Ministry of Industry Investment & Commerce

Jamaica's Business Ministry

HSRA

REGULATORY GUIDE – REQUIREMENTS FOR AUTHORIZATION OF CATEGORY I GAMMA IRRADIATORS

HSRA/AUT/RG/06

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1.0 PURPOSE

The objective of this Regulatory Guide is to specify requirements for authorization of self-contained Category I gamma irradiators under the Nuclear Safety and Radiation Protection Act, 2015 (the Act). Under the Act, the following types of authorities are required for Category I irradiators:

- Licence to possess and use gamma irradiators
- Permit to import or export gamma irradiators
- Licence to supply gamma irradiators
- Licence to transport gamma irradiators
- Licence to service, maintain and repair gamma irradiators.

2.0 SCOPE

This Regulatory Guide has been prepared by the Hazardous Substances Regulatory Authority (HSRA) and sets out requirements for the supply, possess, import, use, storage, servicing, repair and maintenance, and decommissioning of Category I gamma irradiators. Security requirements for use, storage and transport are also included in this guide.

The Guide is structured as follows:

- Requirements for possession, import/export, use or decommission irradiators - Sections 2 to 14
- Requirements for supply Category I irradiators - Section 15
- Requirements for service repair and maintain Category I irradiators -Section 16
- Requirements for transport Category I irradiators - Section 17.

3.0 TERMS AND DEFINITIONS

Term/Abbreviation	Definition
DSP	Dosimetry Service Provider
HSRA	Hazardous Substances Regulatory Authority
IAEA	International Atomic Energy Agency
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
NSRP	Nuclear Safety and Radiation Protection

4.0 OVERVIEW OF GAMMA IRRADIATORS

4.1 GENERAL

Gamma irradiators have widespread use in medical, industrial and research applications. Such irradiators are used in hospitals and blood banks for irradiation of blood and blood products or components, in research facilities as a catalyst to induce reactions between chemical substances and also in sterilisation of insects such as screwworm fly, various fruit flies, sugar cane and corn borers, mosquitoes and other pests.

Gamma irradiators use either 60Co or 137Cs radiation sources with typical radioactivity ranging from tens to hundreds of Tera Becquerel. They are categorized according to the type of source storage/irradiation chamber arrangement and range from Category I to IV irradiators.

4.2 CATEGORY I GAMMA IRRADIATORS

A Category I irradiator provides storage for the sources in a container constructed of solid materials which encloses and provides shielding for the sources at all times. Categories II irradiators use dry storage methods and are used in irradiation rooms with controlled access to irradiation rooms prevented during irradiation. Category III and IV irradiators are used in irradiation rooms in which large volumes and throughputs of industrial products are irradiated. The sources are stored in a water filled pool and the configuration and volume of the irradiation facility are designed to physically restrict human access to the sources.

The Category I gamma irradiators are completely enclosed and shielded at all times to prevent human access to the sealed source or the irradiation chamber during irradiation. As a result, such irradiators are also called as self-contained gamma irradiators (SGI).
The radioactive material is encapsulated in special form sealed sources. The sources are placed within secondary containment within metallic tubes called source capsules or pencils. Each source capsule or pencil has a serial number and is provided with a unique identification. Typically, the sources or pencils are spatially arranged around an irradiation chamber to provide uniform irradiation up to (~25 kGy)/h) of the products or specimens.
Depending on the design, the radiation source within the irradiator may be in a fixed position or may be movable. In the latter case, interlocks are used to ensure that the source does not move into a position that, during normal use of the irradiators, may cause a radiation hazard to any individual. Bypassing or failure of an interlock could cause persons to be exposed to high levels of radiation.

The SGIs typically range in weight from several hundred to several thousand kilograms. Such irradiators are usually designed for use inside a building, protected from the weather, and without wide variations of temperature and humidity. When used as designed, a properly functioning irradiator poses little radiation safety risk. However, improper maintenance, using samples incompatible with an irradiator design, or operating an irradiator in an environment not recommended by the manufacturer (or distributor), could lead to damage or malfunction of an irradiator and high exposure rates near the irradiator.

The high activity of the ^{60}Co or ^{137}Cs sources used in SGIs means that the sources are classed assigned as Category1 sources under the IAEA Categorization of Radioactive Sources Safety Guide and subject to stringent security requirements. As such, measures to comply with the IAEA Code of Conduct on the Safety and Security of Radioactive Sources 2004 and the IAEA Code of Conduct on the Safety and Security of Radioactive Sources: Guidance on the Import and Export of Radioactive Sources 2005 are also included.

5.0 APPLICATION FOR A LICENCE TO POSSESS AND USE CATEGORY I GAMMA IRRADIATORS

5.1 INSTRUCTIONS TO THE APPLICANT

The application form provided in the second schedule of the Nuclear Safety and Radiation Protection Regulation 2019 must be completed and submitted with the applicable fees. Applicants must ensure that the information provided in support of their application for authorisation of Category I irradiators is clear, precise, accurate, and complete. A check list is attached for information.

5.2 ELIGIBILITY

The Act allows for a "person" to be authorized to conduct activities with radiation sources. To ensure the necessary accountability and responsibility, the applicant must be a "person", which is a natural person (an individual), a government or public institution incorporated through enabling legislation or a corporate person (a corporation). A suitability assessment including background and security checks to assess whether the person is suitable to hold an authorisation for gamma irradiators will also be undertaken by the HSRA.

In this document Responsible Person is a natural person or a body corporate who deals with a sealed radioactive source and either:

- has the direct management responsibility for the safety and security of the source and the facility; or
- has the overall control over who may use the source or premises

5.3 LICENCE TO POSSESS AND USE CATEGORY I GAMMA IRRADIATORS

The HSRA may authorise the possession and use of SGIs in steps to verify that the safety measures are implemented for each stage of the authorisation before progressing to the next step. The steps involved are:

a) Licence to possess Category I gamma irradiators
b) Permit to import Category I gamma irradiators.
c) Licence to use Category I gamma irradiators
d) Licence to decommission Category I gamma irradiators when it is no longer required. (NB: Appendix I provides a check list for use by applicants.

6.0 IRRADIATOR DESIGN AND SAFETY FEATURES

This section describes the requirements for sealed sources and design, construction of the irradiator to ensure that the SGI meets the necessary design and safety features.

6.1 SEALED SOURCES

6.1.1 Standard:

a) The sealed source used in SGI must meet the requirements specified under the international standards for sealed sources. Acceptable standards are:
- ISO 2919:2012 Radiological protection - Sealed radioactive sources - General requirements and classification; or
- ANSI Standard N433.1, "Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I)"

6.1.2 Certification

a) A manufacturer's certificate containing the following details in relation to the sealed sources used in the SGI must be provided:
- Make, model number and identification number of source (s), the radioisotope, activity and date of measurement
- Physical and chemical form
- Sealed source classification certificate (e.g. ISO/ANSI)
- Bend test certificate, as per applicable standard
- Leak test certificate, as per applicable standard
- Contamination test certificate, as per applicable standard.
- Special form test certificate for transport purposes

6.2 IRRADIATOR - DESIGN AND SAFETY FEATURES

6.2.1 General

The SGI safety systems are based on the use of timers, radiation detectors and electromechanical devices. These systems and devices should combine to provide protection in depth so that in the event of one system failing, a second or third system can be relied upon to provide the intended protection. There should be redundancy built into each system to reduce the risk of failure. The systems and devices should be independent so that a fault in the irradiator does not impair the safety system which is intended to mitigate the fault. A fault in one system should not cause the collapse of others. Systems should always fail to safety, that is they should be designed and installed to be tamper-proof and difficult to override without the use of special tools. Failure of a system should result in safe conditions.

6.2.2 Design Features

The SGI must be designed to be 'fail safe' with the following safety features:

a) The irradiator must not be able to be function in the 'irradiate' mode until all shielding is in place and all safety devices are activated

b) The irradiator mechanism and controls must 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 be operable

c) There must be a provision for manually returning the SGI to its 'not in use' mode or shielded in the event of power failure

d) The SGI must have a mechanism to be able to terminate an irradiation and return to its 'not in use' mode at any time

e) The SGI must 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 SGI design should have features like password protection, key-operated switch, mechanical lock and key etc.

g) A visual indication of the SGI's operational status (ON/OFF) must be provided at all time

h) Each operational control indicator must be clearly labelled to indicate its function. Appropriate colour indicators should be used:
- Emergency, warning or critical information (e.g. malfunction) – Red
- Caution - Orange or Yellow
- Normal - Green

i) A copy of the engineering specifications and diagrams of the irradiator may be required to be provided to the HSRA. This information will be treated in confidence.

6.2.3 Warning Labels

a) The SGI must be labelled with a metallic label displaying radiation symbol and the words in English and local language as given below:

"CONTAINS ^{60}Co (OR ^{137}Cs) RADIOACTIVE SOURCE"

"CAUTION-THIS UNIT SHOULD NOT BE SCRAPPED/ DISPOSED OF/ DISMANTLED WITHOUT PRIOR APPROVAL OF HAZARDOUS SUBSTANCES REGULATORY AUTHORITY"

NB: The symbol may be magenta or black, on a yellow background.

b) The SGI must have a clearly visible metallic label identifying the contained radionuclide, activity content, and the date of measurement. The label must also include the following information:
- Name and address of manufacturer
- Make, model and serial number
- Type of radionuclide and maximum design activity
- Maximum irradiation volume

- Competent Authority identification mark for Type B package (if the sources are transported within the SGI)

c) If a separate control panel or console is utilized it must be easily identifiable as being part of the SGI

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

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

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

6.2.4 Irradiator - Maximum Radiation Levels

a) The maximum leakage radiation levels from the SGI unit with maximum designed source strength for various modes of operation must not exceed the limits mentioned in Table 1.

Mode of operation	Distance from accessible surface	Maximum radiation levels µSv/h
Storage	5 cm	200
	1 m	20
Irradiation	5 cm	200
	1 m	20
Sample load or unload	5 cm	2000
	1 m	100

6.3 CERTIFICATION BY THE MANUFACTURER

6.3.1 Design and Safety Features

a) The SGI design and safety features must be verified by the manufacturer to be in compliance with section 36.2. by the manufacturer. HSRA will verify this prior to the approval for import of the SGI

b) A set of engineering drawings of the gamma irradiator must be provided to HSRA and/or the licenseeauthorization holder

6.3.2 Radiation Survey Certificate

6.3.3 A radiation survey report from the manufacturer must be provided to the HSRA. The survey report should include the following details as a minimum:

a) Date of radiation protection survey

b) Make, model and serial number of the SGI

c) Sealed source specifications including the following:

- Name of source manufacturer or supplier

- Identity of radionuclide
- Source model, serial number and activity of each sealed source as on date
- Source geometry, total source activity as on date

d) Measured radiation levels with the SGI in different modes of operation
e) A schematic with the positions where readings were taken
f) Make, model, serial number and date of the recent calibration of survey instrument
g) Particulars of the individual responsible for the survey

7.0 IRRADIATION FACILITY REQUIREMENTS

7.1 FACILITY SAFETY REQUIREMENTS

7.1.1 The SGI irradiation facility must be demonstrated to meet the following safety requirements:

a) The facility must be a dedicated room which is able to be secured to prevent unauthorised access
b) The radiation levels outside the facility must not exceed HSRA specified limit of 10 µSv/wk. This dose limit on a dose constraint is 500 µSv per annum
c) The irradiation facility should have following features:
   - located on ground floor for ease of installation, if possible
   - adequate room size to house the SGI unit
   - door size – adequate enough for taking the unit (assembled) inside the room
   - floor loading capacity – as per the weight and base size of the unit
   - the room housing the irradiator should be equipped with an automatically-operated fire detection and control system (sprinkler, chemical, or gas)
d) Warning signs must be posted at each of the entrance to the irradiation facility. The sign must display the following information and be placed in a conspicuous location:

"WARNING: RADIATION AREA"

The symbol may be magenta or black, on a yellow background.

Note: The warning sign must not be placed at main entrance to the building.

7.2 SECURITY REQUIREMENTS

7.2.1 The SGI irradiation facility must be demonstrated to meet the following security requirements:

a) When being stored or in use, the SGI must be protected by, at a minimum, physical security measures capable of providing sufficient delay to allow immediate detection and assessment of the intrusion, and for a guard or police service to interrupt unauthorised removal of the source. The physical security measure must include the following:
   - Access control (at least two physical barriers apart from administrative measures)
   - key control
   - CCTV surveillance
   - Personal surveillance
   - Installation of appropriate detection system for unauthorised removal

7.3 VERIFICATION OF FACILITY DESIGN, SAFETY AND SECURITY

The SGI facility radiation (4.1(b)) and physical security (4.2) certification may be undertaken by the HSRA on prior to granting a licence to use the SGI. The applicant may also use a qualified person approved by the HSRA to certify the premises.

8.0 FINANCIAL ASSURANCE AND RECORDKEEPING FOR DECOMMISSIONING

8.1 APPLICABLE MEASURES

8.1.1 The applicant must ensure that adequate financial resources are available to cover the costs associated with safe decommissioning, including management of the source at the end of its operational life.

a) The amount of the financial resources to be made available for decommissioning activities shall be commensurate with a facility-specific cost estimate forestimate decommissioningfor decommissioning activities and shall be changed if the cost estimate increases or decreases.

b) The HSRA will determine the appropriate financial assurance required prior to the completion of the authorisation requirements.

9.0 IMPORT OF SGI

9.1 APPLICABLE MEASURES

9.1.1 Following an authorisation to possess and acquire category 1 gamma irradiators from HSRA, the Responsible Person must seek approval for import of the SGI from HSRA prior to importing the sources into Jamaica. The Form of application for an Export or Import Authorization must be completed. The completed form must be accompanied with the following documents:

a) Sealed source certificates as per section 3.1b

b) Packaging certificates for imported commodities

c) Certificate from the manufacturer that the design and safety features and labelling are in compliance with Section 3.3.1
d) Radiation survey certificate as per section 3.3.2
e) Evidence that the manufacturer/supplier is authorised to manufacture and/or supply SGIs in the source country (i.e. the country in which the manufacturer operates from).
f) Certification that the sealed sources in the SGI will be accepted back by the manufacturer at the end of the useful life of the irradiator or when it is no longer needed.
g) Approval from the regulatory body in the source country that the manufacturer is approved to:
   - export the SGI to a person holding an appropriate authorisation under the Act
   - accept the disused sealed sources supplied with the SGI for disposal

9.1.2 The HSRA will verify the irradiation facility radiation and physical security prior to granting the import permit.

10.0 SECURITY PLAN AND MANAGEMENT

10.1 SGI SECURITY PLAN

10.1.1 A Source Security Plan for the SGI must include:
a) description of the specific location of the SGI facility (where it is stored and used)
b) plan of the SGI facility including description of the physical security measures used to protect the source
c) a description of the specific security concerns to be addressed, for example theft or sabotage, or mechanical or electronic failure of a physical security measure
d) a description of the physical security measures that will be used to address the security concerns
e) allocation of responsibilities for security to competent and qualified persons with appropriate authority to carry out their responsibilities
f) a description of the procedural security measures that will be used to address the security concerns:
   - access control
   - key control
   - CCTV surveillance
   - personal surveillance
   - detection of unauthorized access and/ removal of source
   - identity checks and security background checks of personnel
   - inventories and records related to the management of sources
   - information security
   - procedures to be followed before, during and after a technical service
   - contact details of first responders and second responders

- contingency and security response arrangements including notification of security breach
- security education and awareness
- actions to be taken in the event of a change in threat level

g) arrangements for review and revision of the Source Security Plan, including maximum time between reviews.

10.2 MEASURES TO DEAL WITH SECURITY BREACHES

10.2.1 The Responsible Person must be able to demonstrate that security management procedures to deal with notifications of a security breach are in place.

10.2.2 The Responsible Person dealing with a radioactive source must:

a) in the event that the security breach is a:
- detectable theft
- unexplained loss
- unauthorised damage
- unauthorised access
- unauthorised transfer

b) notify:
- the local police service and immediately thereafter, the HSRA that a security breach has occurred and provide, as a minimum, the following information:
  - circumstances of the security breach
  - steps taken or proposed to be taken to rectify the breach
  - if the SGI has been stolen, any information that may assist in the recovery of the source

-OR-

c) in the event of any other security breach notify HSRA and immediately thereafter, the local police service that a security breach has occurred and provide, as a minimum, the following information:
- circumstances of the security breach
- steps taken or proposed to be taken to rectify the breach

10.2.3 The Responsible Person must submit a written report of the incident containing the information described in section (b) above to the HSRA within 7 days of the date of the incident

10.2.4 Persons that deal with the SGI should be educated to be alert to suspicious behaviour. Such suspicious behaviour must be reported to the Responsible Person who must report it to the Police and HSRA

10.3 ACCOUNTING OF SOURCES AND RECORD KEEPING

10.3.1 The Responsible Person dealing with the SGI must, at all times, be able to account for the whereabouts of the SGI, which include:

a) detail the whereabouts, serial number or identification number of the radioactive source

b) copy of the radioactive source certificate or other certification

c) detail the physical and chemical composition of the isotope in the source
d) detail the construction details and type of radioactive source
e) detail the activity and date of measurement of the activity of the radioactive source
f) maintain records of leaks test reports, maintenance/service or repairs of unit
g) records of source exchange (if applicable)
h) detail the import, export, transfer, disposal or change in location (within or between premises controlled by the Responsible Person) of the radioactive source in the previous twelve months

11.0 ROLES AND RESPONSIBILITIES

11.1 RESPONSIBLE PERSON

11.1.1 The Responsible Person is a senior-level manager who has been assigned responsibility for overseeing the authorised activities relating to the SGI. The Responsible Person is responsible for committing adequate resources (including facility, equipment, personnel, and other resources) to the radiation protection program to ensure that public and worker safety protection from radiation hazards. Specifically, commitment and compliance with the Nuclear Safety and Radiation Protection Act, 2015 in relation to safety and security of radioactive sources as per the following:

a) Appointment of a suitably qualified person to serve as the Radiation Safety Officer (RSO) for authorised activities
b) Ensure that safety and security risks relating to the SGI are managed in an integrated manner and that safety measures do not compromise or interfere with security measures
c) 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. Such instructions must also include requirements regarding security risks.
d) Provide facilities and equipment to the RSO and other worker(s) to carry out their functions effectively in compliance with the regulatory requirements
e) Ensure that no person is permitted to operate the SGI unit unless she/he has been adequately trained and is competent to operate the SGI unit in accordance with the safety procedures.
f) Provide personnel monitoring devices to radiation workers including instructions for their appropriate use
g) Ensure that worker dose records are maintained for each worker. The records should be kept until the worker attains or would have attained the age of 75 years or, for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure
h) Ensure that the SGI is regularly serviced and maintained in good working order and that servicing and maintenance is carried out as per the manual provided by the manufacturer and records are maintained in a dedicated logbook. All

component replacement record should be maintained in the log-book for inspection by the HSRA

i) Ensure that the SGI is serviced and maintained or repaired by qualified persons approved by the manufacturer
j) Undertake periodic tests and inspections of safety systems and control mechanisms are carried out as specified by the manufacturer. The records of such work are maintained and are available for inspection by the HSRA
k) Ensure that loading, replenishment, redistribution or disposal of sources is carried out only by the authorised manufacturer
l) Radiation monitoring equipment is regularly inspected, maintained and periodically calibrated, at least once in two years
m) Notify HSRA within 48 hours (2(2 days) of an incident involving the SGI
n) Obtain prior approval from the HSRA for any changes to location of SGI

Note: the measures outlined above must be included in a Radiation Safety Management Plan.

11.2 RADIATION SAFETY OFFICER

11.2.1 The RSO shall be assigned the following responsibilities:

a) Establish and maintain an effective radiation protection programme to ensure safety of workers and members of the public
b) Instruct all users on relevant safety measures, provide or arrange for adequate training in radiation protection and safety methodologies and use of personnel monitoring devices (TLD badges)
c) Ensure standard operating procedure (SOP) is developed and implemented to ensure safe operation of the SGI unit
d) Ensure that the samples which are irradiated in SGI unit would not result in hazardous situations such as fire, explosion and corrosion to arise inside the chamber
e) Ensure that personnel monitoring devices are provided to workers in the facility, used as required and are securely stored
f) Maintain personnel monitoring records and analyse the records to ensure that there are no abnormal exposure trends
g) Prepare the standard operating procedure (SOP) from detailed instruction manual provided by manufacturer/supplier of the SGI unit
h) Ensure that radiation monitoring instruments are kept in proper working condition and are periodically calibrated, at least once in two years
i) Assist the licensee in developing suitable emergency response plans to deal with emergencies and ensuring appropriate emergency preparedness
j) Conduct periodic (monthly) radiation protection surveys and leak tests (six monthly) of the SGI and maintain records
k) Maintain inventory of sources including initial and present activity, operational logbook (user log) and associated QA records;

l) Ensure periodic servicing and preventive maintenance of the SGI unit as prescribed by manufacturer/supplier and maintain records
m) Ensure safe work practices during source replenishment and safe disposal of disused sources
n) Report on all hazardous situations along with details of any immediate remedial actions taken are madeand make available to the employer and licensee for reporting to the HSRA
o) Ensure the physical security measures such as physical protection systems, access control procedures to the SGI facility and access to the unit (e.g. key or password protection of unit) are in place

11.3 WORKER

11.3.1 Worker (user of SGI) is the person who is directly involved in day-to-day operation/ use of the SGI unit. The worker should:
a) Be familiar with the basic design, operation and preventive maintenance of the SGI unit including procedures for routine operation and handling emergency situations
b) Operate the SGI unit as per the SOP prepared by the RSO
c) Follow all applicable rules and regulations for safe operation of SGI 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 radiation monitors and personnel monitoring devices as provided
g) Report to RSO/licensee of any issues related to safe operation of the SGI including the circumstances that could adversely affect safe operation of SGI unit
h) Be familiar with area security safeguards such as locks, posting signs, warning lights and interlock systems

12.0 RADIATION MANAGEMENT PLAN

12.1 APPLICABLE MEASURES

12.1.1 The Responsible Person for the SGI facility must ensure that a Radiation Management Plan (RMP) has been prepared and implemented to ensure compliance with the Nuclear Safety and Radiation Protection Act 2015 and conditions of authorisation. SpecificallySpecifically, the RMP must address the following:
a) The Responsible Person, Radiation Safety Officer and worker responsibilities are assigned in accordance with Section 8 of this guide. Adequate governance arrangements are in place to ensure the procedures are followed at all times including reporting of non-compliances or changes to procedures

b) Radiation dose to workers and members of the public are as low as is reasonably achievable and below the prescribed dose limits (see Schedule 9, NSRP Regulations, 2019 dose limits.
c) A source security plan is prepared and implemented as per section 7.1.
d) Transport of SGI is undertaken only by an appropriate authorized licenced transport carrier including during source replenishment.
e) Radiation monitoring devices are provided, used and maintained in good working condition. All survey meters must be calibrated.
f) Personnel radiation monitoring of all relevant workers is undertaken including reporting and record keeping.
g) Training of staff including ongoing routine training in safety procedures and emergency procedures including as well as training in the RMP.
h) Adequate procedures and resources are in place to mitigate/address all foreseeable incident and accidents in relation to SGI unit (Emergency response procedures).
i) Record keeping and reporting obligations are fulfilled in accordance with the legislative requirements.
j) The RMP must be readily accessible to all relevant persons and must be reviewed and updated annually. The RMP must also be updated following an incident or an accident involving the SGI unit to ensure that measure to prevent reoccurrence of incidents are incorporated in the RMP.

13.0 RADIATION MONITORING

13.1 PERSONNEL MONITORING

13.1.1 A personnel monitoring device must be provided to determine radiation doses received by each worker who:
a) is involved in routine operation and maintenance of SGI unit
b) frequently uses the SGI unit for handling the samples for irradiation

13.1.2 The personnel monitoring badges when not in use must be stored in a safe and secure location away from SGI unit as specified by the RSO

13.1.3 The Responsible Person must ensure that personal radiation exposure record as specified by the HSRA under section 58 of the Act is made and retained permanently

13.1.4 Alternatively, the Responsible Person may perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 1mSv per annum

13.2 AREA MONITORING

13.2.1 Radiation protection surveys of SGI unit must be carried out routinely, at least once a month

13.2.2 Readings shall be taken at 5 cm and at 1m from the surface with the source in the irradiate position and in the shielded position

13.2.3 The radiation protection surveys of SGI unit should also be carried out:
- a) after every servicing or any repair of SGI unit.
- b) in the event of any incident which may hamper the functioning of SGI unit, e.g. stuck sample chamber,
- c) breakdown of wire rope/driving mechanism or

13.2.4 Records of routine and unplanned survey must be maintained for inspection by HSRA

13.2.5 All records must be retained for a minimum period of seven (7) years or as approved by HSRA

13.3 RADIATION MONITORING DEVICES

13.3.1 The Responsible Person should ensure that suitable radiation measuring instrument is available in working condition to carry out radiation protection survey SGI unit

13.3.2 The radiation survey meter should be periodically calibrated according to the manufacturer's requirements or, at least once in two years and records maintained

13.3.3 The calibration of a radiation survey meter should be traceable to a national/international standard

13.3.4 The radiation survey meter must be verified for calibration following a service or repair of the device

13.3.5 The calibration and service/repair records must be kept for minimum period of seven (7) years or as approved by HSRA

13.4 LEAK TESTS

13.4.1 A leak test of an irradiator must be performed every six months. The test must be done according to the manufacturer's instructions and records maintained

13.4.2 Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking

13.4.3 A sealed source fails the leak test if the contamination on the filter paper used for the test exceeds 185 Bq/cm2 or (0.005 micro Curies/cm2)

13.4.4 A failure in leak test must be reported to immediately to the HSRA

13.5 TRAINING

13.5.1 All users must be trained in appropriate radiation safety and operational procedures for the use of the irradiator

13.5.2 They must have appropriate training to provide reasonable assurance that they will use the irradiator safely, maintain security of, and access to, the irradiator, and respond appropriately to accidents and malfunctions.

13.5.3 Training should include:
- a) Radiation protection principles
- b) Characteristics of ionizing radiation
- c) Units of radiation dose and quantities
- d) Radiation detection instrumentation

e) Biological hazards of radiation exposure (suitable to radioactive material being used)
f) Standard operating procedures and/protocols for Hands-on use of the irradiator

13.5.4 Also, ancillary personnel such as clerical, housekeeping, security, or management staff must be informed about radiation hazards and the appropriate precautions.

13.5.5 Individuals who perform routine maintenance on irradiators must be trained in radiation safety and in the irradiator manufacturer's operating procedures, or they must work under the supervision and in the direct physical presence of someone who has this training.

13.5.6 Annual refresher training must also be provided as required.

14.0 EMERGENCY RESPONSE PLAN AND PREPAREDNESS

14.1 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. The Responsible Person must have appropriate emergency response action plans to mitigate the consequences of an emergency relating to the SGI unit including preventive measures to avoid any recurrence of such situation in future.

14.2 EMERGENCY RESPONSE PLAN AND PREPAREDNESS

14.2.1 The Responsible Person must prepare emergency response plan which envisages various emergency scenarios/situations that may be encountered in relation to the SGI and action plans for responding to emergencies to mitigate their consequences.

14.2.2 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 SGI unit.

14.2.3 The emergency situation may fall in the following categories:
a) Loss or theft of SGI during transport
b) Damage to the SGI during transport
c) Damage to the SGI during storage, installation and commissioning
d) Radiation levels in excess of the baseline/normal values recorded during installation
e) Fire incident, explosion or natural disaster such as earthquake etc. at SGI installation location
f) Failure in interlock mechanisms leading to the source stuck in the "ON' position
g) Malevolent actions by the anti-social elements leading to damage of SGI

14.2.4 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.

14.2.5 The Responsible Person and the RSO should ensure that all the personnel involved in handling of SGI are familiar with the emergency response action plans and are provided appropriate training in potential emergency situations involving the SGI.

14.2.6 Emergency response plans must be periodically reviewed, updated and tested.

14.3 DISPLAY OF EMERGENCY PROCEDURES

14.3.1 Instructions provided specifying procedures to be followed in an emergency situation, should be displayed at a prominent location in the SGI facility

14.3.2 This should include the name(s) and contact details of responsible personnel of SGI institution, to be contacted in case of emergency

14.3.3 The contact details of emergency response agencies such as the Police Service, Fire Authority, nearest hospital, supplier/ manufacturer, HSRA should also be listed

14.4 REPORTING OF RADIATION EMERGENCY

14.4.1 The Responsible Person should report every unusual incident/emergency to the HSRA immediately and within forty-eight hours (2 days) 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) Probable cause of the incident and action taken
e) Personnel radiation exposure or injury, if any
f) Lessons learned to prevent similar incidents and accidents in the future
g) Improvement in the emergency plans and preparedness, if any

15.0 DECOMMISSIONING

15.1 INTRODUCTION

If the SGI is of no longer required for its intended purpose, the Responsible Person should initiate suitable procedures for decommissioning of the disused SGI unit and return it to the manufacturer/ supplier.

15.2 PROCEDURE FOR DECOMMISSIONING

15.2.1 The Responsible Person should obtain prior approval from the HSRA for decommissioning, transport and safe disposal of SGI

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

15.2.3 The room housing the SGI can be released for any other use by the institution only after decommissioning of the SGI installation and inspection and approval of the facility by the HSRA

15.2.4 Submit the completed form The Form of application for an Export or Import Authorization including relevant certifications from the manufacturer

15.3 TRANSPORT OF SGI FOR DECOMMISSIONING

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

15.3.2 The transportation of SGI units from manufacturer/supplier institution to the user institution and vice-versa should be carried out in accordance with the IAEA Regulations for the Safe Transport of Radioactive Material – 2018

15.4 FACILITY DECOMMISSIONING

15.4.1 In respect of the decommissioning of a facility, the Responsible Person should:

a) Establish a decommissioning strategy and prepare a decommissioning plan
b) Establish a waste management strategy
c) Perform safety assessment and environmental impact assessments related to decommissioning
d) Prepare relevant safety procedures and emergency preparedness plans Ensure properly trained and competent are used during decommissioning process

16.0 SUPPLIERS OF CATEGORY I GAMMA IRRADIATORS

16.1 APPLICATION AND ELIGIBILITY

16.1.1 Only appropriately licensed persons may supply gamma irradiators in Jamaica. The application form provided in the second schedule of the Nuclear Safety and Radiation Protection Regulation 2019 must be completed and submitted with the applicable fees. Applicants must ensure that the information provided in support of their application for authorisation of Category I irradiators is clear, precise, accurate, and complete.

16.1.2 Suppliers of SGI units may be a natural person (an individual), or a corporate person (a corporation). A suitability assessment, i.e. whether the person is a fit and proper person including security and background checks to hold an authorisation for gamma irradiators will also be undertaken by the HSRA. Attachment 1 provides a check list for use by applicants.

16.2 REQUIREMENTS FOR A LICENCE TO SUPPLY

16.2.1 The applicant must provide verification that they hold a current licence in their country of origin to supply SGIs including details (make and model) of all of the SGIs they are approved to supply.

16.2.2 The applicant must supply the SGI unit only to persons who holds both a current licence to possess and a permit to import the sealed sources to be used in a SGI

16.2.3 The applicant must provide verification that they have approval by the regulatory authority in their country of origin:

a) to export the radioactive sources as part of SGI
b) to accept the radioactive sources back to the country of origin once the sources are no longer needed

16.2.4 The applicant must verify that transport of sources in the approved transport container (type B(U) package) and complies with IAEA Regulations for the Safe Transport of Radioactive Material Specific Safety Requirements 2018. The competent authority certificate for transport container must also be provided to the HSRA.

16.2.5 The applicant must also develop a transport security plan for approval by the HSRA. The plan must include the following measures:

a) a description of the source to be transported including: isotope, activity (including date of measurement), physical and chemical form, serial number and transport packaging
b) a statement of the purpose or reason for which the source is being transported
c) a description of the conveyance in which the source will be transported and the arrangements for securing the shipment during trans-shipment or other stops en-route
d) allocation of responsibilities for security to competent and qualified persons with appropriate authority to carry out their responsibilities
e) the name, address and business and after hours contact details for the consignor, consignee, carrier and, where used, guard or police service
f) a description of the specific security concerns to be addressed, for example theft or sabotage, or mechanical or electronic failure of a physical security measure
g) a description of the physical security measures that will be used to address the security concerns
h) a description of the procedural security measures that will be used to address the security concerns including:
i) arrangements for notifying, as deemed appropriate, local police service.
j) contingency or emergency procedures for vehicle accidents or breakdown and a planned principal route and an alternative route
k) security response arrangements including notification of security breach
l) security briefing for persons involved in transporting the source including nature of the threat, threat level and contingency and security response arrangements
m) identity checks and security background checks of personnel
n) information security
o) means of communication between parties involved in transporting the source

Note: the HSRA will on approval of the security plan support the coordination of transport security arrangements with relevant authorities.

16.3 CONDITIONS OF A LICENCE TO SUPPLY SGI

16.3.1 The Responsible Person (holder of a licence to transport radioactive sources) must ensure that they are able to comply with the following requirements:

a) Maintain appropriate records including type of radiation sources, activity as on date, sealed source and leak test certificate, dose rate and dose profile of the unit
b) Ensure the availability of essential spare parts of the SGI unit for its useful life
c) Provide a set of complete engineering drawings of the SGI specific to the make and model of the irradiator supplied if requested by the HSRA
d) Assure the refurbishment and source replenishment in the SGI unit, when requested by user, as applicable in compliance with regulatory procedures
e) Undertake the responsibility for providing technical support in decommissioning and disposal of disused sources of the SGI unit
f) Confirm arrangements to take back the disused sources used in the SGI when it is no longer required.
g) Source loading may be carried out at the site but is subject to the following conditions:
   - Source loading of the SGI is must be carried out by supplier or HSRA authorised representatives who are authorised by the HSRA
   - Availability of necessary infrastructure/gadgets for source transfer operation
   - Availability of trained and experienced persons to support the source loading
   - Supervision by Radiological Safety Officer of the user institution.

17.0 PERSONNEL SERVICING, REPAIRING AND MAINTAINING THE SGI

17.1 APPLICATION AND ELIGIBILITY

17.1.1 Only appropriately licensed persons may service, repair or conduct maintenance of gamma irradiators. The application form provided in the second schedule of the Nuclear Safety and Radiation Protection Regulation 2019 must be completed and submitted with the applicable fees. Applicants must ensure that the information provided in support of their application for authorisation of Category I irradiators is clear, precise, accurate, and complete.

17.1.2 A natural person (an individual), or a corporate person (a corporation) may apply for the above licence. A suitability assessment i.e. whether the person is fit and proper person including security checks to hold an authorisation for gamma irradiators will also be undertaken by the HSRA. Attachment 1 provides a check list for use by applicants.

17.2 REQUIREMENTS FOR A LICENCE TO SERVICE, REPAIR AND MAINTAIN SGI

17.2.1 Persons for the above licence may demonstrate their competency by providing verification that they:

a) hold a current licence to service, repair or conduct maintenance of gamma irradiators in their country of origin (if applicable). The licence must be specific to the type of gamma irradiators proposed to serviced, repaired or maintained. HSRA will assess the licence to verify its suitability for authorisation under the Act.

-OR-

b) have been trained in service, repair or conduct maintenance of gamma irradiators by the manufacturer. The certificate of training from the manufacturer should include:
- safe operation including the sequence of operation
- radiation risks and protection measures
- servicing and preventive maintenance aspects, and security aspects
- procedures for testing of interlocks and control functions

c) Such persons must also provide verification that the manufacturer of the SGI has provided them with:
- make, model and serial number details of radiation sources and activity, sealed source and leak test certificate
- dose rate and dose profile of irradiation chamber and dosimetry report
- gadgets and accessories (hand crank etc.), as required, for the operation of the SGI unit and for handling an emergency situations
- written instruction manual for safe operation, periodic inspection, servicing, preventive maintenance including general description of the SGI 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

18.0 TRANSPORT OF CATEGORY I GAMMA IRRADIATORS

18.1 APPLICATION AND ELIGIBILITY

18.1.1 The SGI contain quantities of radioactive material that require using a Type B package under the IAEA Regulations for the Safe Transport of Radioactive Material Specific Safety Requirements 2018 (IAEA Transport Regulations). Type B packages are designed to transport radioactive material that is certified as special form radioactive material and designed to withstand normal and accidental conditions.

18.1.2 Only appropriately licensed persons under the Act are able to transport SGI. A natural person (an individual), or a corporate person (a corporation) may apply for the above licence. A suitability assessment i.e. whether the person is fit and proper person including security checks to hold an authorisation for gamma irradiators will also be undertaken by the HSRA.

18.1.3 The application form provided in the second schedule of the Nuclear Safety and Radiation Protection Regulation 2019 must be completed and submitted with the applicable fees. Applicants must ensure that the information provided in support of their application for the transport is clear, precise, accurate, and complete. Attachment 1 provides a check list for use by applicants.

18.2 REQUIREMENTS FOR A LICENCE TO TRANSPORT RADIOACTIVE SOURCES

18.2.1 Applicants for a licence to transport radioactive sources used in SGI must demonstrate competency in the IAEA Transport Regulations. This may be achieved in one of the following ways:

a) provide a copy of a current licence to transport radioactive sources in another jurisdiction. HSRA will assess the licence to verify its suitability for a licence to transport SGI under the Act.

-OR-

b) Sit for an assessment prepared by the HSRA to verify competency in the IAEA Transport Regulations.

18.2.2 Applicants must develop safety programs for transport of radioactive sources as per the IAEA Transport Regulations for approval by the HSRA.

18.3 CONDITIONS OF A LICENCE TO TRANSPORT RADIOACTIVE SOURCES

18.3.1 The Responsible Person (holder of a licence to transport of radioactive sources) must implement and comply with the approved safety programs for transport of radioactive sources.

18.3.2 The Responsible Person must comply with the transport security plan approved by the HSRA during the transport of the SGI.

18.3.3 Notify the HSRA in the event of an accident or emergency or loss or theft of source

19.0 APPENDICES

19.1 APPENDIX I - LIST OF DOCUMENTS TO BE SUPPLIED BY THE APPLICANT AT THE TIME OF APPLICATION

19.1.1 Licence to Possess and Use SGI

a) Completed application form and fees
b) Valid Copy of ID
c) Completed Fit and Proper Declaration Form
d) List and qualification of radiation workers
e) Copy of certificate of Incorporation and company TRN
f) SOP/Operation Manual for SGI
g) Safety Assessment
h) Calibration certificate for survey meters
i) Radiation Management Plan including the security plan
j) Financial assurance to cover the SGI
k) Qualifications and experience of the RSO

l) Emergency Response Plan
m) SGI facility plan (to scale) and construction details
n) Details of the SGI proposed to be purchased (if known)
o) Details of the supplier if known

19.1.2 Permit for import of the source
a) Completed application form and relevant fees
b) Sealed source certificates
c) Special form test certificate for transport purposes
d) The competent authority certificate for transport container (type B(U) package)
e) Certificate from the manufacturer regarding:
- SGI design and safety features
- Radiation survey certificate

f) Evidence that the manufacturer/supplier is authorised to manufacture and/or supply SGIs in the source country
g) Certification from the manufacturer that the sealed sources in the SGI will be accepted back by the at the end of the useful life of the irradiator or when it is no longer needed.
h) Approval from the regulatory body in the source country that the manufacturer is approved to:
- export the SGI to a person holding an appropriate authorisation under the Act
- accept the disused sealed sources supplied with the SGI for disposal

19.1.3 Licence to Supply Category I gamma irradiators
a) Completed application form and relevant fees
b) Copy of a current licence in their country of origin to supply SGIs including details (make and model)
c) Approval by the regulatory authority in their country of origin, that the applicant is authorised to:
- to export the radioactive sources as part of SGI
- to accept the radioactive sources back to the country of origin once the sources are no longer needed

d) Certification that the sources will be taken back at the end of their useful life or when no longer needed
e) Source certificates and competent authority certificates for sources and source transport packaging
f) A transport security plan as outlined in section 15 of this guide

19.1.4 Licence to Service, Repair and Maintain SGI
a) Completed application form and relevant fees
b) Copy of a current licence to service, repair or conduct maintenance of gamma irradiators in their country of origin or provide evidence of training in service, repair and maintenance of gamma irradiators by the manufacturer.

c) Verification that the manufacturer of the SGI that are approved to service the gamma irradiators

19.1.5 Licence to Transport Radioactive Sources

a) Completed application form and relevant fees
b) Copy of a current licence to transport radioactive sources in another jurisdiction.
c) A safety programs for transport of radioactive sources as per the IAEA Transport Regulations

20.0 REFERENCES

Author/Source	Title (Year)
Government of Jamaica (GOJ)	Nuclear Safety and Radiation Protection Act, 2015
Government of Jamaica (GOJ)	Nuclear Safety and Radiation Protection Regulation 2019
International Atomic Energy Agency (IAEA)	IAEA GSR PART 1 (Rev. 1) – Governmental, Legal and Regulatory Framework for Safety 2016
International Atomic Energy Agency (IAEA)	IAEA GSR PART 3 – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards 2014
International Atomic Energy Agency (IAEA)	IAEA No. SSR-6 – Regulations for the Safe Transport of Radioactive Material 2018
International Atomic Energy Agency (IAEA)	IAEA Safety Guide No. RS-G.1.9 - Categorization of Radioactive Sources 2005
International Atomic Energy Agency (IAEA)	IAEA Safety Guide Code of Conduct on the Safety and Security of Radioactive Sources 2004
International Atomic Energy Agency (IAEA)	IAEA Code of Conduct on the Safety and Security of Radioactive Sources: Guidance on the Import and Export of Radioactive Sources 2005
ARPNSA	Radiation Protection Series No 11 – Security of Radioactive Sources
AERB	SAFETY GUIDELINES NO. AERB/RF-RPF/SG-2 – Gamma Irradiation Chambers Aug 2015.

Author/Source	Title (Year)
Wisconsin Department of Health Services	Wisconsin WISREG-1556 Vol. 5 Chapter DHS 157-Radiation Protection Regulatory Guide Guidance for Self-Shielded Irradiators 2011
CNSC	Licence Application Guide: Nuclear Substances and Radiation Devices - Canadian Nuclear Safety Commission 2017

DOCUMENT END

(Template reference: HSRA/ADM/TMP/02 Manual Template)