissioning of remote afterloading (RAL) brachytherapy unit the Consentee should arrange to remove the radioactive source and depleted uranium, if present, and return them to the supplier for safe disposal. For the above, the Consentee should obtain an Authorisation from AERB for transfer/disposal of radioactive waste to the authorised waste management agency. The application format for obtaining the said Authorisation for safe disposal of radioactive waste is given in **Annexure 50**. If no contamination or radioactivity is present in the source head, decommissioning may include dismantling. If activity is present, the active component should be disposed off separately.

3.8.7 *Lead Time for Submission/Availability of Documents*

The lead time for submission of documents at any stage of consenting process is 30 days before the desired date of consent provided the application is complete in all respect for review by AERB.

3.9 Gamma Irradiation Chamber (GIC)

3.9.1 *General*

The self-shielded dry source storage gamma irradiator is also known as a gamma irradiation chamber (GIC)/blood irradiator (BI). The GIC/BI are used in academic/medical instituttions for irradiation of blood or chemical or biological samples. The GIC/BI contains either ^{60}Co or ^{137}Cs source of the activity ranging from few TBq to several PBq. The high activity sources are placed in the source cage and shielded by lead/steel material. The GIC/BI housing is normally designed to meet requirements of type B transport package. The GIC/BI should be installed in the room where the floor is suitable for its load, since the weight of the GIC/BI is of the order of 3 MT to 10 MT.

3.9.2 *Procurement of GIC*

The Layout of the GIC installation room needs to be approved by AERB prior to its procurement. The applicant should submit the application form for obtaining the Authorisation for procurement of the GIC/BI to AERB, along with layout details of the GIC installation room.

The applicant should seek a copy of Type approval certificate issued by AERB to the Local supplier before applying for source procurement. In case the GIC is not type approved, the procedures for Type Approval as per subsection 3.18.1 shall be followed.

Prior to the procurement of the GIC the applicant should have the following:

(i) Radiological safety officer (RSO)

(ii) Persons trained for operation by manufacturer/supplier

(iii) Personnel monitoring devices

(iv) Protection level dosimeters

(v) Emergency preparedness plans and procedures (EPP).

(vi) Provisions/commitment for safe disposal of spent/ disused sources.

Based on review of the application, AERB may issue Consent/NOC for Procurement of GIC/BI and the approval of the proposed layout plan of GIC installation room.

The Application form for obtaining Consent/NOC for Procurement is given in **Annexure 31**.

3.9.3 *Commissioning and Operation*

After installation of the GIC, the applicant should submit the Application for Authorisation for commissioning/operation of a GIC along with installation report, dosimetry report and radiation protection survey report of the installation.

Prior to seeking the authorisation for operation of the GIC the applicant should have the following:

(i) Radiological safety officer (RSO)

(ii) Persons trained for operation by manufacturer/supplier

(iii) Personnel monitoring devices

(iv) Protection level dosimeters

(v) Emergency preparedness plans and procedures (EPP).

Based on the review of the application, AERB may issue the Authorisation for commissioning/operation of the GIC/BI. The Application format for obtaining Authorisation for commissioning/operation of GIC/BI is given in **Annexure 32**.

The consentee is required to submit the periodic status reports to AERB. The applicant should ensure that Type approved models of GIC/BI is procured, installed and used. Unusual occurrences should be promptly reported within 24 hours to the AERB and followed by a detailed report within the prescribed period. AERB may conduct inspection for the GIC installation as and when required.

3.9.4 *Decommissioning/Disposal*

When the gamma chamber is no longer used, it is obligatory on the part of the Licensee to undertake decommissioning and safe disposal of spent/ disused sources. The consentee should return the gamma irradiation chamber with radioactive source to the supplier of the source contained in GIC/BI for safe disposal. The Consentee should obtain Authorisation from AERB for transfer of radioactive waste for disposal. The application format for obtaining the Authorisation for transfer of radioactive waste for disposal is given in **Annexure 50**. Completion of such disposal by the consentee should be reported to the AERB along with personnel doses, if any, received during the decommissioning operation.

3.9.5 *Lead Time for Submission/Availability of Documents*

The lead time for submission of documents at any stage of Consenting process is 30 days before the desired date of Consent and the documents should be complete in all respects for review by the AERB.

3.10 Nuclear Medicine Facilities

3.10.1 *Nuclear Medicine Therapy Facility*

3.10.1.1 General

Several megabequerel (millicuries) of radioactivity in unsealed form are administered to patients either orally or by other routes. Patients may be hospitalised and should be discharged only when the activity in them has reduced to levels prescribed by AERB. Such patients are instructed to maintain isolation from relatives even after discharge from hospital for some period. During this time even nursing of infants by mother patient is not allowed.

3.10.1.2 Site and Layout Plan Approval/ Design of Facility

The isolation ward should be located at one end of the facility and preferably contiguous with the other radiation facilities. The Site and layout of the nuclear medicine facility should be approved by AERB. While planning the facility, the areas for source storage, source preparation, dose administration, isolation ward, radioactive waste storage, decontamination room, delay tank etc. should be segregated, graded in terms of activity level, and access controlled accordingly. Floors must be lined and walls painted with special materials to facilitate easy decontamination. The application for approval of Site and Layout Plan for nuclear medicine facility is given in **Annexure 33a**.

3.10.1.3 Construction

The construction of the nuclear medicine facility can be started after obtaining layout plan approval. No separate regulatory clearance is required for construction. However, AERB may inspect the facility while under construction to verify whether the construction is as per design layout plan approved.

3.10.1.4 Commissioning and Operation

Prior to seeking Authorisation for commissioning and operation, the applicant should have

(i) qualified and trained manpower - Nuclear Medicine Physician, RSO Level-III or RSO Level-II with special training in isolation ward, Nuclear Medicine Technologist,

(ii) personnel monitoring devices for all workers,

(iii) radiation protection instruments (survey meters, contamination monitors, dose calibrators),

(iv) radiation protection accessories, and

(v) waste disposal facility with provisions for monitoring.

AERB may inspect the facility before granting an Authorisation for commissioning of nuclear medicine facility. The application format for obtaining the Authorisation for operation of the nuclear medicine facility is given in **Annexure 34**. The application format for procurement of radioisotopes for nuclear medicine facilities is given in **Annexure 33b**.

The Consentee is required to submit to the AERB, periodic safety status reports. Unusual occurrences should be promptly reported within 24 hours and this should be followed by a detailed investigation report. The Consentee shall report any misadministration[1] (wrong radionuclide, wrong patient, wrong dose or wrong pathway). This should be investigated and reported to AERB.

The Consentee should promptly report to AERB about details of cadavers with substantial activity in their body. AERB may conduct inspection of the radiation facility as and when required.

The Consentee shall arrange to constitute a Local Safety Committee with the Head of the institution as Chairman and the RSO as Members Secretary, to review the safety status of all radiation facilities in the institution. The minutes of the meetings and the action taken reports shall be available for inspection by AERB.

3.10.1.5 Decommissioning/Disposal

The Consentee should obtain an Authorisation for disposal of radioactive wastes, which include the routine discharge within authorised activity limits in to sewerage, in the prescribed format. The application format for obtaining the Authorisation for disposal of radioactive waste is given in **Annexure 49**. When the nuclear medicine facility is no longer to be used, the Consentee should arrange to check for any contamination in the facility and carry out decontamination, if necessary. If no contamination is present, the facility could be authorised for decommissioning and could be released for any other purpose. The Consentee should submit to the AERB the decommissioning

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1 Misadministration (nuclear medicine)

The administration of any one of the following:

(a) a radiopharmaceutical other than the one intended;

(b) a radiopharmaceutical to the wrong patient;

(c) a radiopharmaceutical by a route of administration other than that intended by the prescribing physician;

(d) a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent;

(e) a therapeutic dose of radiopharmaceutical differing from the prescribed dose by more than 10 percent.

plan and obtain the necessary consent. RSO is required to submit to AERB, report on safe decommissioning, disposal of radioactive wastes, and personnel doses received during the decommissioning operation.

3.10.1.6 Lead Time for Submission/Availability of Documents

The lead time for submission of documents at any stage of consenting process is 30 days before the desired date of consent and the documents should be complete in all respects for review by AERB.

3.10.2 *In-vivo Nuclear Medicine Diagnostic Facility*

3.10.2.1 General

A small quantity of radionuclides such as ^{99m}Tc, ^{131}I, ^{201}Tl and ^{18}F in a form that can be readily absorbed by an organ/tissue of interest is administered by a chosen route (e.g. intravenous/oral). Preparation of radiopharmaceuticals, dose administration, imaging and waste collection and disposal should be done by persons qualified and specially trained in these aspects as stipulated by AERB.

3.10.2.2 Site and Layout Plan Approval

While planning the nuclear medicine diagnostic facility, areas for source storage, source preparation and dose administration, and radioactive waste storage and disposal, should be segregated, graded in terms of activity level, and access controlled accordingly. The Floor must be lined and walls painted with special materials to facilitate easy decontamination. The site and layout plan of the laboratory should be approved by AERB. The application for approval of site and layout plan for nuclear medicine facility is given in **Annexure 33a**.

3.10.2.3 Construction

The construction of the nuclear medicine diagnostic facility can be started after obtaining layout plan approval and no separate regulatory clearance is required for construction. However, AERB may inspect the facility while under construction to verify whether the construction is as per approved design and layout.

3.10.2.4 Commissioning and Operation

Prior to seeking Authorisation for commissioning, the Consentee should have:

(i) qualified and trained manpower - Nuclear Medicine Physician, Nuclear Medicine Technologist and RSO Level-II,

(ii) personnel monitoring devices for all workers,

(iii) protection level survey meters, contamination monitors,

(iv) radiation protection accessories and source for calibration, and

(v) waste disposal facility with provisions for monitoring.

AERB may inspect the nuclear medicine facility before granting Authorisation for nuclear medicine diagnosis. The application format for obtaining the Authorisation for operation of the nuclear medicine facility is given in **Annexure 34**. The application format for procurement of radioisotopes for nuclear medicine facilities is given in **Annexure 33b**.

The Consentee is required to submit to AERB, periodic reports on the safety status. Any unusual occurrences should be promptly reported within 24 hours and this should be followed by a detailed investigation report within the prescribed period. The Consentee shall report any misadministration (wrong radiopharmaceutical, wrong patient, wrong activity or wrong pathway). This should be investigated and reported to AERB. AERB may conduct inspection for the radiation facility as and when required.

The Consentee shall arrange to constitute a Local Safety Committee with the Head of the institution as Chairman and RSO as Member Secretary to review the safety status of all radiation facilities in the institution. The minutes of the meetings and the action taken reports shall be available for inspection by AERB.

3.10.2.5 Decommissioning/Disposal

The decommissioning plan should be submitted to the AERB for necessary consent when the nuclear medicine facility is no longer to be used. The Consentee should check for any contamination in the facility and carry out decontamination, if necessary. The Consentee should obtain an Authorisation for disposal of radioactive waste, which include the routine discharge within authorised activity limits into sewerage, in the prescribed format given in **Annexure 49**. If no contamination is present, the facility can be decommissioned and could be released for any other purpose. The Consentee should submit to AERB, report on safe decommissioning, and safe disposal of radioactive waste and personnel doses received during the decommissioning operation.

3.10.2.6 Lead Time for Submission/Availability of Documents

The lead time for submission of documents at any stage of consenting process is 30 days before the desired date of consent and the documents should be complete in all respects for review by AERB.

3.11 Facilities Engaged in the Commercial Production of Nucleonic Gauges and Consumer Products Containing Radioactive Material

3.11.1 *Facilities Engaged in the Commercial Production of Nucleonic Gauges (NGs)/ Ionising Radiation Gauging Devices (IRGDs)*

3.11.1.1 General

The nucleonic gauges (NGs), also known as Ionising radiation gauging devices (IRGDs), consist of source housing and radiation source such as radioactive material or electrically generated X-ray sources. The NGs are commercially manufactured and extensively used in all types of industries in our country. The gauges are used for measuring the various monitoring and quality controlled parameters during construction and manufacturing process. This includes online measurement of various physical parameters such as thickness, density, level, moisture content and analysis of the composition of metals. The typical activity of radiation sources used in NGs ranges from few MBq to hundreds of GBq.

3.11.1.2 Site and Layout Plan Approval

The manufacturing workplace should be in non-residential or industrial premises, and should have sufficient space for secured storage of the radiation sources. The applicant should submit application for the Authorisation to manufacture the IRGDs/NGs along with detailed layout plan indicating the source handling area and provisions made for secured storage of radiation sources and no separate layout plan approval is issued. The Applicant should also submit the authenticated documents issued by relevant Government agency showing the status of ownership/lease of the premises.

3.11.1.3 Commissioning and Operation

No separate clearance for commissioning and operation of the facility manufacturing nucleonic gauges is required. However, Authorisation for commercial production of IRGDs/NGs is required as mentioned in subsection 3.11.1.2 and the Application for the same is given in **Annexure 35**. The AERB may carry out the inspection of the manufacturing facility.

Prior to seeking the permission for the Authorisation, the manufacturer should have:

(i) Radiological safety officer (RSO)

(ii) Protection level dosimeters

(iii) Personnel monitoring services

(iv) Safe and secure source storage facility

(v) Facility to demonstrate the compliance with type approval performance tests

(vi) Emergency preparedness plans and procedures (EPP)

Based on the review of the application and inspection, if any, AERB may issue Authorisation for the commercial production of NGs/IRGDs.

The manufacturer shall not manufacture, supply or undertake the marketing of the IRGDs without obtaining the Type Approval certificate. The type approved IRGDs shall be supplied only to the users authorised by AERB and records to that effect should be maintained and submitted periodically to AERB. Any unusual occurrence during manufacture should be promptly reported within 24 hours and this should be followed by a detailed report within the prescribed period. The Consentee shall submit to AERB the periodic status reports on manufacturing and supply of IRGDs to the authorised users.

3.11.1.4 Decommissioning/Disposal

The decommissioning plan should be submitted to the AERB when the facility is no longer to be used for manufacturing of IRGDs. The Consentee should check for any contamination in the facility and carry out decontamination, if necessary. The Consentee should obtain an Authorisation for disposal of radioactive waste, if no contamination is present, the facility can be decommissioned and could be released for any other purpose. The Consentee should submit to AERB, report on safe decommissioning, and safe disposal of radioactive waste and personnel doses received during the decommissioning operation.

3.11.1.5 Lead Time for Submission/Availability of Documents

The lead time for submission of documents at any stage of Consenting process is 30 days before the desired date of Consent and the documents should be complete in all respects for review by AERB.

3.11.2 *Facilities Engaged in the Commercial Production of Consumer Products Containing Radioactive Materials*

3.11.2.1 General

Consumer products containing radioactive substances, which are commercially manufactured and extensively used in India, are the radioluminous timepieces and watches, gaseous tritium light sources (GTLS), gaseous tritium light devices (GTLD), ionisation chamber smoke detectors (ICSD), fluorescent lamp starters, anti-static devices and the incandescent gas mantles. The regulatory control is exercised only at the manufacturing stage.

3.11.2.2 Site and Layout Plan Approval

Each of the commercial premises where one or more of the above consumer products containing radioactive substances, is manufactured, has to be approved by AERB. AERB reviews the application for manufacture. The quantity of radioactive substance contained in each product shall not exceed the values specified in the AERB standard specification for 'Radiological

Safety in the Design and Manufacture of Consumer Products Containing Radioactive Substances', (AERB/SS-4). Based on an inspection of the facility and ensuring the availability of trained manpower including RSO Level I, AERB grants Authorisation for the manufacture of the consumer products. The detailed layout plan of the facility should also be submitted at the time of application for authorisation. However, no separate layout plan approval is issued.

3.11.2.3 Commissioning and Operation

No separate clearance for commissioning and operation is issued for the facility engaged for manufacturing of consumer products containing radioactive material. However, an Authorisation for the manufacture of the consumer products is required as mentioned in subsection 3.11.2.2. The application format for obtaining the Authorisation for manufacturing (covering the layout plan approval) of consumer products containing radioactive material is given in **Annexure 36**.

AERB grants Type Approval for each type of consumer product containing radioactive substance material separately prior to its release in the market. Any unusual occurrence during manufacture should be promptly reported within 24 hours and this should be followed by a detailed report within the prescribed period. The consentee has also to submit to AERB periodic reports about the products distributed to each customer and location of its use, wherever applicable.

3.11.2.4 Disposal

The manufacturing premises should be checked for contamination. If contamination exists the premises should be decontaminated to an acceptable level. It can then be declared fit for any use. The active waste should be disposed off after obtaining regulatory clearance.

The user, may procure such consumer product and eventually dispose it off in the public domain without any further control. If large number of consumer products have to be stored/disposed off by the user, the user is advised to seek approval from AERB.

3.11.2.5 Lead Time for Submission/Availability of Documents

The lead time for submission of documents at any stage of Consenting process is 30 days before the desired date of Consent and the documents should be complete in all respects for review by AERB.

3.12 Radioactive Sources in Well Logging

3.12.1 *General*

Well logging is an evaluation technique, which provides fast and detailed data for subsurface and structural mapping of geological formation for exploration of mineral resources particularly oil, gas and coal. The well logging operation involves the use of sealed radioactive sources and portable mini-neutron generators in suitable logging tool for oil exploration. The different techniques like Neutron-Neutron (n-n) Logging, Neutron-gamma (n- γ) logging, Gamma-Gamma (γ- γ) logging are used for detection purpose. The commonly used gamma and neutron sources for this purpose are ^{137}Cs, ^{60}Co, ^{241}Am, ^{241}Am-Be and ^{239}Pu-Be.

3.12.2 *Procurement of Source(s)*

The well logging operation involves the use of sealed radioactive sources in suitable logging tool for oil exploration. For this purpose, the applicant needs to submit an Application to obtain consent for procurement of sealed radioactive sources. This also requires submission of layout details for radiation source storage facility, which is to be approved by AERB.

Based on review of the Application, AERB may issue Consent for the procurement of sealed radioactive sources which includes approval of the layout plan proposed for source storage facility.

In case of import of sealed radioactive sources, a 'No Objection Certificate (NOC)'/Consent for import as part of procurement need to be obtained from AERB.

The Application form for obtaining Authorisation for NOC/Consent for import/procurement of sealed sources for well logging operations is given in **Annexure 37**.

3.12.3 *Commissioning/Operation*

On the procurement of radioactive source(s) by the applicant and its secured storage in approved storage pit, the applicant should intimate the AERB about the receipt of the source(s) and submit the Application for obtaining Authorisation for Commissioning/Operation for well logging activities. The AERB may conduct inspection at the site(s) where well logging operation(s) are undertaken and source storage facilities located as and when required.

Prior to seeking Authorisation for use the radiation source(s) for well logging operation, the applicant should have the following:

(i) Radiological safety officer (RSO)

(ii) Protection level dosimeters

(iii) Personnel monitoring services

(iv) safe and secure source storage facility

(v) Emergency preparedness plans and procedures (EPP)

Based on the review of the Application for Authorisation and information obtained from inspection, if any, AERB may issue the Authorisation for use the radiation source(s) for well logging operation.

The Application format for obtaining the Authorisation for commissioning/ operation for well logging activities involving radiation sources is given in **Annexure 38**.

The Consentee is required to submit to AERB, periodic safety status report. The Consentee should not transfer/move the well logging source(s) to other site(s), without the permission of AERB.

Any unusual occurrence or loss of radioactive source or devices with source therein should be promptly reported within 24 hours and this should be followed by a detailed report within the prescribed period. The AERB may conduct inspection of well logging site as when required.

3.12.4 *Disposal*

When the well logging source is no longer to be used, the Consentee should return the radioactive sources for safe disposal to its original supplier. For this purpose, the Consentee should obtain an appropriate Authorisation from AERB. The application format for obtaining the Authorisation for transfer of radioactive waste for disposal is given in **Annexure 50**.

3.12.5 *Lead Time for Submission/Availability of Documents*

The lead time for submission of documents at any stage of Consenting process is 30 days before the desired date of Consent and the documents should be complete in all respects for review by AERB.

3.13 Medical Diagnostic X-ray Equipment including Therapy Simulator

3.13.1 *Radiotherapy Simulator*

3.13.1.1 General

The aim of simulation is to accurately target or localise the volume which is to be treated. The treatment is planned or simulated on a specially calibrated diagnostic X-ray machine known as a simulator. Most of the radiotherapy centres use either conventional radiotherapy simulator or CT-simulator for localising the target volume and simulating the equipment parameters prior to the actual radiation dose delivery. Both conventional simulator as well as CT-simulator use diagnostic X-ray tube (having tube potential ranging from 40 kVp to 150 kVp and tube current ranging from 20 mA to 800 mA).

3.13.1.2 Site and Layout Plan Approval

The Site and Layout Plan of the radiotherapy simulator/CT-simulator room has to be approved by AERB prior to its construction. The technical parameters as applicable for Site and Layout Plan approval are to be submitted by the applicant.

The format for Application for Site and Layout Plan Approval for radiotherapy simulator/CT-simulator is given in **Annexure 20**.

3.13.1.3 Construction

The construction of radiotherapy simulator/CT-simulator facility can be started after obtaining layout plan approval and no separate regulatory approval is required for construction.

3.13.1.4 Procurement of Radiotherapy Simulator

In order to localise the target volume and simulate the equipment parameters prior to the actual radiation dose delivery using Radiotherapy simulator/CT-simulator unit, the applicant should first submit an application to obtain consent for procurement of radiotherapy simulator/CT-simulator unit. The consentee should ensure before procurement that the radiotherapy simulator/CT-simulator unit is type approved. In case the radiotherapy simulator/CT-simulator unit is not type approved, the local manufacturer/local supplier should submit the documents to AERB demonstrating the compliance with the applicable national/international standards and the Type Approval procedures as per subsection 3.18.1 shall be followed.

Prior to the procurement of the source or equipment with source the applicant should have the following:

(i) Radiological safety officer (RSO)

(ii) Personnel monitoring devices

(iii) Protection level dosimeters

(iv) Radiation protection manual

(v) Room constructed as per AERB approved layout plan.

The Radiation Protection Manual is as per **Appendix 7E**.

Based on review of the Application, AERB may issue Consent for the procurement of radiotherapy simulator/CT-simulator unit. The Application format for obtaining Consent for procurement/import of radiotherapy simulator is given in **Annexure 21**.

3.13.1.5 Commissioning and Operation

After installation of radiotherapy simulator/CT-simulator unit, the Consentee is required to evaluate the performance/acceptance test of the type-approved radiotherapy simulator/CT-simulator unit and reports are to be prepared by the applicant and submitted to AERB for its review prior to grant of consent for commissioning and operation..

The application format for obtaining consent for commissioning and operation of the radiotherapy simulator/CT-simulator unit is given in **Annexure 22**. However, in case the CT-simulator unit is to be used for diagnostic purpose, licence for commissioning and operation shall be obtained as outlined in subsection 3.6.

In case the radiotherapy simulator/CT-simulator unit is not type approved, AERB considers for type approval of the radiotherapy simulator/CT-simulator unit separately as explained in subsection 3.18.1.

Prior to seeking regulatory approval for commissioning and operation, the Consentee should have:

(i) Qualified and trained manpower - radiation oncologist, medical physicist, RSO, and radiation therapy technologist

(ii) Personnel monitoring devices for all workers

(iii) Protection level dosimeters

The Consentee should ensure that

(i) quality assurance (QA) of the radiotherapy simulator/CT-simulator unit, and

(ii) measurement of radiation levels at all occupied locations

are carried out at the time of commissioning and periodically or whenever repairs are carried out that is likely to affect the performance and radiation safety of the unit.

The Consentee is required to submit annual safety status report to AERB at the end of each calendar year. Unusual occurrences should be promptly reported within 24 hours and this should be followed by a detailed report. AERB may conduct inspection for the radiation facility as and when required.

The Consentee shall arrange to constitute a Local Safety Committee with the Head of the institution as Chairman and the RSO as Member Secretary, to review the safety status of all the radiation facilities in the institution. The Committee may also include the service engineer as a member. The minutes of the meetings and the action taken reports shall be available for inspection by AERB.

3.13.1.6 Lead Time for Submission/Availability of Documents

The lead time for submission of documents at any stage of consenting process is 30 days before the desired date of consent provided the application is complete in all respects for review by AERB.

3.13.2 *Medical Diagnostic X-ray Equipment*

3.13.2.1 General

The most common and reliable diagnostic technique in use today is X-ray imaging. In India more than 50,000 X-ray machines are currently in use. The types of X-ray radiography machines vary from simple mobile X-ray units (ranging from 40 kVp to 100 kVp with 20 mA to 100 mA) to larger stationary X-ray units (ranging from 100 kVp to 150 kVp with 100 mA to 800 mA). Radiography is sometimes combined with fluoroscopy (conventional/IIT/ digital). Special machines are capable of dental radiography, ortho-pan-tomograph (OPG), bone densitomet and mammography. Simulator is another X-ray unit used for the verification of the therapy technique prior to start of the external beam therapy in radiotherapy.

3.13.2.2 Site and Layout Plan Approval

The room housing fixed radiography/fluoroscopy units, should be planned in accordance with the radiation safety requirements stipulated by AERB in Safety Code for 'Medical Diagnostic X-ray Equipment and Installations', [AERB/SC/MED-2(Rev.1), 2001]. These are essential in the nature of access control, patient flow control and radiation shielding. Adequate distance from the X-ray unit to walls and ceiling obviates the need for unnecessary shielding and lead lining. Conventional fluoroscopy rooms require proper darkening so that illumination on the screen is possible with minimal beam current and hence minimal patient dose. The format of Application for Site and Layout plan approval of diagnostic X-ray installation is given in **Annexure 39**.

3.13.2.3 Construction:

The construction of the diagnostic X-ray facility can be started after obtaining layout plan approval from regulatory board and no separate regulatory clearance is required for construction.

3.13.2.4 Procurement:

It is to be ensured that only AERB Type Approved diagnostic X-ray units should be installed and used for patient diagnosis in India. In case unit is not Type Approved, supplier/manufacturer has to submit application for Type Approval along with relevant documents to AERB for issuing Type Approval as referred in subsection 3.18.1.

The diagnostic X-ray unit should be installed after obtaining layout plan approval from AERB.

3.13.2.5 Commissioning and Operation

The applicant shall submit an application for Registration of the X-ray facility. The Consentee should have qualified and trained radiologist and radiography technologist/radiographer. The radiographer or the radiologist, who is familiar with basic principles of radiation protection, should be responsible for radiation safety of the patient and the medical staff and may be designated as RSO Level-I with the approval of AERB. The RSO should ensure that personnel monitoring device is made available. QA test reports as per format given in **Appendix 8C-II** OR **8C-III** as appropriate should be prepared and submitted along with the application for registration.

Prior to seeking Regulatory Approval for commissioning and operation, the Consentee should have:

(i) Qualified and trained manpower -X-ray technician, radiologist;

(ii) Personnel monitoring devices for all workers;

In response to the application for registration, AERB may inspect the installation and grant the Registration of the X-ray installation. Any unusual occurrences should be promptly reported within 24 hours and this should be followed by a detailed report.

The application format for obtaining the Registration of the diagnostic X-ray facility is given in **Annexure 40**. For applicants seeking Renewal of Registration, the requisite details need to be filled in the same Registration application format as per **Annexure 40**.

3.13.2.6 Lead Time for Submission/Availability of Documents

The lead time for submission of documents at any stage of Consenting process is 30 days before the desired date of Consent and the documents should be complete in all respects for review by AERB.

3.14 Baggage Inspection System

3.14.1 *General*

Baggage inspection systems are commonly used in airports for identifying the contents inside the baggage. Medium energy X-ray unit is used for scanning the baggage while the latter passes through the conveyor belt.

3.14.2 *Safety Assessment and Approval*

The X-ray unit of the baggage inspection system requires Type Approval from the AERB. Type Approval is issued to the manufacturer, which is explained in subsection 3.18.1.

The AERB assesses the application for use of the certain type of baggage inspection systems. Based on review of the application and inspection of the unit, AERB grants Registration for the installation at a specified location. If the unit is no longer to be used, it can be dismantled and disposed off.

3.14.3 *Lead Time for Submission/Availability of Documents*

The lead time for submission of documents at any stage of Consenting process is 60 days before the desired date of Consent and the documents should be complete in all respects for review by AERB.

3.15 Nucleonic Gauges (NGs)/Ionising Radiation Gauging Devices (IRGDs)

3.15.1 *General*

The nucleonic gauges also known as ionising radiation gauging device (IRGD) contain sealed radioactive source(s), radiation shields, useful beam controls and other components, which form an intergral part of the device. The nucleonic gauges are used for the purpose of determining and/or controlling thickness, density, moisture, level, interface location, and/or qualitative or quantitative chemical composition. These IRGDs are being used by various types of industries. These devices are provided with maximum built-in safety features and consequently need minimum operational controls. Different types of radiation sources with activity ranging from several MBq to hundreds of GBq are being used for this purpose depending on the applications and characteristics of sources. X-ray sources are also used in place of sealed radioactive sources.

3.15.2 *Procurement and Registration*

IRGDs/NG containing sealed radioactive sources or X-ray sources are used for different industrial applications. For this purpose, the applicant needs to submit an Application to obtain consent for procurement of IRGDs/NGs containing sealed radioactive sources. This also requires submission details indicating the layout of the site of installation of IRGD(s) or source storage facility, wherever necessary, which is to be approved by AERB. The device to be procured should also be type approved.

In case IRGD is not type approved, the applicant should submit the documents to the AERB demonstrating compliance with the applicable relevant national/ international standards.

Based on review of the Application, AERB may issue Consent for the procurement IRGD(s) which includes approval of the layout plan of installation of IRGD(s) and/or proposed source storage facility.

In case of import of IRGDs containing sealed sources, a 'No Objection Certificate (NOC)' for import as part of procurement needs to be obtained from AERB.

The format for Application for NOC for import/procurement of IRGD(s) containing radioactive sources is given in **Annexure 41**.

On the procurement of IRGD(s), the applicant should intimate AERB about the receipt of IRGD(s) at the site.

After completion the installation of the IRGD(s) by authorised manufacturer/ vendor/supplier, the applicant should submit the Application for Registration of the IRGD(s) as per the format given in **Annexure 42**. AERB may inspect the IRGD(s) installation site or source storage facility as and when required..

Prior to seeking Registration for the operation of IRGD(s), the applicant should have the following:

(i) Radiological safety office (RSO)

(ii) Protection level dosimeters

(iii) Personnel monitoring services, if necessary

(iv) Safe and secure source storage facility

(v) Emergency response plans and preparedness

Based on the review of the Application for Registration and information obtained from inspection, if any, AERB may issue the Registration of the IRGD(s) installation.

The Consentee is required to submit to AERB periodic safety status report. The Consentee should not transfer the IRGD(s), without the permission of AERB.

Any unusual occurrence or loss of radioactive source or devices with source therein should be promptly reported, within 24 hours, to the AERB and this should be followed by a detailed report within the prescribed period.

In case of a device with a X-ray unit, the same procedure as given in subsection 3.15.2 is to be followed.

3.15.3 *Decommissioning/Disposal*

When the IRGD(s) is no longer to be used, the Consentee should return the radioactive source or IRGD(s) containing radiation source(s) for safe disposal to its original supplier. For this purpose, the Consentee should obtain an appropriate Authorisation from AERB. After the removal of the source for disposal if the contamination exists on the empty source housing of IRGD the contaminated component should be disposed off as radioactive waste through its original supplier. The application format for obtaining the Authorisation for transfer of radioactive waste for disposal is given in **Annexure 50**. The Consentee is required to submit to AERB, a report on

completion of decommissioning, covering safe disposal of the source and contaminated components and personnel doses received during decommissioning operation.

3.15.4 *Lead Time for Submission/Availability of Documents*

The lead time for submission of documents at any stage of Consenting process is 30 days before the desired date of Consent and the documents should be complete in all respects for review by AERB.

3.16 Research Applications using Radioisotopes

3.16.1 *Sealed Radioisotopes in Research and Calibration*

3.16.1.1 General

Sealed radioisotopes in small quantities are used in various research applications such as agriculture, industry, biomedical, biological sciences, education and training. The sources are also being used for calibration of radiation measuring/monitoring devices and pilots in crawler units etc.

3.16.1.2 Procurement and Registration

The applicant needs to submit an Application to obtain consent for procurement of sealed sources. This also requires submission of details indicating the layout of the site of handling/installation , source storage facility, wherever necessary, which is to be approved by AERB. The sealed source should be type approved or in case of low activity sources it should at least meet the relevant standards prescribed by AERB.

In case sealed source is not type approved, the applicant should submit the documents to the AERB demonstrating compliance with the applicable relevant national/international standards as per the application format prescribed in **Annexure 53**.

The AERB assesses the application for the use of sealed sources in the research application, along with the layout plan of the laboratory. Based on nature of radioactive work to be undertaken by the laboratory, availability of trained manpower, qualified radiological safety officer (RSO), radiation protection and monitoring accessories and counting equipment, AERB may grant permission for procuring the radioactive source and may issue Registration of the facility. The format of Applicant or Consent or procurement of sealed radioactive sources for research/calibration purposes is given in **Annexure 66**.

On the procurement of sealed sources(s), and after its installation and or before its use the applicant should submit the application for Registration of sealed radiation sources used in research, calibration of radiation monitors and other applications as per the format given in **Annexure 67**.

AERB may inspect the sealed source installation site or source storage facility as and when required.

Prior to seeking Registration for the use of sealed sources, the applicant should have the following:

(i) Radiological safety officer (RSO)

(ii) Protection level dosimeters

(iii) Personnel monitoring services, if necessary

(iv) Safe and secure source storage facility

(v) Emergency response plans and preparedness

(vi) Provisions/commitment for safe disposal of spent/ disused sources.

Based on the review of the Application for Registration and information obtained from inspection, if any, AERB may issue the Registration of the sealed sources.

The Consentee is required to submit to AERB periodic status report. The Consentee should not transfer the sealed source(s), without the permission of AERB.

Any unusual occurrence or loss of radioactive source or devices with source therein should be promptly reported, within 24 hours, to the AERB and this should be followed by a detailed report within the prescribed period.

3.16.1.3 Disposal

When the sealed sources is no longer to be used, the Consentee should return the radioactive source for safe disposal to its original supplier. For this purpose, the Consentee should obtain an appropriate Authorisation from AERB. After the removal of the source for disposal, if the contamination exists on the empty source housing of sealed sources the contaminated component should be disposed off as radioactive waste through its original supplier. The application format for obtaining the Authorisation for transfer of radioactive waste for disposal is given in **Annexure 50**.

3.16.1.4 Lead Time for Submission/Availability of Documents

The lead time for submission of documents at any stage of Consenting process is 30 days before the desired date of Consent and the documents should be complete in all respects for review by AERB.

3.16.2 *Research Applications using Unsealed Isotopes*

3.16.2.1 General

Unsealed radioisotopes in small quantities are used in various research applications such as in agriculture, industry, biomedical, biological sciences,

and also in teaching. Normally, a few kBq of radioactive sources like ^{3}H, ^{14}C, ^{32}P, ^{35}S, ^{125}I, etc. are used as tracers in such applications.

3.16.2.2 Layout Plan Approval

The layout plan for laboratory handling of unsealed sources shall be approved by AERB. The application format for obtaining the layout plan approval is given in **Annexure 43a**.

3.16.2.3 Commissioning and Operation

The AERB assesses the application for the use of unsealed sources in the research application, along with the layout plan of the laboratory. Based on nature of radioactive work to be undertaken by the laboratory, availability of trained manpower, qualified radiological safety officer (RSO), radiation protection and monitoring accessories and counting equipment, AERB may grant permission for procuring the radioactive source and may issue Registration of the facility. The application format for procurement of radioisotopes for research facilities is given in **Annexure 43b**. The application format for obtaining the Registration of Radioisotope Research Facility is given in **Annexure 44**.

The Consentee should submit to AERB, periodic reports on the safety status.

3.16.2.4 Decommissioning/Disposal

When radioactive work is to be discontinued, the laboratory should be checked for possible contamination and should be decontaminated. The Consentee should obtain an Authorisation for disposal of radioactive waste, which include the routine discharge within authorised activity limits in to sewerage, in the prescribed format. If no contamination is present, the facility could be authorised for decommissioning and could be released for any other purpose. RSO is required to submit to AERB, report on safe decommissioning, disposal of radioactive waste, and personnel doses received during the decommissioning operation. The application format for obtaining the Authorisation for disposal of radioactive waste is given in **Annexure 49**.

3.16.2.5 Lead Time for Submission/Availability of Documents

The lead time for submission of documents at any stage of consenting process is 30 days before the desired date of consent and the documents should be complete in all respects for review by AERB.

3.16.3 *Biomedical Studies on Humans*

3.16.3.1 General

Controlled studies involving exposure of humans to radiation are carried out for various biomedical investigations. It is necessary that the individuals

should be volunteers drawn from a large population, after obtaining their informed consent. Any biomedical work involving radiation should serve a useful purpose and the results should be applied for beneficial knowledge in the subject. It is also important that such results are not already available. Any unnecessary exposure to individuals should be avoided. An Ethical Review Committee of the hospital should review all the proposed biomedical procedures, before Approval of AERB is sought.

3.16.3.2 Commissioning and Operation

The AERB shall review applications for approval of a procedure for biomedical research. Such studies shall be undertaken in laboratories having AERB approval for handling radioisotopes in unsealed form (eg. nuclear medicine laboratory)

The applicant should establish the procedures through animal studies, prior to seeking permission for biomedical programme on humans. The report along with details of the biomedical programme should be submitted to the Ethical Review Committee of the institution. The Ethical Review Committee's recommendation that the procedure adopted might have beneficial results is an essential requirement for carrying out the programme. The applicant should follow the Helsinki Declaration (18th World Medical Assembly, Helsinki, 1964) in selecting the human subjects for the biomedical research.

Based on the inspection and assessment of facilities and availability of trained manpower to carry out the required research work, AERB may grant Registration for the said biomedical research with certain stipulations on radiation safety. The Consentee should follow the stipulations and report to AERB on the safety aspects of the research.

The application format for obtaining the Registration for the biomedical research/studies is given in **Annexure 45**.

3.16.3.3 Lead Time for Submission/Availability of Documents

The lead time for submission of documents at any stage of consenting process is 30 days before the desired date of consent and the documents should be complete in all respects for review by AERB.

3.17 Radio-Immuno Assay (RIA)

3.17.1 *General*

Radio-immuno assay (RIA) is an in-vitro procedure in which radioactivity is not administered directly to patients. Tests are carried out by adding radioactivity to blood samples drawn from patients. Since RIA is a laboratory process, the source storage, assay and waste handling areas need to be demarcated and contamination prevented, contained or controlled.

3.17.2 *Layout Plan Approval*

The layout plan for RIA laboratory has to be approved by AERB. The application format for obtaining the layout plan approval is issued in **Annexure 46**.

3.17.3 *Commissioning and Operation*

Prior to seeking Registration for RIA laboratory, the applicant should have the RIA lab and associated facilities constructed as per plan approved by AERB. The RIA laboratory should have, before commissioning

(i) Technician with prescribed training, and

(ii) Necessary laboratory accessories.

AERB may grant Registration for the facility on the basis of the review of the application form for Registration/NOC for RIA facility, the format of which is given in **Annexure 47**. The NOC for import of radioactive material is a kind of consent issued to enable the consentee to procure radioactive material for the use in the approved RIA facility. This is given as per **Annexure 48**.

3.17.4 *Lead Time for Submission/Availability of Documents*

The lead time for submission of documents at any stage of consenting process is 30 days before the desired date of consent and the documents should be complete in all respects for review by AERB.

3.18 Consent/Type Approval

3.18.1 Type Approval of Sources, Equipment, Devices and Packages

The AERB against an application complete in all respects grants Type Approval for the sources, equipment, devices and packages after detailed review. The pre-requisites for approval of indigenously manufactured items include submission of:

(i) Technical specifications, design and other relevant information

(ii) Quality assurance (QA) programme, wherever applicable, as given in national/international standards

(iii) Test report meeting the relevant specifications in accordance with standards approved by AERB or National/International standards followed.

AERB may carry out review of the test procedures on which the information is provided in the Application.

In the case of imported equipment and devices, AERB may grant 'No Objection Certificate (NOC)' for import based on an application submitted

along with technical details and Certificate of Approval of the country of origin.

The Formats of Application for NOC/Type Approval for various equipment of radiation facilities are given in respective Annexures as indicated in Table given below.

TABLE-1: APPLICABLE FORMAT FOR APPLICATION (ANNEXURE NO. IN THE GUIDE) AND AERB STANDARDS/CODES FOR TYPE APPROVAL OF EQUIPMENT/DEVICES/PACKAGE

Type approval for	Applicable AERB standards/code*	Application format
Package design for transport of radioactive material	AERB /SC/TR-1, 1986	Annexure 52
Sealed sources	AERB /SS-3(Rev.1) 2001	Annexure 53
Telegammatherapy equipment	@	Annexure 54
Medical linear accelerator (MLA)	@	Annexure 55
Brachytherapy equipment	@	Annexure 56
X-ray radiography/Fluoroscopy/ Radiotherapy simulator	@	Annexure 57
Baggage inspection system	@	Annexure 58
Industrial gamma radiography exposure device (IGRED)/Source changer/ Industrial X-ray machine	AERB/SS-1(Rev.1) 2008	Annexure 59
Ionizing radiation gauging device (IRGDs) /Nucleonic gauges(NGs)	AERB/SS-2(Rev.1) 2001	Annexure 60
Consumer products containing radioactive material	AERB /SS-4, 1991	Annexure 61
Medical cyclotron	@	Annexure 62
Industrial accelerator facility [(IARPF) / (PARF<10 MeV)/ (IAF-NDT)]	@	Annexure 63
Gamma irradiation chamber (GIC)	@	Annexure 64
Medical diagnostic equipment (CT/ CATH-Lab)	@	Annexure 65

* List of the applicable AERB standards/codes are given in **Appendix 10**.

@ Applicable IEC, ANSI, DIN, national guidelines and other national/ international standards shall be followed.

The applicant (local supplier) should ensure that the user, to whom equipment is to be supplied, is authorised by AERB to procure the radiation source/ radiation generating equipment. The local supplier should give periodic reports covering addresses of agencies to whom equipment/devices are supplied and submit to AERB a programme made for clients to support activities such as arrangement for calibration etc.

After import and installation of the equipment/device, performance test of the same is to be conducted as applicable by the applicant to demonstrate that its functions meet design intent. This performance verification tests may be witnessed by AERB as required.

Subsequent to grant of NOC by AERB, there is no need to submit separate application form for Type Approval. The same NOC Application form would be reviewed for considering Type Approval. However, other documents as required by AERB as indicated in the respective Annexure for Type Approval should be submitted.

The AERB may grant Type Approval based on the verification of performance and on being satisfied that the equipment/device/package meets the requirements of National/International standards specified in the technical information provided to AERB.

In case of certain imported equipment/devices (such as IRGD), AERB may also consider granting Type Approval based on reviewing of the compliance with applicable national/international standards.

For applicants seeking Renewal of Type Approval, the requisite details need to be filled in a different sections of the same Type Approval application formats (given as per Annexure Nos. mentioned in Table-1). The renewal is also subject to satisfactory compliance with commitments made by the supplier.

3.18.2 *Approval of Shipment for Radioactive Consignment under Special Arrangement*

Certain shipments of radioactive consignment which do not meet all the regulatory requirements can be undertaken only under the provision of Special Arrangement provided in the regulations for safe transport of Radioactive Material. The compensatory safety measures required should be achieved through operational control. The application format for obtaining Approval for shipment under special arrangement is given in **Annexure 51**. The AERB issues approval for such shipments after a detailed assessment.

3.18.3 *Safety Manpower Approval (i.e. RSO Approval)*

The AERB against an application complete in all respects grants Safety Manpower Approval, upon verification of compliance with the qualifications,

training in radiological safety and experience if any, as prescribed by AERB. The radiological safety officer (RSO) may be of Level I, II or III. The level of the RSO and requisite training courses are given in the table below.

Level of RSO	Training course to be completed
RSO Level I	Radiological safety aspects of nucleonic gauges or safety aspects in the research applications of ionising radiation, or any other training on radiation safety deemed to be appropriate and approved by AERB.
RSO Level II	Radiography testing Level- 2, or any other training on radiological safety deemed to be appropriate and approved by AERB.Diploma in Radiation Medicine, Diploma in medical radioisotope technology or any other training courses plus RSO Level- II Certification examination deemed to be appropriate and approved by AERB.
RSO Level III	Diploma course in radiological Physics (Dip. R.P.) or any other equivalent courses, deemed to be appropriate and recognised by AERB.

The application format for obtaining Approval of the radiological safety officer (RSO) for different types of facilities is given in **Annexure 68**. RSO is required to carry out his designated duties including submission of periodic reports on the safety status of the institution to AERB.

3.18.4 *Lead Time for Submission/Availability of Documents*

The lead time for submission of documents is 60/30 [2] days before the desired date of approval and the documents should be complete in all respects for review by AERB.

3.19 Channels of Communication

It is essential that proper channels of communication between the different parties involved be clearly established at the earliest possible stage of the consenting process. This should facilitate a smooth and continuous flow of information and documents to the AERB for its review and assessment, and expediting the consenting process.

The applicant should designate a group or an individual who will be the coordinating agency/representative of the applicant for interaction with the AERB, for a specific facility. This coordinating agency/representative will interact with the concerned safety review committee of the AERB and will submit the requisite documents to the committee, and provide necessary clarifications and supplementary information.

2 For Approvals of shipment and safety manpower

4. REVIEW AND ASSESSMENT PROCESS

4.1 General

The review and safety assessment of a proposed radiation facility is performed by AERB, based on the technical documents submitted in support of the application for regulatory consent. The review enables the AERB to arrive at appropriate decisions regarding the acceptability of the site, design and layout of the radiation facility from considerations of safety. The review and assessment takes into account the safety objectives and requirements specified by AERB in the relevant safety codes and guides and rules issued by the Government of India

The safety objectives are primarily related to the protection of the personnel, the general public and the environment. During normal operation of the facility, the radiation exposures to the personnel within the facility, and exposures to the public frequenting the facility should be kept as low as reasonably achievable (ALARA) and within the prescribed limits.

In the event of unusual occurrences/accidents/incidents in any facility, the radiological consequences should be minimal and the radiation exposures should be within the emergency reference levels.

The AERB performs a step-by-step review and assessment of the proposed facility and the procedure consists of examining the submissions from the applicant on siting of the facility, design of the facility, QA aspects, safety analysis, operational procedures, administrative arrangements, decommissioning of the facility and waste management.

The AERB may also perform an independent analysis on its own, to verify the applicant's evaluations. The submissions to be made by the applicant for Consenting stages for the various facilities have been identified in Section 3.

4.2 Consent for Site

The site identified for locating the facility is reviewed for the favourable characteristics and assessed to verify that no adverse interaction exists between the facility and the site and the suitability of the site for setting up the facility is confirmed.

In the review, AERB takes note of the site characteristics that influence the design of the facility and also the impact on the environment that may lead to specific design or operational requirements.

Seismic aspects of the site are also critically examined, particularly for gamma irradiator facility and integrated facility for radiation technology, where large activity radioactive source is involved and accelerators, such as particle

accelerator facility, medical cyclotron facility, photon and electron beam accelerator radiation processing facility.

Based on these reviews, AERB considers issuance of consent, for the site for locating the radiation facility. In certain cases, inspections are also considered necessary prior to giving regulatory consent.

4.3 Consent for Construction/Layout Plan Approval

For construction clearance, the design of the facility is reviewed in detail with the aid of preliminary safety analysis report (PSAR), wherever applicable. Important to this stage of review is the safety approach of the applicant in respect of defence-in-depth and redundancy in design and accident prevention, which is applicable for gamma radiation processing facility and accelerators. An assessment is made to determine whether all the design safety requirements are met, the design features are compatible with the site, where required, and the facility can be constructed to operate safely.

Issue of construction Consent is considered by the AERB, on compliance with the requirements brought out in the above review. In many cases, where radiation hazard potential is not high, the layout plan approval either as part of site approval or as a separate layout plan approval is treated as part of construction consent and no separate construction clearance is granted. In certain cases, an inspection is also considered necessary prior to giving regulatory clearance.

4.4 Consent for Commissioning

Prior to the issue of Consent for commissioning of equipment and units, the AERB reviews the final and as-built design and conformity of the construction with the design and regulatory requirements.

The programme of commissioning tests and procedures, operating limits and conditions, adequacy of manpower available and their qualification and training are reviewed. In addition, quality assurance reports on installation of equipments and units, are also examined.

The Consent for commissioning of the facility is given in one or more interim stages, as appropriate, depending upon the type of radiation facility. For some of the radiation facilities (see subsections 2.5.1, 2.6.2 and 2.7.2), a combined consent covering both commissioning and operation is granted and hence no separate commissioning clearance is required.

4.5 Consent for Operation

Consenting for the operation of the radiation facility is a major stage in the review process and requires a detailed examination of the facility as a whole, to ensure implementation of all safety provisions and recommendations of the reviewing agency.

A final review of the design of the as-built facility including modifications incorporated and safety analyses, including revisions made in the evaluations due to changes in the design or assumptions, if any, is carried out. This is accomplished by review of the final safety analysis report (FSAR) as submitted by the applicant as part of the review requirement towards this consent stage(see Section 3.0). The status of implementation of the recommendations of the safety review committees is also reviewed, with appropriate follow-up actions. All pending safety issues should be resolved before the consent for operation is considered by AERB.

The technical specifications for the operation of the facility, specifying the safety limits, safety system settings, limiting conditions for operation, surveillance and in-service inspection requirements, are reviewed and approved by AERB for adoption, wherever required, by the radiation facility. The availability of all operating manuals, including operating procedures under emergency condition, is verified.

The radiation protection programme, treatment and discharge of radioactive effluents, management of solid radioactive waste, wherever applicable, and qualification and training for the operating personnel, are important subjects that need to be assessed, before commencement of operation of the facility. Emergency preparedness plans for the radiation facility are also reviewed depending on the type of the facility.

On confirmation of the overall safety of the facility, AERB issues a Consent to the applicant in the form of a licence for continued operation of the facility. The licence may stipulate certain conditions and requirements governing the operation of the facility and also specify a time limit on the validity of the licence.

At times, the AERB may also issue a Consent for operation of a facility for a limited period, if there are certain pending recommendations, which are safety related, and if an undertaking is given by the applicant for their implementation before the expiry of the Consent. On implementing the pending recommendations, the applicant may apply for Consent for continued operation as for normal circumstances.

The facility continues to remain under regulatory control after commencement of operation and is subjected to regulatory inspections and enforcement, to ensure that the facility is being operated as per the regulatory requirements. Details of the periodicity for inspection of the radiation facilities are given in AERB/RF/SM/G-3 (under preparation).

The Licensee is required to submit to the AERB periodic reports on the performance of the facility and its safety status. In addition, data on radiation exposures to the workers and public, disposal of radioactive waste, etc. should

be furnished. It is mandatory for the Licencee to promptly inform any safety related unusual occurrence at the facility and follow it up with a detailed report. Violations of the approved technical specifications for operation should also be reported promptly to AERB, explaining the circumstances/justification for the violation.

4.6 Renewal of Consents for Operation

Before expiry of the validity period of the licence, the Applicant/Licensee should apply for renewal of the Licence. The AERB, after a detailed review of the safety performance of the facility, considers renewal of the Licence.

4.7 Consenting Decisions

The AERB, on the basis of its review and assessment of the radiation facilities, may issue or refuse a regulatory consent. The findings and recommendations of the safety review committees form the basis for such decisions.

Where the AERB had issued a consent for the operation of a facility or trial operation of the facility, the applicant should fulfil the requirements specified in the Consent within the stipulated period. The applicant may apply for an extension of the Consent but should justify with proper reasons for the failure to meet the stipulations in the Consent. The AERB will take an appropriate decision based on the recommendations of the safety review committees.

Any new information that becomes available to the AERB from research and development results, experience at similar radiation facilities elsewhere by way of incidents or accidents, change in off-site conditions etc. will be considered by AERB in its review and assessment process. Where such information has relevance to the safety of the facility, the AERB may stipulate modifications.

The AERB may also perform a review and assessment of previously approved facilities in the light of the new information and make additional recommendations for implementation.

4.8 Licence

4.8.1 *Review Process*

Stagewise regulatory clearances are issued depending on each successfully completed stage of the radiation facility wherever applicable. The AERB may carry out inspection at certain stages, to verify the information provided in the application. In general, a two-tier review process is followed by the AERB before License is granted for radiation facilities as defined in subsection 2.5 (i-viii). Two-tier review includes safety review and assessment by the radiological safety division (RSD) of AERB followed by review in the safety review committee for application of radiation (SARCAR). For gamma

radiation processing facility and high energy particle accelerator facility used for research and industrial processing applications, threetier review is followed. Threetier review includes safety review and assessment by the Radiological Safety Division of AERB followed by review in the safety committee on gamma radiation processing plants (SCOGRAPP) or safety committee for medical, industrial and tesearch accelerators (SCMIRA) which is further followed by the review in the apex committee i.e. safety review committee for applications of radiation (SARCAR).

4.8.2 *Assessment Process*

For consideration of Licence for the facilities defined in subsection 2.5(i-viii), the applicant is required to furnish generally the following

(i) submission of a preliminary safety analysis report(PSAR) covering the design of the source, equipment and facility, layout, wherever applicable;

(ii) proposed quality assurance (QA) programme;

(iii) commissioning/performance tests and results;

(iv) availability of trained and certified manpower such as radiological safety officer (RSO), operators;

(v) availability of personnel monitoring devices;

(vi) availability of radiation monitoring and measuring instruments;

(vii) waste disposal measures; and

(viii) preparedness of plans for likely radiation emergency.

Licence is granted only at the final stage i.e. for regular operation of the facility based on the submission of final safety analysis report(FSAR), wherever applicable; and review of the same by AERB (see section 3). The earlier stages are covered by the regulatory clearances of the siting, construction, commissioning and initial operation.

The Licence is, unless otherwise specified, normally valid for a period of five years and may be renewed after appropriate review of the safety performance.

4.9 Authorisation

4.9.1 *Review Process*

In general, the review for Authorisation for the facilities covered under subsection 2.6.1(i-v), is only one-tier. The AERB may inspect the facility to verify the information provided in the application. The application is reviewed by the Radiological Safety Division, AERB, based on the criteria and guidelines set in the rules, standards, codes and guides.

4.9.2 *Assessment Process*

For consideration of Authorisation for the facilities defined in subsection 2.6.1(i-v), the applicant is required to furnish generally the following:

(i) the submission of the required information covering the design of the source, equipment and layout of the facility, wherever applicable;

(ii) proposed quality assurance (QA) programme;

(iii) availability of type approved sources and devices;

(iv) availability of trained and certified manpower such as radiological safety officer (RSO), operators;

(v) availability of personnel monitoring devices;

(vi) availability of radiation measuring and monitoring instruments; and

(vii) waste disposal measures

The AERB against an application complete in all respects grants Authorisation after review. The AERB may also inspect the facility on the basis of information provided in the application. The Authorisation, unless otherwise specified, is valid for a period of five years and may be renewed after review of the safety performance.

For consideration of Authorisation for the practices defined in subsection 2.6.3 (i-iii), the applicant is required to ensure the following

(i) availability of approved source and radioactive waste transport containers; and

(ii) availability of trained and certified manpower such as radiological safety officer (RSO), operators and technical manpower specified by AERB for specific facility.

For transfer of decayed radioactive sources or radioactive waste to an authorized waste management agency/supplier of the radioactive source, the Authorisation is, unless otherwise specified, valid for a period of three years and may be renewed subsequently. The Authorisation for decommissioning of a facility is granted for a period specified by AERB as required for the purpose of decommissioning.

4.10 Registration

4.10.1 *Review Process*

In general, the review for Registration for the facilities covered under subsection 2.7.1(i-v), is only one-tier review. The AERB may inspect the facility to verify the information provided in the application. The application is reviewed by the Radiological Safety Division, AERB, based on the criteria and guidelines set in the rules, standards, codes and guides.

4.10.2 *Assessment Process*

For consideration of Registration for the facilities defined in subsection 2.7.1 (i-v), the applicant is required to furnish generally the following:

(i) submission of technical details and layout of the radiation facility, where applicable;

(ii) availability of type approved sources and equipment, where applicable;

(iii) availability of trained and certified manpower;

(iv) availability of personnel monitoring devices;

(v) availability of radiation measuring and monitoring survey instruments; and

(vi) waste disposal measures, wherever applicable

The AERB against an application complete in all respects grants Registration after review. The Registration is, unless otherwise specified, valid for a period of five years and may be renewed subsequently.

4.11 Consent/Approval

4.11.1 *Type Approval of Sources, Equipment, Devices, Packages and Approval of Shipment*

4.11.1.1 Review Process

In general, a two-tier review process is followed by AERB before issuance of Type Approval for sealed sources or equipment. Two-tier review includes safety review and assessment by the Radiological Safety Division of AERB followed by review in the safety review committee for application of radiation (SARCAR). For high energy particle accelerators used for research and industrial processing applications, sealed source to be approved as special form and package design, three-tier review is followed, which includes safety review and assessment by the Radiological Safety Division of AERB followed by review in the safety committee for medical, industrial and research accelerators (SCMIRA) or committee for safe transport of radioactive material (COSTRAM) and further followed by the review in the apex committee i.e. safety review committee for application of radiation (SARCAR). For approval of shipment of radioactive consignment one-tier review is followed by AERB. The review includes reasons for application of shipment and safety assessment of the shipment done by the Radiological Safety Division of AERB.

The AERB will examine or scrutinise the test procedures submitted along with the application for type approval of the items and approval of shipment defined in subsection 2.8.1 and review the test results to ensure safety in the operations.

In case of imported equipment and devices, AERB may grant No Objection Certificate based on an Application submitted along with technical details and Certificate issued by the competent authority of the country of origin. The NOC is only for the import of the equipment. After import and installation of the equipment/device, the AERB may carry out verification of performance test of the unit. The AERB may grant Type Approval based on the verification of performance and on being satisfied that the equipment/device meets the requirements of National/ International standards specified in the technical information provided to AERB.

4.11.1.2 Assessment Process

For consideration of Approvals for equipment, devices, sources and shipments listed in subsection 2.8.1, the applicant is required to furnish generally the following:

(i) safety analysis report, as applicable;

(ii) compensatory safety measures to be achieved through operational controls (applicable for shipment approval only);

(iii) quality assurance (QA) programme;

(iv) test report meeting the relevant specifications in accordance with Standards approved by AERB or details of National/International Standards followed along with the certificate issued by the AERB of the country of origin (where applicable).

The AERB against an application complete in all respects grants Approval after review. The Type Approval is, unless otherwise specified, valid for a period of five years and may be renewed subsequently based on its continued compliance wherever applicable.

The Consentee is required to submit to AERB periodic reports on the quality control and quality assurance measures being followed in the manufacture of the approved equipment/devices, transport packages or encapsulation of sealed sources.

4.11.2 *Safety Manpower Approval (i.e.RSO Approval)*

4.11.2.1 Review Process

A two-tier review process is followed by the AERB before issuance of approval of Radiation Safety Officer (Level I, II & III) designated for a radiation facility. Two-tier review includes review by AERB for checking the essential qualifications, training and experience, meeting the requirement, followed by review in the safety review committee for application of radiation (SARCAR).

4.11.2.2 Assessment Process

For consideration of Approval as defined in subsection .2.9.2, the applicant is required to furnish generally the following:

(i) qualification, training and experience etc.;

(ii) institution and nature of the work involved; and

(iii) details of the employer.

The AERB against an application complete in all respects grants Approval, upon verification of compliance with the qualifications, training in radiation safety and experience, if any, as prescribed by AERB. The Approval is valid for a period of three years and may be renewed subsequently on satisfactory performance of duties by the approved individual.

RSO is required to carry out his designated duties including submission of periodic reports on the safety status of the institution to AERB.

4.12 Codes and Guides as Reference Documents

The information and documents to be submitted by the applicant, along with his/her applications for Consent at various stages, and the requirements he/she has to comply with are spelt out in the codes on the subject issued or accepted by AERB. Details are furnished in the guides issued by AERB. Thus codes and guides will be useful to the applicant/Consentee while complying with the requirements, and to AERB while reviewing and assessing the status. **Appendix 10** lists the relevant AERB codes and standards currently available.

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	October 1,	2008
	November 6, 7,	2008
	December 1, 2, 3, 4, 5, 8, 11, 12, 29,	2008
	January 13, 27,	2009
	February 3, 4, 5, 11, 12, 13, 17, 18,	2009
	March 2, 3,	2009
	April 11, 12, 13,	2009
	May 7, 8, 13, 14, 15, 18, 19, 21, 22,	2009

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	June 17, 1999	July 12, 1999
	October 5 & 6, 2000	October 17, 2000
	April 1, 2005	August 4, 2006
	September 25 & 26, 2006	October 5, 2006
	November 24, 2007	July 4, 2008
	August 7 & 8, 2008	November 28, 2008

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PROVISIONAL LIST OF CODES, GUIDES AND MANUALS FOR REGULATION OF NUCLEAR AND RADIATION FACILITIES

Safety Series No.	Titles
AERB/SC/G	Regulation of Nuclear and Radiation Facilities
AERB/NPP&RR/ SG/G-1	Consenting Process for Nuclear Power Plants and Research Reactors
AERB/NF/SG/G-2	Consenting Process for Nuclear Fuel Cycle Facilities and Related Industrial Facilities other than Nuclear Power Plants and Research Reactors
AERB/RF/SG/G-3	Consenting Process for Radiation Facilities
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	Codes, Standards and Guides to be Prepared by the AERB for Nuclear and Radiation Facilities
AERB/SG/G-7	Regulatory Consents for Nuclear and Radiation Facilities: Contents and Formats
AERB/SG/G-8	Criteria for Regulation of Health and Safety of Nuclear Power Plant Personnel, the Public and the Environment
AERB/NPP&RR/ SM/G-1	Regulatory Inspection and Enforcement in Nuclear Power Plants and Research Reactors
AERB/NF/SM/G-2	Regulatory Inspection and Enforcement in Nuclear Fuel Cycle and Related Industrial Facilities other than Nuclear Power Plants and Research Reactors
AERB/RF/SM/G-3	Regulatory Inspection and Enforcement in Radiation Facilities

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