

AERB SAFETY GUIDELINES NO. AERB/RF-RPF/SG-2

GAMMA IRRADIATION CHAMBERS

**Atomic Energy Regulatory Board
Mumbai - 400 094
India**

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Order for this 'Safety Guidelines' should be sent to:

**Chief Administrative Officer
Atomic Energy Regulatory Board
Niyamak Bhavan,
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FOREWORD

Activities concerning establishment and utilization 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 occupational workers, members of the public and 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 has, therefore, undertaken a programme of developing safety standards, safety 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 safety standards are formulated on the basis of internationally accepted safety criteria for design, construction and operation of specific equipment, structures, systems and components of nuclear and radiation facilities. Safety codes establish the objectives and set requirements that should be fulfilled to provide adequate assurance for safety in nuclear and radiation facilities. 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. These documents are revised, when necessary, in the light of experience and feedback from users as well as new developments in the field.

This 'safety guidelines' specifies and elaborates the regulatory requirements for compliance by manufacturers/users of Self-contained Dry Source Storage Gamma Irradiator (Category-I), also known as Gamma Irradiation Chamber (GIC). It gives guidance on consenting stages from design, site and layout for installation, commissioning, operation to ultimate decommissioning and disposal of disused sources. The 'safety guidelines' also specifies the design safety aspects of various critical components and sub-assemblies of the source container of GIC including the quality assurance programme during its design, fabrication, and commissioning. The 'safety guidelines' stipulates requirements of personnel and their responsibilities, safety infrastructure from radiation safety and security considerations.

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

Specialists in the field drawn from Atomic Energy Regulatory Board, the Bhabha Atomic Research Centre, Board of Radiation and Isotope Technology and Indira Gandhi Centre for Atomic Research have prepared this 'safety guidelines'. It has been reviewed by experts and Safety Review Committee for Radiation Processing Plants (SRC-RPP), Standing Committee for Review and Revision of Radiation Safety Documents (SC-RR-RSD) and Advisory Committee on Radiological Safety (ACRS).

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


(S. S. Bajaj)
Chairman, AERB

DEFINITIONS

Activity, A

The quantity 'A' for an amount of radionuclide in a given energy state at a given time is 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).

Accessible Surface

Any surface of the source housing that can readily be reached by any part of the human body without the use of tools or without the removal of any part of the housing.

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 regulatory consent issued by the regulatory body to a proposal.

Atomic Energy Regulatory Board (AERB)

A national authority designated by the Government of India having the legal authority for issuing regulatory consent for various activities related to the nuclear and radiation facility and to perform safety and regulatory functions, including their enforcement for the protection of 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').

Carrier

An individual, organisation or government, undertaking the transport of radioactive material by any mode of transport. The term includes both carriers for hire (known as contract carriers) and carriers on own account (known as private carriers).

Commissioning

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

Competent Authority

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

Consent

A written permission issued to the 'Consentee' by the regulatory body to perform specified activities related to nuclear and radiation facilities. The types of consents are 'Licence', 'Authorisation', 'Registration' and 'Approval', and will apply according to the category of the facility, the particular activity and radiation source involved.

Consentee

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

Consignee

Any individual, organisation or government which receives a consignment.

Consignment

Any package or packages, or load of radioactive material, presented by a consignor for transport.

Consignor

Any individual, organisation or government, which presents a consignment for transport, and is named as consignor in the transport documents.

Contamination

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

Controlled Area

A delineated area to which access is controlled and in which specific protection measures and safety provisions are, or could be, required for:

- controlling normal exposures or preventing the spread of contamination during normal working conditions; and
- preventing potential exposures or limiting their extent should they occur.

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.

Disposal (Radioactive Waste)

Emplacement of waste in an appropriate facility without the intention of retrieval.

Disposal

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

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.

Dose Limit

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

Effective Dose

The quantity 'E', defined as a summation of the tissue equivalent doses, each multiplied by the appropriate tissue weighting factor:

$$E = \sum_T W_T \cdot H_T$$

where 'H_T' is the equivalent dose in tissue 'T' and 'W_T' is the tissue weighting factor for tissue 'T'.

Emergency

A non-routine situation that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human health and safety, quality of life, property or the environment. This includes nuclear and radiological emergencies and conventional emergencies like fires, release of hazardous chemicals, storms, tsunamis or earthquakes. It includes situations for which prompt action is warranted to mitigate the effects of a perceived hazard.

Emergency Plan

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

Employer

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

Exposure

The act or condition of being subject to irradiation. Exposure can be either external (irradiation by sources outside the body) or internal (irradiation by sources inside the body). Exposure can be classified as either normal exposure or potential exposure; either occupational, medical or public exposure; and in intervention situations, either emergency exposure or chronic exposure. The term 'exposure' is also used in radiation dosimetry to express the amount of ions produced in air by ionising radiation.

Handle

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

Incident

Any unintended event, including operating errors, equipment failures, initiating events, accident precursors, near misses or other mishaps, or unauthorized act, malicious or non-malicious, the consequences or potential consequences of which are not negligible from the point of view of protection or safety.

Inspector (Regulatory)

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

Irradiation

Exposure to ionising radiation.

Irradiator

A facility that houses a particle accelerator, X-ray machine or large radioactive sources for imparting high radiation dose 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 or to an organisation having overall responsibility to perform specified functions related to a facility or an activity.

Monitoring

The continuous or periodic measurement of parameters for reasons related to the determination,

assessment in respect of structure, system or component in a facility or control of radiation.

Occupational Worker

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

Operation

All activities following and prior to commissioning performed to achieve, in a safe manner, the purpose for which a nuclear/radiation facility is constructed. For nuclear power plants, this includes maintenance, refueling, in-service inspection and other associated activities.

Operating Personnel

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

Operational Limits (Radiation)

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

Package

The packaging with its radioactive contents as presented for transport.

Packaging

The assembly of components necessary to enclose the radioactive contents completely.

Personnel Monitoring

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

Prescribed Limits

Limits established or accepted by the regulatory body.

Public Exposure

Exposure incurred by members of the public from radiation sources, excluding any occupational or medical exposure and the normal local natural background radiation, but, including exposure from authorised sources and practices and from intervention situations.

Quality Assurance

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

Quality Control (QC)

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

Radiation

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

Radiation Facility

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

Radiation Generating Equipment

Device capable of generating radiation, such as X-rays, neutrons, electrons or other charged particles.

Radiation Incident

An incident associated with the possibility of exposure.

Radiation Protection Survey/Radiological Survey

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

Radiation Surveillance

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

Radiation Worker

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

Registration

A type of regulatory consent issued by the regulatory body for sources and practices of low hazard (see also 'Consent').

Regulatory Body

(See 'Atomic Energy Regulatory Board').

Radioactive Material / Radioactive Substance

Any substance or material, which spontaneously emits radiation in excess of the levels prescribed by notification by the Central Government.

Radioactive Waste

Material, whatever its physical form, left over from practices or interventions for which no further use is foreseen: (a) that contains or is contaminated with radioactive materials 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.

Radiological Safety Officer

Any person who is so designated by the employer and who, in the opinion of the Competent Authority, is qualified to discharge the functions outlined in the Radiation Protection Rules, 2004.

Regulatory Inspection

An examination through review of documents, observation, measurement or test undertaken by or on behalf of the regulatory body during any stage of the regulatory consenting process, to ensure conformance of materials, components, systems and structures as well as operational and maintenance activities, processes, procedures, practices and personnel competence with predetermined requirements.

Rules

Atomic Energy (Radiation Protection) Rules, 2004.

Sealed Source

Radioactive source material that is either permanently sealed in a capsule or is closely bounded and in solid form. The capsule or material of a sealed source should be strong enough to maintain leak tightness under conditions of wear and tear for which the source was designed and also under foreseeable mishaps.

Source

Anything that causes radiation exposure, either by emitting ionising radiation or releasing radioactive materials or materials.

Source Holder (Source Cage)

A device used to support and retain the source in position.

Source Housing (Container)

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

- (a) define the useful beam; and
- (b) limit the radiation level outside the useful beam to maximum permissible leakage levels, as specified by the Competent Authority.

Special Form Radioactive Material

Either an in dispersible solid radioactive material or a sealed capsule containing radioactive material and approved by the Competent Authority as special form radioactive material.

Type B (M) Package

A package, whose design or shipment requires multilateral approval because it does not meet all requirements of a Type B (U) package.

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'.

Type Approval

Approval, issued by the Competent Authority, based on evaluation of the device to ensure that it conforms to the safety standards prescribed by the Competent Authority.

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 worker).

SPECIAL DEFINITIONS
(Specific for the present 'Safety Guidelines')

Capsule

Protective envelope used for prevention of leakage of radioactive material from a sealed source.

Encasement

A cover suitably designed to protect the enclosed primary shielding material; this does not include cosmetic shells and cabinets.

Operator

The person responsible for operation of the radiation facility as per written instructions and established standard operating procedures and, complying with the eligibility criteria as specified by the regulatory body.

Primary Shielding

The material integral to the design of the irradiator that has its primary function as attenuation of radiation emitted by the sealed source(s) to acceptable levels.

Safety Interlock

A safety interlock is an engineered device for precluding likely exposure of an individual to ionizing radiation, either by preventing entry to the controlled area or by automatically removing the cause of the hazard.

Gamma Irradiation Chamber

The Self-Contained Dry Source Storage Gamma Irradiator is also known by its commercial names, such as Gamma Irradiation Chamber (GIC). An irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source(s) is shielded at all times, and human access to the sealed source(s) and the volume(s) undergoing irradiation is not normally possible in its design configuration.

All the terms not defined in this 'Safety Guidelines' but defined in the Rules have the meaning assigned to them in the Rules.

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LIST OF PARTICIPANTS

TASK GROUP FOR PREPARATION OF 'SAFETY GUIDELINES' ON GAMMA
IRRADIATION CHAMBER (TG-SG-GIC)

SAFETY REVIEW COMMITTEE FOR RADIATION PROCESSING PLANTS (SRC-RPP)

STANDING COMMITTEE FOR REVIEW AND REVISION OF RADIATION
SAFETY DOCUMENTS (SC-RR-RSD)

ADVISORY COMMITTEE ON RADIOLOGICAL SAFETY (ACRS)

LIST OF REGULATORY DOCUMENTS ON RADIATION PROCESSING FACILITIES

1. INTRODUCTION

1.1 General

The Self-contained Dry Source Storage Gamma Irradiators are also known by its commercial names, as Gamma Irradiation Chambers (GIC), Gamma Chambers, Blood Irradiators (BI) or Gamma Cells. Such irradiators are being extensively used in various universities, academic and research institutions for research and development purposes. Gamma Irradiation Chambers are also used in hospitals and blood banks for irradiation of blood and blood products/components, for clinical and research purposes.

GIC unit mainly houses either ^{60}Co or ^{137}Cs radiation sources with typical radioactivity ranging from tens to hundreds of TBq. These doubly encapsulated high activity sources are placed in a source cage assembly and kept shielded at all times by lead encased in stainless steel material. X-ray based irradiation chambers with operational rating in terms of hundreds of keV, are also used in research institutions, hospitals and blood banks for irradiation of blood and blood products/components.

Considering that the GIC house/possess radioactive material or radiation generating equipment (X-ray device), certain requirements have to be met to ensure the safety of radiation workers and members of the public. All manufacturers / suppliers of GIC are required to seek approval from AERB for the design of GIC (i.e. Type approval certification from design and safety considerations), prior to its supply and routine operation.

1.2 Objective

The objective of this 'safety guidelines' is to stipulate the radiation safety and regulatory requirements and provide guidance covering consenting stages from design, site and layout for installation, commissioning, operation to ultimate decommissioning and disposal of disused sources of GIC unit, in line with AERB Safety Code on 'Regulation of Nuclear and Radiation Facilities' (AERB/SC/G) and AERB Safety Guide on 'Consenting Process for Radiation Facilities' (AERB/RF/SG/G-3), in order to ensure that radiation workers and members of the public do not receive radiation dose in excess of the limits specified by the Competent Authority.

1.3 Scope

This 'Safety guidelines' covers safety requirements and procedures for Self-contained, Dry Source Storage Gamma Irradiators (Category-I) that contain sealed sources and X-ray based irradiators for their installation, operation, servicing and maintenance and decommissioning from radiation safety considerations as well as security of radioactive material during their use, storage and transport.

It also stipulates the requirements for availability of the trained manpower for safe operation, servicing and maintenance of GIC along with appropriate radiation monitoring instruments.

It also provides 'safety guidelines' for manufacturer for design, manufacturing, supply, installation and commissioning of the GIC unit. However, the design aspects for X-ray based devices are not covered in this 'safety guidelines'.

2. DESIGN SAFETY ASPECTS OF GAMMA IRRADIATION CHAMBERS

2.1 Introduction

Self-contained, Dry Source Storage Gamma Irradiation Chamber of Category-I, contains sealed gamma radiation emitting sources of high intensity which are completely enclosed in a dry container (source transport container) constructed of solid materials. Radiation sources are shielded at all times and human access to the sealed source and the volume undergoing irradiation is not physically possible in the designed configuration.

Gamma Irradiation Chambers (GIC) are required to be transported by road, sea and air to different locations for their use and operation. In view of this, the design of GIC shall be in compliance with national/international standard. This section describes the requirements for safe design, construction, installation and operation of GIC, so that all built-in-safety design features are incorporated while manufacturing and supplying such units. The detailed design requirements of source container for housing the radioactive source of GIC unit are as given in **Appendix A**.

2.2 Sealed Sources

2.2.1 Performance Requirements:

The sealed source for GIC (Category-I irradiator) should meet the minimum performance requirements of C/E 43423 with Bend Test 4 as specified in AERB Safety Standard on, 'Testing and Classification of Sealed Radioactive Sources' [AERB/SS/3 (Rev.1), 2001].

Imported sources should satisfy the requirements specified in AERB/SS/3 (Rev.1), 2001 or an international standards for sealed sources such as ISO, ANSI or other relevant standards.

2.2.2 Certification and Documentation

The source manufacturer or supplier should maintain records relating to the sealed source(s) and provide this information to meet the requirements of licensing, transportation etc.

The records should include the following:

- (a) Make, model number and identification number of source (s), the contained radioisotope, activity and date of measurement
- (b) Physical and chemical form
- (c) Sealed source classification certificate (e.g. AERB/ISO/ANSI)
- (d) Bend test certificate, as per applicable standard
- (e) Leak test certificate, as per applicable standard
- (f) Contamination test certificate, as per applicable standard.
- (g) Special form test certificate if required by the transportation authorities
- (h) Any other documentation required by the Competent Authority.

The certificates listed above should be obtained from accredited laboratory/ manufacturer.

2.3 Leakage Radiation Levels for GIC

The maximum permissible leakage radiation levels from GIC unit with maximum designed source strength for various modes of operation shall not exceed the limits as mentioned in the Table given below:

Mode of Operation	Location	Radiation Level should not Exceed
Irradiate/ Storage	5 cm from the accessible surface	200 μ Sv/h
	1m from the accessible surface	20 μ Sv/h
Sample Load / Unload / Transient	5cm from the accessible surface	2 mSv/h
	1m from the accessible surface	100 μ Sv/h

2.4 Radiation Protection Survey and Radiometry of GIC

2.4.1 The RSO of manufacturer institution should conduct a radiation protection survey and radiometry of each GIC unit after manufacturing and prior to its dispatch/supply, to establish compliance with radiation levels as given in section 2.3. A copy of the survey report and radiometry report should be retained by the manufacturer or person in charge of the GIC for inspection by the AERB.

2.4.2 A calibrated survey meter capable of measuring the required radiation levels shall be used for radiometry.

2.4.3 The radiometry test report should include the following information of GIC:

- (a) Make, model and serial number
- (b) Sealed source specifications including the following:
 - (i) Name of source manufacturer or supplier
 - (ii) Identity of radionuclide
 - (iii) Source model, serial number and activity of each sealed source as on date
 - (iv) Source geometry, total source activity as on date.
- (c) Date of radiation protection survey
- (d) Measured radiation levels with the GIC in different modes of operation other than the transient condition giving the highest external radiation readings. The positions where readings were taken should be recorded.
- (e) Make, model, serial number and date of the recent calibration of survey instrument.
- (f) Particulars of the individual responsible for radiometry.

2.5 Measurement Configuration

The exposure rates measured at 1 meter from the accessible surface of the GIC to the effective center of the detector chamber should be averaged over an area of 100 square centimeters (cm²) having no linear dimension greater than 20 cm. Measurements at a distance of 5 cm from the accessible surface of the GIC to the effective center of the detector chamber should be averaged over an area of 10 square centimeters (cm²) having no linear dimension greater than 5 cm.

2.6 Operational Safety Features

General radiation safety features should be provided to preclude the presence of radiation levels in excess of the levels specified in section 2.3 of this 'safety guidelines'.

- (a) The irradiator should not be operable until all shielding is in place and all other safety devices are actuated.
- (b) The GIC mechanism and controls should be designed to protect against operational errors. Should the irradiator be operated in incorrect sequence or in case more than one control/command is actuated at the same time, it should not function.
- (c) There should be a provision for manually returning the GIC to its 'not in use' mode in the event of power failure.
- (d) Means should be provided to terminate an irradiation and return to its 'not in use' mode at any time.
- (e) Each irradiator should have a master control that should be used to prevent unauthorized operation. This control may be a key operated switch.
- (f) For operational security the GIC design should have features like password protection, key-operated switch, mechanical lock and key etc.

2.7 Indicators

- (a) Each indicator should be clearly labeled to indicate its function.
- (b) Appropriate colour indicators may be used to identify operational status of GIC unit.

Condition	Recommended Colour
Emergency (stop buttons or lights)	Red
Warning-Hazard	Red
Critical Information (source in use or malfunction)	Red
Caution (no emergency, but awareness of some function taking place)	Orange or Yellow
Normal	Green
Information	Blue

- (c) A visual indication of the GIC's operational status (ON/OFF) should be provided at all times.

2.8 Labeling

2.8.1 General

2.8.1.1 Each GIC unit should bear a metallic label displaying radiation symbol and the words in English, Hindi and local language as given below:

“RADIATION- KEEP AWAY”

AND

“CAUTION-THIS UNIT SHOULD NOT BE SCRAPPED/ DISPOSED OFF/ DISMANTLED WITHOUT PRIOR APPROVAL OF SUPPLIER AND REGULATORY BODY (ATOMIC ENERGY REGULATORY BOARD)”

2.8.1.2 The GIC should have a clearly visible metallic label identifying the contained radionuclide, activity content, and the date of measurement.

The label should also include the following information:

- (a) Name and address of manufacturer
- (b) Make, model and serial number of GIC
- (c) Type of radionuclide and maximum design strength
- (d) Competent Authority identification mark for Type B package
- (e) Maximum irradiation volume

2.8.1.3 If a separate control panel or console is utilized it should be easily identifiable as being part of the GIC.

2.8.1.4 While securing labels, care must be taken not to drill through the metal container shell into the lead shield.

2.8.2 Depleted Uranium (DU) Shielding

2.8.2.1 If depleted uranium (DU) material is used in GIC for shielding purposes, each piece should be clearly stamped or engraved with the words:

CAUTION: RADIOACTIVE MATERIAL FOR SHIELDING-
DEPLETED URANIUM (DU)

2.8.2.2 In addition, any part or component of the GIC containing depleted uranium as shielding should be clearly stamped, engraved, or labeled with the words:

CAUTION:
THIS COMPONENT CONTAINS RADIOACTIVE MATERIAL FOR
SHIELDING - DEPLETED URANIUM (DU)

3. QUALITY ASSURANCE

3.1 Introduction

An adequate Quality Assurance (QA) programme, including appropriate Quality Control (QC) measures should be employed in the design and manufacturing of GIC including operation, and servicing and maintenance of the unit to ensure that the products and services are designed and delivered in conformance to national/international 'Engineering and Safety Standards'.

The following aspects should be considered for developing an adequate QA & QC programme:

- (a) Quality assurance organization
- (b) Design control
- (c) Manufacturing process controls
- (d) Documentation and records

A brief description of the various aspects of QA/QC programme is as follows:

3.2 Quality Assurance Organisation

Designer/manufacture of GIC should establish, implement and monitor the QA programme at all levels within the system. The QA policy of the organization should be to ensure that the products and services are designed and delivered as per national/international standards. A sample QA programme for manufacturer of GIC is given in **Appendix B**.

3.3 Design Control

3.3.1 Design

Design of the equipment should be based on functional requirements, relevant national and international engineering codes and standards and other regulatory requirements as specified in the applicable AERB/ IAEA safety documents.

The requirements of these Codes and Standards should be fully met in the equipment design, specification and testing. A design safety report and design drawings should be prepared for the review and discussion purposes, to ensure that all the requirements are met.

3.3.2 Compliance with Design Requirements

The design of source transport container should meet the performance requirements of Type B Transport Package also, as specified in the national / international regulations for the Safe Transport of Radioactive Material.

Compliance with design requirements should be demonstrated to the AERB by subjecting validated scale model or prototype of the unit to the test prescribed in relevant AERB safety document or by appropriate simulated analytical/ computational methods.

Final design and fabrication drawings should be prepared based on the above test results before obtaining type approval from the Competent Authority.

3.3.3 Design Changes

Design changes in any component affecting radiation safety should be carried out only with the prior approval of the Competent Authority.

3.4 Manufacturing Process Controls

Manufacturing of the product should be carried out as per the approved drawings, specifications, processes and testing procedures provided by the manufacturer.

Each unit should be checked for operational requirements by subjecting it to a number of trials in all modes as per the operating instructions manual.

The equipment should be tested before and after source loading. The shielding integrity (radiometry) test for GIC unit as given in **Appendix C**, should be carried out to confirm that the radiation levels are within the limits specified in section 2.3 of this 'safety guidelines'.

3.5 Documentation and Records

All documents and records pertaining to material and component tests, dimensional inspections, functional tests, operational performances and servicing and maintenance should be maintained by the manufacturer / supplier of the unit. These records should be available for traceability till the unit is disposed off by the supplier / manufacturer as per the decommissioning and disposal guidance provided in Section 8 of this 'safety guidelines'.

4. REGULATORY REQUIREMENTS

4.1 Introduction

The licensee shall meet the various regulatory requirements for siting, layout, construction, import/procurement of GIC unit, its installation, routine operation, decommissioning, disposal and security aspects of GIC, given in this section. It also covers the design approval requirements for manufacturer/supplier of the GIC unit.

4.2 Site and Layout

Once the proposed installation site is assessed for its suitability by an applicant after consultation with manufacturer/supplier of the GIC unit, the applicant should submit to AERB the proposed layout of the GIC installation site along with floor plan of entire building, for layout approval. AERB may carry out the inspection of proposed location. The site and layout requirements for installation of GIC unit are specified in **Appendix D**.

The site should be preferably at ground floor of the building with accessibility for movement of GIC for installation and commissioning in view of the concentrated heavy weight of the unit, which is about 5 tons.

It should be located in an exclusive room having provisions of lock and key arrangement restricting access for unauthorized entry. The room for GIC installation may be of normal brick wall construction. However, it should be ensured that radiation levels outside the room housing GIC unit shall not exceed the AERB specified limit of 1 $\mu\text{Sv/h}$.

4.3 Import/ Procurement of GIC

For procurement of an indigenously manufactured GIC unit, applicant should submit the application in the prescribed format to the Competent Authority for obtaining the consent after ensuring that the manufacturer/supplier of the GIC unit is in possession of valid Type Approval certificate issued by the Competent Authority.

For first time import of any GIC model, the supplier should obtain 'No Objection Certificate (NOC)' from the Competent Authority by submitting the application in prescribed format. Upon import and installation of the equipment in the country, the supplier shall demonstrate Type Approval testing of the equipment to AERB. Based on the satisfactory demonstration of Type Approval testing, Type Approval certificate for such equipment shall be issued by the Competent Authority. Only Type Approved GIC equipment shall be used in the country.

The applicant should comply with the requirements for availability of manpower and safety infrastructure as stated below:

- (a) Radiological safety officer (RSO)
- (b) Personnel monitoring devices (e.g. TLD)
- (c) Radiation monitoring devices (e.g. radiation survey meter)

- (d) Emergency response plans and procedures (EPP)
- (e) Security plan for the facility
- (f) Provision /commitment for safe disposal of spent/disused sources.

The applicant shall not operate the GIC unit without obtaining the Licence for Operation from the Competent Authority.

4.4 Licence for Operation

- 4.4.1 Once the unit is received and installed at the approved site, the applicant is required to submit to the Competent Authority the intimation of receipt and installation of the GIC unit in the prescribed format at the earliest.
- 4.4.2 After installation of the GIC unit by manufacturer /their authorized supplier, the applicant should obtain the Licence in the form of Authorization from the Competent Authority for operation of the GIC unit.
- 4.4.3 The Licensee shall ensure compliance with regulatory requirements in respect of trained manpower and safety infrastructure as stipulated in section 4.3 and terms and conditions of the Licence.
- 4.4.4 The GIC unit or its part thereof should not be transferred by sale or otherwise to any person without obtaining prior approval from the Competent Authority.
- 4.4.5 Prior to obtaining the licence, a separate fund should be earmarked by the employer (in the form of bank guarantee) towards expenditure for removal and transport of sources if required. The bank guarantee for such purpose should be deposited in consultation with supplier of GIC/source. The quantum of the fund shall be reviewed periodically by the user in consultation with supplier of GIC/source.

4.5 Decommissioning and Disposal

The decommissioning of GIC unit and safe disposal of disused radiation sources should be carried out, as per the procedures specified in section 8 of this 'safety guidelines'.

4.6 Type Approval of GIC Unit

Every GIC unit should meet the requirement for design safety and QA aspects as given in sections 2 and 3 of this 'safety guidelines', for obtaining Type Approval from the Competent Authority.

4.6.1 Type Approval/No Objection Certificate

4.6.1.1 *Indigenously Manufactured GIC Unit*

Prior to supply of the GIC unit, the indigenous manufacturer should obtain a Type Approval certificate from the Competent Authority to supply GIC unit. Type Approval certificate may be issued only if the equipment, radioactive source and transport package satisfy the safety specifications prescribed in the applicable standards and this 'safety

guidelines'. The indigenous manufacturer should demonstrate test results as specified for the Type Approval compliance to AERB for seeking Type Approval certification.

4.6.1.2 Imported GIC Unit

No Objection Certificate (NOC)/ Type Approval certificate may be issued by the Competent Authority in respect of imported GIC unit, if equipment, radioactive source and transport package satisfy the safety specifications prescribed in the applicable standards and this 'safety guidelines'.

Upon import and installation of the GIC unit, the supplier should demonstrate various test results as specified for the Type approval compliance to AERB for seeking Type Approval certification.

4.7 Dose Rate Profile Verification of GIC for Sample Irradiation

The initial dose profile inside the sample chamber should be provided by manufacturer during supply and installation of GIC unit to the user institution.

However, if the Licensee desires to verify the dose rate and dose profile of GIC unit in their possession, a fresh dosimetry/ inter comparison may be carried out either with the help of manufacturer/supplier of the GIC or through national/international standards laboratory or an accredited laboratory by using appropriate dosimetry methods.

4.8 Security of Gamma Irradiation Chamber

The employer should make adequate provisions for the security of GIC unit all the time, against all envisaged sabotage or any other kind of security threat; as per the guidance specified in AERB Safety Guide on 'Security of Radioactive Sources in Radiation Facilities' [AERB/RF-RS/SG-1, (2011)].

5. PERSONNEL REQUIREMENTS AND RESPONSIBILITIES

5.1 Introduction

The responsibilities of various personnel involved for ensuring safety in manufacture, supply and use of GIC are prescribed as given in subsequent sub sections.

5.2 Employer

The employer should have responsibilities listed in Rule 20 of the Atomic Energy (Radiation Protection) Rules, 2004 including those to:

- (a) designate, with the written approval of the Competent Authority, a person having qualifications as specified in this 'safety guidelines', as Radiological Safety Officer (RSO);
- (b) ensure that provisions of this 'safety guidelines' are implemented by the licensee, Radiological Safety Officer and other worker(s);
- (c) provide facilities and equipment to the licensee, RSO and other worker(s) to carry out their functions effectively in conformity with the regulatory constraints;
- (d) prior to employment of a worker, procure the dose records and health surveillance reports, from his former employer, where applicable. Also upon termination of service of worker provide his/her dose records and health surveillance reports, to his/her new employer on request;
- (e) arrange for health surveillance of workers as specified under Rule 25 of Atomic Energy (Radiation Protection) Rules, 2004;
- (f) provide personnel monitoring devices to radiation workers, and ensure that they are worn as required, and also ensure that individual dose records are maintained as prescribed by the Competent Authority;
- (g) furnish to each worker dose records and health surveillance reports of the worker in his/her employment annually, as and when requested by the worker and at the termination of service;
- (h) inform the Competent Authority if the licensee or the RSO leaves the employment,
- (i) inform the Competent Authority, within twenty four hours, of any accident involving a source or loss of source of which he/she is the custodian;
- (j) in case of permanent termination of the use of GIC with radioactive source due to any reason, should decommission the unit and return the source to the supplier with prior permission of the competent authority;
- (k) should keep the documents/history of GIC in safe custody. Hand them over to new custodian with intimation to the Competent Authority;
- (l) should obtain prior permission of the competent authority in case of transfer of ownership of GIC unit;
- (m) obtain prior approval from the Competent Authority for any modifications in location of installation, and

- (n) ensure that all applicable requirements of other relevant regulatory authorities are met.

5.3 Licensee

5.3.1 The licensee should have responsibilities listed in Rule 21 of the Atomic Energy (Radiation Protection) Rules, 2004 including those as follows:

- (a) all applicable rules and procedures specified in this 'safety guidelines' are established and maintained;
- (b) all requirements of other relevant regulatory authorities are met;
- (c) the necessary equipment to enable the working rules and emergency procedures to be efficiently carried out is readily available;
- (d) radiation monitoring is carried out in accordance with the regulatory requirements;
- (e) all systems/components features are regularly serviced and maintained in good working order; servicing and maintenance should be carried out and as per the manual provided by the manufacturer/designer and records are maintained. All component replacement record should be maintained in the log-book;
- (f) radiation monitoring equipment is regularly inspected, maintained and periodically calibrated, at least once in two years;
- (g) periodic tests and inspections of safety systems and control mechanisms are carried out; the records are maintained and are available for inspection by the regulatory body;
- (h) adequate instruction is given to employees concerning any radiation hazards associated with their work, and any precaution necessary to limit radiation exposure of persons and to avoid radiation accidents and injuries;
- (i) no person is permitted to operate the GIC unit unless she/he has been adequately trained and is competent to operate the GIC unit in accordance with the safety procedures;
- (j) the Competent Authority is informed promptly of the occurrence, investigation and follow up actions in cases of exposure in excess of regulatory constraints, including steps to prevent recurrence of such incidents;
- (k) periodic safety status report of the facility in the prescribed format is submitted to the Competent Authority;
- (l) loading, replenishment, redistribution or disposal of sources is carried out only by the authorised source supplier;
- (m) standard operating procedure (SOP) is developed and implemented during operation of GIC unit. This SOP should include specific Dos and Don'ts;
- (n) it is ensured that the samples which are irradiated in GIC unit would not result in hazardous situations such as fire, explosion and corrosion to arise inside the chamber, and

- (o) in case licensee leaves the organization or discontinues the use of GIC, she/he should handover documents/details/keys etc. to employer and advice about decommissioning of the unit, as per regulatory requirements.

5.4 Radiological Safety Officer (RSO)

5.4.1 Qualification of RSO

The person to be designated as RSO should have minimum qualification as given below:

- (i) Basic Degree in Science from a recognized University/Institution; or Diploma in Engineering from a recognized University/Institution; and
- (ii) A training course as prescribed and approved by the Competent Authority ,i.e. ‘RSO Certification for Gamma Irradiation Chamber’.

5.4.2 Responsibilities

The RSO shall have responsibilities listed in Rule 22 of the Atomic Energy (Radiation Protection) Rules, 2004, including those to:

- (a) ensure that the provisions of the Atomic Energy (Radiation Protection) Rules, 2004 , are implemented;
- (b) advice and assist the employer and licensee in ensuring regulatory compliance for obtaining consent from the competent authority for procurement, use, transport or disposal of radioactive material;
- (c) implement all radiation surveillance measures including display of radiation symbol and warning at the entrance door of room where GIC unit is installed. Implement continuous display of the radiation symbol, warning, marking and labeling on the unit;
- (d) establish and maintain an effective radiation protection programme to ensure safety of workers, members of the public and the environment;
- (e) instruct all operators/users on relevant safety measures, provide adequate training in radiation protection and safety methodologies, use of personnel monitoring devices (TLD badges);
- (f) ensure that personnel monitoring devices are provided to radiation workers in the facility, used as required and are securely stored in radiation-free zone
- (g) maintain personnel monitoring records, analyse personnel exposure records to ensure that there are no abnormal exposure trends;
- (h) prepare the standard operating procedures (SOP) from detailed instruction manual provided by manufacturer/supplier of the GIC unit;
- (i) ensure that radiation monitoring instruments are kept in proper working condition and are periodically calibrated, at least once in two years;
- (j) assist the licensee in developing suitable emergency response plans to deal with emergencies and ensuring appropriate emergency preparedness;
- (k) conduct periodic radiation protection surveys and maintain records;
- (l) maintain inventory of sources including initial and present activity, operational logbook and associated QA records;
- (m) ensure periodic servicing and preventive maintenance of the GIC unit as

- prescribed by manufacturer/supplier and maintain records;
- (n) ensure safe work practices during source replenishment and safe disposal of disused sources;
- (o) furnish to the licensee and the Competent Authority periodic reports on safety status of the GIC unit;
- (p) investigate any situation that could lead to potential exposures and submit report to the competent authority;
- (q) report on all hazardous situations along with details of any immediate remedial actions taken are made available to the employer and licensee for reporting to the Competent Authority;
- (r) ensure the physical security measures such as physical protection systems, access control procedures to the GIC room and access to the unit (e.g. key or password protection of unit) are in place;
- (s) advise the licensee on the modification in the working condition of female worker after her notification about pregnancy and
- (t) inform the competent authority when she/he leaves the employment;

5.5 Worker (Operator/User of GIC)

Worker (Operator/user of GIC) is the person who is directly involved in day-to-day manufacture/operation/ use of the GIC unit.

The worker (operator/user) should:

- (a) be familiar with the basic design, operation and preventive maintenance of the GIC unit including procedures for routine operation and handling emergency situations;
- (b) operate the GIC unit as per the standard operating procedures (SOP) prepared by RSO from detailed instruction manual provided by manufacturer/supplier of the GIC unit;
- (c) follow all applicable rules and regulations for safe operation of GIC unit;
- (d) ensure proper handling and placement of the sample/product inside the sample chamber based on the dose profile of the sample chamber;
- (e) maintain the logbook in respect of use and operation of the unit including personnel details and of samples/objects under irradiation, dose rate, dose delivered and time of irradiation;
- (f) make proper use of protective equipment, radiation monitors and personnel monitoring devices as provided;
- (g) report to RSO/licensee of any issues related to safe operation of the GIC; including the circumstances that could adversely affect safe operation of GIC unit;
- (h) be familiar with area security safeguards such as locks, posting signs, warning lights and interlock systems; and
- (i) in case of a female worker, on becoming aware that she is pregnant, notify the employer, licensee and RSO in order that her working conditions may be modified, if necessary.

5.6 Manufacturer/Supplier of GIC unit

5.6.1 The manufacturer/supplier should:

- (a) ensure that only Type Approved GIC units are supplied ;
- (b) ensure compliance with terms and conditions of Type Approval;
- (c) supply the GIC unit only to the users authorised by the Competent Authority;
- (d) maintain records of units manufactured and supplied, including type of radiation sources, activity as on date, sealed source and leak test certificate, dose rate and dose profile of the unit;
- (e) ensure the availability of essential spare parts of the GIC unit for its useful life;
- (f) ensure that the GIC unit is serviced and maintained whenever required;
- (g) assure the refurbishment and source replenishment in the GIC unit, when requested by user, as applicable in compliance with regulatory procedures;
- (h) undertake the responsibility for providing technical support in decommissioning and disposal of disused sources of the GIC unit; and
- (i) take back the disused sources supplied by them for disposal.

5.6.2 The manufacturer/supplier should provide appropriate training to the personnel of user institution involved in operation, servicing and maintenance of GIC, which should include:

- (a) sequence of operation,
- (b) precautionary measures,
- (c) Dos and Don'ts during safe operation,
- (d) servicing and preventive maintenance aspects, and
- (e) security aspects

5.6.3 The manufacturer/supplier should provide following to the user:

- (a) Unit make, model and Sr. No., details of radiation sources and activity, sealed source and leak test certificate;
- (b) Dose rate and dose profile of irradiation chamber and dosimetry report;
- (c) Radiometry report of the GIC unit;
- (d) Gadgets and accessories (hand crank etc.), as required, for the operation of the GIC unit and for handling an emergency situations;
- (e) Procedures for testing of interlocks and control functions; and
- (f) Written instruction manual for safe operation, periodic inspection, servicing, preventive maintenance including general description of the GIC unit and detailed operating instructions and procedures to follow in case of an emergency situation that has caused or may cause a radiation hazard to any individual.

6. RADIOLOGICAL SAFETY REQUIREMENTS

6.1 Introduction

The activity of the radioactive material used in GIC unit is typically in the order of tens to hundreds of TBq. As part of radiation protection programme the employer should provide the following safety infrastructure.

6.2 Personnel Monitoring Service

The employer should provide an appropriate personnel monitoring device to determine radiation doses received by each person who:

- (a) is involved in routine operation and maintenance of GIC unit, and
- (b) frequently uses the GIC unit for handling the samples for irradiation.

When not in use, the TLD badges should be kept in isolated and specified location away from GIC installation in a radiation free area under custody of RSO.

6.3 Radiation Monitoring

- (a) The employer/licensee should ensure that suitable radiation measuring instrument should be available in working condition to carry out radiation protection survey of GIC unit.
- (b) The radiation survey meter should be periodically calibrated, at least once in two years and records are maintained.
- (c) The calibration of a radiation survey meter should be traceable to the national/international standards laboratory.

6.4 Radiation Protection Surveillance of GIC Unit

- 6.4.1 The manufacturer/supplier should carry out the initial radiation protection survey in and around the room where GIC unit is installed and provide the radiation protection survey report as well as installation report to user institution. These initial radiation levels are the baseline measurements at the site for future reference.
- 6.4.2 The employer/licensee should ensure that the RSO carries out the routine radiation protection surveys of GIC unit at least once in three months and maintain the records.
- 6.4.3 The radiation protection surveys of GIC unit should be carried out in the event of any incident which may hamper the functioning of GIC unit, e.g. stuck sample chamber, breakdown of wire rope/driving mechanism or after every servicing or any repair of GIC unit.

7. SOURCE LOADING AND REPLENISHMENT

7.1 Introduction

Source loading/replenishment operation should be carried out by manufacturer/ authorised supplier of the GIC unit, who is equipped with necessary infrastructure (such as hot cell, remote handling tools, suitable radiation monitors, material handling systems etc.) and trained and experienced manpower for these purposes.

7.2 Source Loading in a New GIC Unit

Source loading may be carried out in a newly fabricated GIC unit which is manufactured as per the relevant Safety Standard and the guidelines.

The following measures should be adopted:

- (a) The source of desired activity not exceeding the designed/approved strength should be loaded in the source cage.
- (b) The radiation levels and contamination levels, if any, of GIC unit loaded with source should be measured and records maintained.
- (c) Further tests and trials such as functionality, radiometry, dosimetry, proper markings and labeling should be carried out prior to dispatch of the GIC unit.

7.3 Source Replenishment

In case of source replenishment of GIC unit the manufacturer should carry out various checks on components and the systems such as source container assembly of GIC from radiation safety point of view, critical weld joints (circumferential and longitudinal) of the outer shell of the container and for subsequent repair if required.

Based on checks, furnish report to AERB for obtaining the source replenishment permission. The source loading to be carried out as per the guidance given in section 7.2.

7.4 Source Loading at the Site

Source loading can be carried out at the site subject to the following conditions:

- (a) It should be carried out by supplier or authorised representatives with prior approval of the Competent Authority
- (b) Transport of sources in the approved transport container
- (c) Availability of necessary infrastructure/gadgets for source transfer operation
- (d) Availability of trained and experienced manpower
- (e) Supervision by Radiological Safety Officer of the user institution/supplier.

8. DECOMMISSIONING AND DISPOSAL

8.1 Introduction

In case GIC is of no use to the institution for its intended purpose and the institution desires its safe disposal, the employer/licensee should initiate suitable procedures for decommissioning of the disused GIC unit and safe disposal of the radioactive sources by returning the GIC to the manufacturer/ supplier.

8.2 Procedure for Disposal

Licensee shall obtain prior approval from the Competent Authority for decommissioning, transport and safe disposal of radioactive material by submitting the application in the prescribed format.

Upon obtaining the approval for decommissioning, licensee should approach the manufacturer/supplier for its decommissioning and transportation of disused sources in GIC unit.

The room housing GIC can be released for any other use by the institution only after decommissioning of the GIC installation.

8.3 Transport of GIC for Disposal

The packaging and transport of GIC unit should be in compliance with requirements for safe transport of radioactive material as prescribed by the Competent Authority.

The transportation of GIC units from manufacturer/supplier institution to the user institution and vice-versa should be carried out by adhering to the security guidance specified in AERB Safety Guide on 'Security of Radioactive Material during Transport' [AERB/NRF-TS/SG-10, (2008)].

9. EMERGENCY RESPONSE PLANS AND PREPAREDNESS

9.1 Introduction

An emergency is a non-routine situation that necessitates prompt action, primarily to mitigate a hazard or adverse consequences for human health and environmental safety. Being the custodian of the radiation sources, handling of the radiation emergency situation, mitigating the consequences and making preventive measures to avoid any recurrence of such situation in future are the responsibilities of the employer.

9.2 Emergency Response Plans and Preparedness

The licensee should prepare emergency response plans, as per Rule 33 of Atomic Energy (Radiation Protection) Rules, 2004, in coordination with the RSO, which envisages various emergency scenarios/situations that may be encountered and action plans for responding to emergencies to mitigate their consequences.

Action plans corresponding to emergencies should be made available to mitigate any consequences of emergency scenarios/situations that may occur during transportation, installation, routine operation and decommissioning of GIC unit.

The emergency situation may fall in the following categories:

- (a) Receipt of a GIC from the supplier in a damaged condition
- (b) Loss or theft of GIC during transport
- (c) Damage to the GIC during transport
- (d) Mechanical damage to GIC unit during storage at the site prior to installation
- (e) Damage to the GIC, if any, during installation and commissioning
- (f) Radiation levels in excess of the baseline/normal values recorded during installation of the GIC by the manufacturer/supplier
- (g) Fire incident, explosion or natural disaster such as earthquake etc. at GIC installation location
- (h) Malevolent actions by the anti-social elements leading to damage of GIC.

The emergency response plan shall be specific to each situation and should include following aspects:

- (a) Identification of reasonably foreseeable accidents and other incidents or occurrences and their predicted consequences
- (b) Communication procedures, including an emergency call out list
- (c) Availability of emergency equipment, including a list of the equipment that should be available and its location
- (d) Availability of first aid equipment, including a list of the equipment that should be available, its location and the names of persons trained to use it (where applicable)
- (e) An outline of the post-emergency recovery procedures designed to restore normal operating conditions.

The model emergency response plans and procedures are as given in **Annexure I**.

9.3 Display of Emergency Procedures

Instructions should be provided specifying procedures to be followed in an emergency situation, which should be concise, unambiguous, easily followed, practicable and simple to restore the normal situation by keeping exposures to individuals at ALARA. The procedures laid down for this purpose should be displayed in the GIC room. This should include the name(s) and contact details of responsible personnel of GIC institution, to be contacted in case of emergency.

In addition, the contact details of important persons from outside agencies like, local Law Enforcement Authority (police), fire brigade, nearest hospital, source supplier, AERB and Crises Management Group (CMG), DAE should also be listed in the procedures.

9.4 Identification and Training of Emergency Handling Personnel

The licensee should ensure that all the personnel involved in handling of GIC are familiar with the emergency action and should be educated about emergency situations. They should be informed that the potential radiological consequences of an emergency situation involving GIC are limited because of the design and construction standards of GIC.

9.5 Reporting of Radiation Emergency

Employer/licensee should report every unusual incident/emergency to the Competent Authority immediately and certainly within 24 hours of its occurrence. The details should include:

- (a) Date and time of its occurrence
- (b) Brief description of the unusual incident
- (c) Source activity at the time of incident
- (d) Action taken
- (e) Probable cause of the incident
- (f) Personnel radiation exposure, if any
- (g) Lessons learned to prevent similar incidents and accidents in the future
- (h) Improvement in the emergency plans and preparedness, if any.

APPENDIX - A

DESIGNING OF SOURCE CONTAINER FOR GIC UNIT

Primary shielding material of this source transport container is generally lead (Pb) which is completely encased and seal welded inside a material whose melting point is above 700 °C. Depleted Uranium (DU)/tungsten can also be used for primary shielding. In case of DU appropriate cladding should be provided over it to prevent degradation of the material due to oxidation and hydride formation. The combination of all these materials (Lead, Depleted Uranium / Tungsten) can also be used as primary shielding material for the construction of source container of GIC.

Design and fabrication guidelines with respect to certain critical components/sub- assemblies of source container of GIC are as follows:

A.1 Outer Shell Encasement Thickness

The recommended minimum outer shell encasement thickness for lead –in-steel container may be calculated by the following equation:

$$t_{os} = 1.3 (w/s)^{0.71}$$

where:

t_{os} = Outer shell thickness of container in mm,

w = Total mass of container in kg,

s = ultimate tensile strength of encasement material in MP_a,

(1MPa = 0.102 kgf/ mm², i.e. kilogram-force/square millimeter)

- Note: (i) The above thickness is to be multiplied by a factor 1.3, when diameter of container is less than 760 mm (30 inches), and
(ii) Ultimate elongation of the encasement material should be greater than 40%.

A.2 Inner Shell Thickness (t_{is})

Thickness of the inner shell cavity of source container which houses radioactive material should be calculated and established carefully such that the inner shell cavity remains serviceable under all expected external and internal loads.

External loads are imposed due to:

- (a) static head of molten lead during pouring,
- (b) the shrinkage of lead upon cooling, and
- (c) expansion of lead resulting from a fire, or displacement of lead as a result of impact.

Whereas the internal loads occur possibly from the thermal expansion of internal components such as source cage or basket etc.

In view of the above, the inner shell thickness of the source container should be designed as if it were an unfired pressure vessel and meets, as a minimum requirements of Division

1 of Section VIII of the ASME Boiler and Pressure Vessel Code. This Code relates size, material of construction, and internal and external pressures to thickness.

The inner shell thickness so derived from the above considerations should have a minimum thickness equal to that of outer shell thickness due to its service conditions and other fabrication criteria such as for preparation of weld joints particularly that for corner joints which have been found to be most vulnerable from development of gross crack during 'Mechanical Test' (9 meter drop test followed by 1 meter puncture test) for Type B package.

A.3 Encasement Penetration

When lead is encased in steel, it is recommended not to carry out any tapping or drilling holes into the encasement without providing suitable size welded backing steel material, so that molten lead does not flow out from the container as a result of any fire.

A.4 Tubes through Encased Shielding

Access tubes or drain tubes which pass through any encased shielding should be seal welded to the encasement and should have a wall thickness which is at least 5% of the tube outside diameter. The orientation of access tubes or drain tubes passing through the shielding material inside the source container should not have a straight path; it should have a zigzag path, so as to restrict the leakage radiation levels on the outer surface within the permissible limits.

A.5 Dished End for Corner Welds Joints of Encasement

Most vulnerable weld joints are corner welds joining the shells to top and bottom plates of the container. During the mechanical test (9 meter drop test and 1 meter puncture tests) of Type B package, these welds are required to bend or rotate through an angle of 90° , which may result in developing a gross crack unless the corner is adequately designed.

In view of this it is recommended to remove the weld joints from the vulnerable areas by using a dished or formed head in place of a flat plate for ends of the container. The design of other welded joint that is not a part of the container assembly, should be carried out based on sound engineering practices.

A.6 Container Closure Lid (Lead Plug) & Closure Bolts

The primary functions of a closure lid or lead plug is to provide proper access to the inner shell cavity within the container for source loading / unloading operations inside a hot cell and then firmly securing the sealed sources after source loading in such a manner that the source assembly remain confined inside the container during both normal as well as accident conditions of transportation.

Closure bolting system of lead plug which fastens the lid with the main body of the container is, therefore, recommended to be designed to withstand expected decelerating forces resulting from 9 meter drop and 1 meter puncture tests.

Bolt size of less than 12 mm diameter normally should not be selected because of the danger of overstressing the smaller sizes of bolts.

A.7 Source Cage Assembly

Source cage assembly facilitates holding of the sealed sources normally in cylindrical configuration and it is loaded remotely in the container. A properly spaced locations of sealed sources inside the source holder helps to provide a better dose uniformity inside the sample chamber of GIC.

A.8 Lifting Lugs of Outer Shell (Encasement) and Slings

Lifting lugs for the purpose of this 'safety guidelines' are the lifting devices that are integral part of the container and should be capable of withstanding a load arising due to snatch lifting. Therefore, these lifting lugs system along with their lifting wire rope slings are recommended to be designed to withstand a total load of at least three times the weight of the package (total weight of container and its packaging) to meet the snatch lifting requirements.

A.9 Construction of Materials of Encasement and other Related Components

The primary objectives of source container are to shield and to contain adequately a source of radioactive material while meeting all the stipulated requirements under a number of environmental conditions as specified in the safety regulations.

The properties of material of construction therefore should have adequate strength at elevated temperatures, and ductility and resistance to brittle fracture at -40 °C. In addition, factors such as ability to resist corrosion by decontamination solutions, galvanic corrosion between adjacent materials and stress corrosion should be considered.

Materials that require a minimum of 20 Joule (15 ft-lb) energy to break a 'Charpy keyhole Specimen' at temperature of -40 °C are considered adequate to meet the safety requirements.

Austenitic stainless steels conforming to ASTM specifications or equivalent standards should be meeting the above properties adequately and it is recommended to use ASTM A240 type stainless steel of grade 304 for outer and inner shells as well as for other structural parts of container unless the applications require the added corrosion resistance for decontamination in the heat affected weld zones that is provided by grade 304L, 321, and 347 of stainless steel.

However considering all the above requirements, it is advisable to use SS 304L grade or its equivalent for fabrication of source container.

A.10 Materials for Bolting, Pipes and Tubes

Materials for bolting, pipes and tubes should be also of austenitic stainless steel from the above considerations. However, wherever the above stringent criteria are not required in

the case of bolting materials, the low alloy steel bolting material could be used rather than stainless steel to minimise galling of threads during repeated assembly operations.

A.11 Shielding Material

If lead is used for shielding, it is normally specified as ASTM B29, pig lead, chemical grade having minimum of 99.96% purity. No Antimony (Sb) material should be added as alloying material to lead, as it lowers the melting point and has tendency to form cracks, spongy area and voids.

APPENDIX- B

A SAMPLE QUALITY ASSURANCE PROGRAMME FOR MANUFACTURING OF GIC

An effective Quality Assurance (QA) Programme should be followed during the manufacturing process of GIC to ensure that a good quality product as per the design, drawings and specifications is delivered for the safe operation and handling by the users.

The following QA aspects should be adhered to during manufacturing with duly observing applicable industrial safety standards:

- (a) All materials used for fabrication should comply with the standards specifications. They should be properly marked and correlated with the mill test reports or supported by test certificates from accredited laboratories. Copies of all approved test reports and certificates should be documented.
- (b) Bought out components should be inspected and approved /certified by the manufacturer and the compliance certificates should be submitted.
- (c) All the weldings and their NDT tests should comply with requirements of ASME Boiler and Pressure Vessel Code (Section IX).
- (d) Radiographic tests (RT) of welding should be carried out as specified in individual drawing as per the acceptance criteria in Section - V of ASME Boiler and Pressure Vessel Code.
- (e) Inspection/verifications of dimensions and alignment of sub-assembly/ assembly should be carried out at various stages of fabrication, including tests like hydrostatic pressure and lead filling etc.
- (f) The fabricator should prepare a detailed lead pouring procedure with approval of manufacturer. Lead pouring should be done in a single, continuous operation ensuing that no high, local/ streaming radiation (hot spots) observed at the outer surface of the container.
- (g) The integrity of casted lead should be checked by radiometric test by using an appropriate radioactive source and detector.
- (h) Documentation and records should be maintained pertaining to various stages of fabrication and testing of the unit.

APPENDIX – C

SHIELDING INTEGRITY (RADIOMETRY) TEST

Shielding integrity tests should be carried out because a void or low-density region will create a 'hot spot' or elevated radiation region on the cask surface when in use.

Before the initial use of the source container for transportation of radioactive source, the integrity of the shielding of the container/cask should be demonstrated. The container should be loaded with the type of radioactive source for which it is designed (or an equivalent source), and the entire outer surface should be surveyed for ascertaining that the leakage radiation levels are within the permissible limits as specified in section 2.3 of this 'safety guidelines'.

Gamma Scanning and Probing

This test is a quality control operation often specified to ensure that the container will comply with the prescribed radiation leakage requirements when it is loaded with the radioactive material to be transported. When the test is included in the contract, the requirements should be given as below:

The fabricator should prepare a gamma scanning procedure, which should include following information in detail:

- (a) Electronic equipment used
- (b) Radiation source and its activity/strength
- (c) Type of radiation detector with its desired sensitivity
- (d) Calibration standards for both scanning and probing
- (e) Grid pattern
- (f) Positioning equipment
- (g) Method of reading and recording the radiation levels observed
- (h) Measuring technique
- (i) Acceptance criteria.

The procedure used for assessing the shielding integrity/radiometry of GIC should be acceptable to the manufacturer / their authorised representative prior to its application. The results of radiometry should be recorded. The procedure and all the results should be made a part of the fabrication record.

APPENDIX – D

SITING AND LAYOUT REQUIREMENTS FOR GAMMA IRRADIATION CHAMBER

The site layout for installation of Gamma Irradiation Chamber (GIC), should meet the following requirements:

- (a) The room for installation of GIC should be an exclusive room having provisions of lock and key arrangement for preventing access by unauthorised personnel.
- (b) This room for GIC installation may be of normal brick wall construction. However, it should be ensured that radiation levels outside the room housing GIC unit shall not exceed the AERB specified limit of 1 $\mu\text{Sv/h}$.
- (c) The room should have following features:
 - (i) Preferably located on ground floor for ease of installation
 - (ii) Adequate room size to house the GIC unit
 - (iii) Door size – adequate enough for taking the unit (assembled) inside the room
 - (iv) Floor loading capacity – as per the weight and base size of the unit.

ANNEXURE-I

MODEL EMERGENCY RESPONSE PLANS AND PROCEDURES

I.1 Introduction

The action plans prescribed in these procedures should be implemented in the event of occurrence of an emergency involving a Gamma Irradiation Chamber (GIC). The criteria for declaring and for terminating an emergency, as stipulated should be adhered to.

I.2 Emergency Situations

The following emergency situations may occur during transportation, installation, routine operation, decommissioning and disposal of GIC unit.

- (a) Receipt of GIC from the supplier in a damaged condition
- (b) Loss or theft of GIC during transport
- (c) Damage to the GIC during transport
- (d) Mechanical damage to the GIC unit during storage at the site prior to installation
- (e) Damage to the GIC, if any, during installation and commissioning
- (f) Radiation levels in excess of the baseline/normal values recorded during installation of the GIC by the manufacturer/supplier
- (g) Fire incident, explosion or natural disaster such as earthquake etc. at GIC installation location
- (h) Malevolent actions by anti-social elements leading to damage of GIC.

Any person noticing any of the above mentioned emergency situations should immediately bring to the notice of Employer/Licensee/RSO of the institution.

Action plans that should be implemented for various emergency scenarios are as follows:

I.3 Emergency Scenarios

- (a) Receipt of a GIC from the supplier in a damaged condition
- (b) Mechanical damage to the GIC unit during storage at the site prior to installation
- (c) Damage to the GIC, if any, during installation and commissioning

Action Plan

Licensee/RSO:

- (i) Check with carrier how the GIC device has got damaged.
- (ii) Inform the Competent Authority and the manufacturer/ supplier, that GIC unit is received in a damaged condition
- (iii) Measure the radiation levels around the device and record the observations. If the measured levels are in excess of the prescribed limits, report the matter to manufacturer/supplier and the Competent Authority
- (iv) Cordon off an area of at least 3 metres around any unsecured source(s)
- (v) Arrange for adequate security for the damaged GIC unit

- (vi) Act as advised by the Competent Authority manufacturer / supplier for corrective measures
- (vii) If the device is examined by the supplier and thereupon declared safe for installation and operation inform the employer
- (viii) Inform the Competent Authority regarding the action taken.

I.4 Emergency Scenario: Damage to the GIC during transport

Action Plan

Carrier:

- (i) Immediately inform the consignor and the consignee
- (ii) Cordon off an area of at least 3 metres around any unsecured source(s); and
- (iii) Inform the nearest police station for help.

Manufacturer/User institution:

- (i) Upon receipt of information about a transport accident involving GIC from the transporter, the consignor should inform to the Competent Authority, manufacturer and the Employer/Licensee of user institution
- (ii) The intimation should be sent immediately to the Crisis Management Group (CMG), DAE and AERB
- (iii) Responsible officer from manufacturer and/or user institution should be deputed to the site of accident with emergency accessories (eg. survey meter, TLD etc.) to assess the extent of physical damage to the GIC consignment and the radiation levels around it
- (iv) The decision for its further transportation to the manufacturers place or the users place should be based on the assessment of severity of the damage
- (v) In case of significant damage to the GIC and observation of excessive radiation level, adequate additional shielding should be provided for further transportation of GIC to manufacturer's place for rectification and necessary action.
- (vi) Upon controlling the emergency situation, intimate the Consignor, the Consignee and the Competent Authority.

I.5 Emergency Scenario: Loss or theft of GIC during transport

Action Plan

Carrier:

- (i) Immediately inform the Consignor, the Consignee, AERB and the Crisis Management Group (CMG), DAE, about the incident;
- (ii) Follow the instruction stipulated in emergency preparedness procedures sheet and TREM CARD; and
- (iii) Inform the nearest police station about the incident and seek help.

Consignor:

- (i) Upon receipt of information about an incident from transporter involving the GIC, the intimation should be sent immediately to the Crisis Management Group (CMG), DAE and the Competent Authority
- (ii) Immediately establish contact with nearest police station and seek its help by sensitizing the police officials regarding the seriousness of the incident in view of involvement of loss/untraced radioactive material consignment
- (iii) Responsible officer from the manufacturer and/or the user institution should be deputed to the location of the incident with emergency accessories (e.g. sensitive survey meter, direct reading pocket dosimeter, TLD etc.) to trace the consignment.
- (iv) In case, the consignment is not traceable:
 - (a) continue the efforts for locating the consignment;
 - (b) inform all the concerned authorities and get updates regularly till consignment is located;
 - (c) make public aware through media/news channels etc. in consultation with the Competent Authority, about the loss of radioactive material and its serious consequences, if the lost consignment is damaged while lying in public domain; and
 - (d) urge the public to immediately report to the nearest police station about such consignment, if they come across.
- (v) In case, the consignment is located:
 - (a) cordon off an area of at least 5 metres, around the GIC unit;
 - (b) assess the extent of damage in terms of physical integrity and radiation leakage that has occurred to the GIC;
 - (c) decision for its further transportation to manufacturers place or users place should be based on the assessment of severity of the damage;
 - (d) in case of significant damage to the GIC and observation of excessive radiation levels, adequate additional shielding should be provided for further transportation of GIC to manufacturer's place for rectification and necessary action, and
 - (e) upon controlling of the emergency situation, intimate all the concerned authorities about the same.

I.6 Emergency Scenario: Radiation levels in excess of the baseline/normal values on the GIC unit during routine operation**Action Plan****Licensee/RSO:**

- (i) Counter check the radiation levels with a calibrated and functional survey meter
- (ii) Provide temporary additional shielding to reduce the radiation levels to permissible limit

- (iii) Inform the manufacturer/supplier and the Competent Authority for further course of action
- (iv) Investigate personnel exposure, if any, to the radiation workers involved in the remedial action.

I.7 Emergency Scenario: Fire incident, explosion or natural disaster such as earthquake etc. at the GIC installation location

Action Plan

Licensee/RSO :

- (i) In case of fire or explosion contact the fire department for help
- (ii) RSO should provide guidance to fire fighters about the safe handling of the fire incident, as GIC is housed with a radioactive material, there is a possibility of loss of shielding integrity during fire and may cause higher radiation levels around GIC
- (iii) After controlling the fire measure the radiation levels to check the shielding loss if any. If required temporary additional shielding should be provided to reduce the radiation levels to permissible limit
- (iv) Check the radiation contamination, if any
- (v) Inform the manufacturer/supplier and Competent Authority for further course of action
- (vi) Investigate personnel exposure, if any, to the radiation workers involved in the remedial action.

The Employer/Licensee/RSO should submit a detailed report on the fire incident, with radiation exposures to personnel, if any, to the Competent Authority.

Manufacturer/Supplier:

- (i) On receipt of information, responsible officer from manufacturer should be deputed to the institution to assess the extent of damage in terms of physical and radiation leakage occurred due to the fire accident.
- (ii) Repair of GIC for re-use or decommissioning can be taken up by the manufacturer based on the assessment of the damage.

I.8 Emergency Scenario: Malevolent actions by the anti-social elements leading to damage of the GIC

Action Plan

Licensee/RSO :

- (i) Close down the GIC facility to prevent access, depute the response force (Security personnel) to prevent unauthorized access
- (ii) Inform the nearest police, i.e. Law Enforcement Authority
- (iii) In case of damage, assess the situation and if needed, provide temporary

- additional shielding to reduce the radiation levels to permissible limit
- (iv) In case of fire or explosion contact the fire department for help and follow the procedures as given in fire incident
- (v) Inform CMG, DAE, Competent Authority and manufacturer/supplier
- (vi) Investigate personnel exposure, if any, to the radiation workers involved in the remedial action.

The Employer/Licensee/RSO should submit a detailed report on the incident, with radiation exposures to personnel, if any, to Competent Authority.

I.9 List of Important Contact Numbers for Emergency

List of important personnel/agencies to be contacted in the event of an emergency should include the following. This list should be displayed in GIC room as well as available with all the personnel who have a role in the emergency plan.

Name of Person/ Agency	Designation	Mobile Number	Address		Telephone No	
			Office	Residence	Office	Residence
Employer						
Licensee						
RSO						
Security Officer						
Fire Brigade						
Local Police						
Local Hospital						
Manufacturer/Supplier						
AERB						
CMG, DAE						
Any other relevant Authority						

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February 28, 2013
November 11, 2013
January 28, 2014
June 13 & 27, 2014
July 31, 2014
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October 08, 2014

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Date of meeting : March 26, 2015

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LIST OF REGULATORY DOCUMENTS ON RADIATION PROCESSING FACILITIES

Safety Series No.	Title
AERB/RF-RPF/SC-1	Radiation Processing Facilities
AERB/RF-RPF/SG-1	Plant Commissioning/Re-commissioning Dosimetry for Food & Allied Products in Gamma Radiation Processing Facilities- Type II & IV
AERB/RF-RPF/SG-2	Gamma Irradiation Chambers
AERB/RF-RS/SG-1	Security of Radioactive Sources in Radiation Facilities
AERB/NRF-TS/SG-10	Security of Radioactive Material during Transport
AERB/SC/G	Regulation of Nuclear and Radiation Facilities
AERB/RF/SG/G-3	Consenting Process for Radiation Facilities
AERB/SG/G-4	Regulatory Inspection and Enforcement in Nuclear and Radiation Facilities
AERB/RF/SM/G-3	Regulatory Inspection and Enforcement in Radiation Facilities