# Radiation Safety Manual

# Forward

This Radiation Safety Program has been put together with procedures and guidelines to be consistent with ALARA principles. Service work is often not in the classification of routine maintenance, however to those who perform the service on a regular basis, the work becomes an everyday practice. This program isn't designed to replace the proper hands-on training needed to perform daily operations in a safe and consistent manner. As with health physics technicians in commercial nuclear power plants, job qualifications are only granted when task completion and knowledge of the job is reviewed and signed off. The utmost priority of the service technician is to present, upon completion of work, a radiologically-safe device that has been performance tested and confirmed to be operating within manufacturer's specifications, or to identify what repair or maintenance needs to be performed in order to return the device to original specifications for safe operation.

This Manual is meant to cover both State of PA and NRC license requirements, so some information is included that may be relevant for one regulator but not the other. Information not applicable to a particular regulator may be regarded as a point of information.

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## Emergency telephone numbers

**RSO** D.T. Stout business phone ..... 570-925-5681

**RSO** cell phone ..... 267-235-5782

For NRC incident notification

**NRC Operations Center**..... 301-816-5100

## Definitions

1. **ALARA** = as low as reasonably achievable; this statement means that personnel dose is of the utmost concern, and that every possible consideration should be weighed towards decisions keeping the individual as well as the collective man rem dose as low as possible.

2. **ALARA Document** = A review of job task that takes a procedure step by step and reviews each task for the engineering controls, planning, hold points, shielding and use of remote handling tools, bore scope, camera or mirrors needed to ensure the lowest dose possible for the job. An ALARA Document shall be completed prior to (and as soon as the source transfer procedure is developed) the start of a high-risk job. All personnel involved in the job will be trained on the specific tasks involved with the procedure and the ALARA document present. Specifics of each individual and his responsibilities will be documented.

3. **Category I** = Self-contained, dry source storage irradiators, defined as American National Standard N43.7. An irradiator in which the sealed source is completely contained in a dry container constructed of solid materials, the sealed source is shielded at all times, and human access to the sealed source and the volume undergoing irradiation is not physically possible in its designed configuration.

4. **Category II** = Panoramic, dry source storage irradiator, defined as American National Standard N43.10. A controlled human access irradiator in which the sealed source is contained in a dry container constructed of solid materials, and the sealed source is fully shielded when not in use; the sealed source is exposed within a radiation volume that is maintained inaccessible during use by an entry control system.

5. **CPM** = observed counts on a scalar or frisker per minute; to find disintegrations per minute, divide by the decimal efficiency for the instrument being used.

6. **DPM** = Disintegrations Per Minute; observed net counts per minute (net counts = observed cpm – the background cpm) divided by the instrument's efficiency, e.g. if efficiency is 10 % then the net counts would be divided by 0.10 to give dpm.

7. **MDA** = Minimal Detectable Activity: the lowest activity an instrument can reliably detect for a specific radionuclide and survey methodology.

8. **Radiation Surveys** = The task of surveying, with a properly calibrated survey instrument, for the presence of radioactivity in the form of dose rates or surface contamination.

9. **Leak Test** = The task of determining if a source is considered to be leaking (a leaking source is >.005 uCi removable contamination).

10. **Dosimetry** = Either a film badge or TLD used for the purpose of monitoring an individual for occupational exposure to ionizing radiation, which is recorded and becomes a permanent record.

11. **Interlock** = A mechanical, electrical or combination means to prevent access to high radiation areas when irradiator chamber is exposed to the source.

12. **Safety system** = A combination of interlocks, relays, micro-switches and key switches to prevent unauthorized use and/or exposure to high radiation fields.

13. **RSO** = Radiation Safety Officer; the person responsible for the overall radiation safety program. The Radiation Safety Officer on this license is D.Terry Stout.

14. **Area monitor** = an instrument to detect increased levels of radiation, with either a visual or audible indication, or both, that alarms above a predetermined trigger point.

15. **N.I.S.T.** = National Institute of Standards and Technology

16. **SS&DR** = Sealed Source and Device Registry; a list of registered devices and sources showing the maximum curie loading and any "Conditions of Normal Use" and "Limitation and Other Considerations of Use". In addition, the SS&DR may list recommendations by the manufacturers such as working life of the source, environmental conditions, temperature, vibrations, etc.

17. **Authorized User** = A person designated as a level II Health Physicist, listed on the license, with the training, experience and knowledge to provide reasonable assurance that services involving licensed material will be provided in a safe manner, will maintain security and prevent unauthorized access, and emergencies will receive the appropriate response. Before using licensed material, authorized users will receive training described in Appendix H in NUREG-1556, Vol 18, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Providers Licenses", dated November 2000.

18. **Non-Routine Maintenance** = Installation, relocation, alignment of the sealed sources (only on Category I irradiators); work on components, including electronics, related to the radiological safety of the device (e.g. the source, source holder, source drive mechanism, door, door control, or shielding); removal and disposal of sealed sources (only on Category I irradiators); removal of a sealed source/device from service; any job in which there is a potential for any portion of the body to come in contact with the primary beam; or any other activity during which personnel could receive a radiation dose exceeding NRC limits.

19. **Routine Maintenance** = Maintenance that is allowed to be performed by the irradiator user and is recommended by the manufacturer. Routine maintenance is a task that can't change dose rates or reduce shielding, and does not include any task that affects the safety system. It includes routine preventive maintenance, service repair work, testing/inspection of irradiators, and/or leak test performance. Specific examples of routine maintenance would be repair of the turntable system on a Category I irradiator, repair to the air compressor system or adding oil to the air lubrication system.

20. **SRD** = self-reading dosimeter: a pocket ion chamber that responds to the amount of gamma radiation received, sometimes called a Pocket Ion Chamber or **PIC**. The dosimeter is charged by a charger and

returned to zero on the scale; as the SRD receives radiation it changes the reading on the scale (scale is viewed by holding the SRD up to the light and looking through the appropriate end).

21. **GM** = Geiger Mueller: a detector that is more sensitive to lower levels of radiation because it has the largest pulse size.

22. **Emergency** = A situation that poses an immediate risk to health, life, property or environment.

23. **ED** = Electronic Dosimeter; a personnel dosimeter capable of measuring gamma and x-rays that typically has an alarm function for either dose or dose rate.

24. **Response Test** = Evaluation of a survey meter to determine its qualitative response to radiation.

25. **High Risk Job** = Any job where the potential for an unshielded beam from the source exists and will be covered by a separate ALARA procedure.

26. **OSL** = Optically-Stimulated Luminescence; OSLD and Thermo-Luminescent Dosimeters (**TLD**) are personnel dosimeters that are quite similar in that both respond to the absorption of energy from ionizing radiation by trapping electrons that are excited to the conduction band by the interactions. Unlike TLD, in which electrons are released from the traps by the application of heat, the trapped electrons in an OSL dosimeter are released by the application of green light from a laser or LED light source.

## Posting requirements

3.0. High Radiation Area signs are posted in areas where an individual could receive a deep dose equivalent of 100 millirem in one hour at 30 cm from the source or the surface where the radiation penetrates. High Radiation Areas could be present during source transfers and signage should be posted at the 100 millirem boundary. Radiation Area signs should be posted in areas where an individual could receive a 5 millirem deep dose equivalent in one hour at 30 cm from the source or the surface where the radiation penetrates. Signs for Radioactive Materials Areas should be posted where items or containers of radioactive materials in quantities exceeding 10 times the values provided in Appendix C of 10 CFR Part 20 are used, handled, or stored.

3.1. When temporary postings are placed, a radiation survey shall show the room or area with boundaries, along with measured dose rates at the boundaries. All posting shall be consistent with 10 CFR Part 20 requirements. Labeling on all devices should meet the requirements of the U.S. NRC for labeling of Radioactive Material containers.

## ALARA

4.0 The ALARA concept is an excellent foundation for any radiation safety program; when practiced it allows for the lowest dose to be received by occupationally exposed personnel. Service personnel should receive less than 5 millirem per week average. If personnel routinely exceed this, an investigation to determine the cause shall be performed by the RSO. Extremity dosimetry shall be worn, if calculated exposures exceed 100 millirem DDE per job and 5 times whole body exposure. All measures shall be considered when planning for a source transfer or any other high risk activity, e.g. shielding, mirrors, cameras and monitors, remote handlers, use of

time and distance, dose estimates, mock up, and practice with dummy sources mock up and dry run.

4.1 ALARA Review Document: Any time a non-routine (high risk) job is planned, an ALARA Review Document will be generated in accordance with GIS ALA-001 procedure. Before a job begins, the completed document shall be reviewed, including all steps in the source transfer procedure and specifically addressing conditions that could change dose rates and increase personnel exposure. Examples of steps that should be addressed include (but are not limited to) engineering controls for restriction of source movement, prevention of shielding reduction, practice run, additional shielding, stops for transfer shield drawer hold points, dose calculations based on time and expected exposure rates, and the ready availability of all needed tools for emergency operation (long reach handlers, etc.)

## Qualifications for Service Technicians

5.0. Each individual qualified to perform preventative or non-routine maintenance on Category I or Category II devices shall be qualified by 40 hours of Health Physics and a minimum of 8 hours of hands-on for each model of device to be worked on. The on-the-job training shall be in the presence of a named authorized user or the RSO. When the individual has demonstrated the proper Health Physics knowledge, knowledge of the emergency procedures, understanding of the limitations of the license, mechanical and electrical aptitude, and the ability to read wiring diagrams, he will be given a written (for new training) or oral (for refresher) test. Upon successful completion of the written or oral test, the individual will be approved, by RSO signature, to work on that model.

5.1. Being qualified to perform non-routine maintenance does not authorize the individual to change any conditions on the device such as source removal, reduction in shielding (other than for normal non-routine operations which is temporary and does not create a high radiation area), change of safety systems from original configuration or a modification that would change the SS&D for that device.

5.2. Initial training shall consist of 40 hours Health Physics to include:

Fundamentals of Radiation Safety:
- *Characteristics of radiation;
- *Units of radiation dose and quantity of radioactivity;
- *Hazards of exposure to radiation;
- *Levels of radiation from licensed material;
- *Methods of controlling radiation dose (time, distance and shielding);
- *ALARA concept.

Radiation Detection Instruments:
- *Operation;
- *Calibration;
- *Limitations of radiation survey instruments;
- *Radiation survey techniques for measuring fixed and removable contamination;
- *Handling and proper use of personnel monitoring equipment.

Radiation protection equipment and use:
- *Proper use of protective equipment;
- *Decontamination of contaminated equipment.

NRC regulations (10 CFR 19 and 20).
NRC regulations (10 CFR 21, 30,_31, 32, 34, 35, 36, 39, 40, 70, 71) as applicable.
License operating and emergency procedures.
Case histories relevant to operations and lessons learned.

Course examination (Didactic):

*Successful completion of closed-book written or oral examination.

*Review of incorrect answers with student.

Discussion on emergency procedures

Retraining in any areas found to be deficient

5.3 Refresher Training shall be a minimum of 8 hours with review of the above plus current events and lessons learned.

5.4 Records will include date of training, topics covered, list of attendees, including name of trainer. New training will include a written test; documents will be retained forever as part of a user's record. Refresher training will include an oral test, documents will be retained for 5 years.

**Operating and Emergency Procedures**

6.0. Verification of Authorized Work Procedure: reference Document AP-004. No work will be performed unless work activities have been confirmed to fall within the allowed licensed activities.

6.1 Responsibilities of customer and service provider

Devices that are serviced at the customer's facility will be serviced under the Gamma Irradiator Service license. Gamma Irradiator Service will comply with facility's rules for maintaining control of radioactive material and security while service work is being performed, and will also comply with all facility requirements for safety including postings. In addition, Gamma Irradiator Service may use additional locks or tag outs to control use while service is being provided. Any degradation of the safety system or any part of the device that could cause failure will be identified and recommendations made to the customer.

**Routine maintenance only will be performed on ANSI Category II irradiators.** If source exchange work is to be performed **(for Category I irradiators only)**, possession of sealed sources will remain on the customer's license until transferred to an authorized NRC or Agreement State licensee. Only authorized shippers will be used for transportation of radioactive sources and/or devices. **Any high risk jobs that include source transfers or source reloads (for Category I irradiators only) will incorporate the guidance of the GIS EMP-001 Emergency Procedures Manual if a problem arises because of the source transfer.** An agreement between Gamma Irradiator Service and the customer will be established that specifies all aspects of the work provided including individual responsibilities, licensed activity responsibilities, safety commitments, and site decontamination or cleanup if necessary. This document will be maintained for inspection.

6.2. Instructions for handling and use of radioactive material (all devices)

All personnel working under the Gamma Irradiator Service license will be monitored for radiation exposure using a self-reading dosimeter or electronic dosimeter and NVLAP approved dosimetry. Personnel working on a routine basis providing service under the Gamma Irradiator Service license shall have completed the 40 hour health physics class (refresher training annually) and be monitored for radiation exposure with a TLD or OSL or film badge, and a self-reading dosimeter or electronic dosimeter. Extremity monitors will be worn for High-Risk source loading, exchange, or reloading activities. Operation and use of devices shall be consistent with the manufacturer's recommendations and Emergency Procedures in the manual for the device for which service is being provided. Personnel working on all devices shall use a calibrated and operational survey meter in the area at all times. ALARA will be practiced when servicing all devices. Personnel shall comply with the customer's

security of licensed material when service is being performed. A smear survey of portions of the device (per manufacturer's recommendation) most likely to show if a source is leaking, **should** be taken prior to service work if applicable. If smear results **are greater than 0.005 µCi (185 Bq), follow the guidance in GIS EMP-001 Emergency Procedures.** Determine if the smears are the same isotope as in the device by using absorbers or a single or multi-channel analyzer. If a source is determined to be leaking (≥ .005 µCi) immediately remove from service, develop a plan for decontamination, repair or disposal with the customer.

6.3. Instruction for self-shielded irradiators and Calibrators (ANSI Category I)

Self-shielded irradiators and calibrators are basically of three different designs. The first design is with stationary sources in which a drawer moves the sample to the position of the shielded sources. The second design is also with stationary sources in which a drum rotates the sample chamber to face the source. The third design is with a moveable source that repositions the source into the shielded sample chamber, exposes the sample, and then returns to the shielded position. The moveable source design usually has more than one interlock to prevent the chamber door from opening with the source in the irradiate position. On this type of irradiator, the door must be locked closed when working on the source operator or inside the tower to prevent exposure outside the door area. Locking can be accomplished with mechanical interlocks, padlocks or electrical interlocks. Use of seals to the access path of safety-related parts should be used to confirm that no unauthorized access has been attempted. **If a seal is broken or shows evidence of tampering by an un-authorized individual notification, to the responsible regulatory authority may be required.**

The manufacturer's procedures for inspection, maintenance, source exchange and operations that involve access to the sealed source(s) and safety systems, if applicable, shall be followed. Procedures required to perform non-routine maintenance on these irradiators includes but is not limited to the following: leak test, check of operator or drawer for smooth operation, check of all interlocks and safety systems, source centering, pneumatics, drives, lubrication per manufacturer's recommendation, micro switches, relays, timers, and mechanical wear on parts. Replacement parts will be in conformance with the parts that have been identified in the sealed source and device registration and in agreement with the manufacturer's recommendation. Any non-manufacturer supplied replacement components or the use of materials (e.g, lubricants) other than those specified or recommended by the manufacturer will be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration before they are used.

A dose rate survey of the device will be recorded along with the results of the leak test. Detailed dose rate surveys will be taken on devices at Irradiate and Load positions with measurements in transit. The Irradiator Inspection/Performance Test report acts as the procedure for guidance to ensure all components are tested as needed for all irradiators. Service will not be completed until after an Inspection/ Performance Test List is completed and after operating the unit more than 35 times or sufficient times to ensure proper operation of the safety system and interlock system. Any customized irradiator devices will have the same stringent Inspection/Performance Test List conducted upon device approval.

Procedures required to perform preventive maintenance are the same as for performing non-routine maintenance and include all tasks as specified.

Procedures required to perform source loads, reloads, and transfers are specified in the required ALARA Review Document, which will detail the job-specific step by step procedures to be followed. Reference GIS ALA-001 document. As a minimum, all tasks specified in the procedures for performing non-routine maintenance will be performed for these high-risk jobs.

If these operations are not performed properly with attention to radiation safety principles, the irradiator may not operate as designed and personnel performing these tasks could receive radiation doses exceeding NRC limits. Only personnel with documented training on the Category I model being serviced can perform work on the device; personnel will follow appropriate procedures consistent with the manufacturer's written instructions and recommendations that address radiation safety concerns at all times.

6.4. Irradiator relocation: Reference GIS REL-003 document. The hazards of an irradiator relocation are not the radiological concern but the movement itself. For all irradiators with moveable sources that are being moved from floor to floor or room to room, the source(s) (if they are the moveable type such as a Mark 1) will be locked down in the same manner as if it were being readied for transport, using the manufacturer's recommended process. Items to take into consideration when relocating are floor loading, walk down of the travel path noting any floor changes or ramps, and elevator rated load capacity. Security must be arranged with the customer prior to moving. Equipment for the actual move may include engine lifts, roll-A-lifts, and pallet jacks; pry bars, cribbing, steel plates for irregularities in the floor or entrance or exit off an elevator; and a calibrated survey meter for use during irradiator movement. If equipment fails during movement and the irradiator or calibrator falls or topples over there would be little risk of the source becoming dislodged or exposed. Reference GIS EMP-001 Emergency Procedures for steps to follow.

## 6.5 **EMERGENCY PROCEDURES**

GIS document EMP-001 will be readily available and accessible to GIS staff at all times.

Self-shielded Irradiators and Calibrators: Emergency Procedures will follow the recommendation in the manufacturer's operator's manual for normal service work (note: a source stuck in the shielded position does not constitute an emergency but it does constitute the need for a well-developed plan prior to execution). Non-routine work such as source transfer or reloading of sources will require a separate ALARA Review Document to address ALARA, and detailed step by step procedures with hold points incorporated into the reload or source transfer procedure, specific to the device being worked on. A requirement for a dry run will be included in the ALARA Review Document for all high-risk jobs. This is so that everyone involved, including the customer, has a clear understanding of what the procedure is in the event of an emergency.

All personnel involved shall have a documented meeting prior to any source transfer or reload (or any other high-risk job). At this meeting all personnel will be made clear in their duties associated with the team effort. If there is a question about procedure at any time it is the team member's duty to stop and ask for clarification before continuing work. Exits and low dose rate areas shall be identified and discussed at the pre-job meeting and in the ALARA Review Document.

To help prevent a source becoming unshielded, the ALARA Review Document will address the specific precautions based on the steps in the source transfer procedure, type of transfer involved, location and/or room design, and training. Personnel will follow the requirement to wear all required dosimetry including extremity monitors.

An emergency situation may be one of the following examples, although this is not a comprehensive list:

- The irradiator device falls or topples over
- An alarm from an area monitor, Electronic Dosimeter, or an off scale self-reading dosimeter or PIC
- An over-exposure event takes place, including public dose limits in unrestricted areas
- A source becomes unshielded or dislodged and a safe setting is unattainable
- A source becomes stuck in an unshielded position

Anytime there is an emergency, work will immediately cease. More detail on Emergency Procedures is summarized in GIS Emergency Procures Manual (EMP-001), including a ready reference to the points of contact in Agreement States, taken from the website at http://nrc-stp.ornl.gov/asdirectory.html.

## Health Physics Instrumentation

7.0. Dose rate instruments should be capable of measuring dose rates in the anticipated range for the device and the work being performed. Examples are preventative maintenance and normal service work. A calibrated operating survey meter with an upward range of 100 mR/hr would be sufficient for these tasks. If performing source transfers, a meter capable of 10,000 R/hr may be required and should be spelled out in the ALARA review. All dose rate instruments will be calibrated annually. Survey meter calibration program published in Appendix J of NUREG-1556, Vol. 18, "Consolidated Guidance about Service Providers Licenses" dated November 2000, will be followed. Gamma Irradiator Service reserves the right to upgrade survey instruments as necessary.

7.1. Portable instruments used in the field can be GIS-supplied or customer-supplied. Instruments will be verified to be calibrated and operational before being used in the field. Instruments used to verify smears will have thin window GM detectors to identify possible leaking sources. Gamma Irradiator Service may use customer's instrumentation if isotopic identification is needed.

7.2. Instruments used in the field shall have an audible alarm to alert the service personnel if a change in condition occurs. For high risk jobs such as source exchange an alarming area monitor with remote detector and audio visual indications shall be used.

7.3. Detectors for instruments listed are GM, Ion Chamber, and NaI (Tl) 2" x 2". Instruments read in various quantities such as cpm, dpm, mR/hr, R/hr, and uR/hr. Instruments used should have the capability of detecting alpha, beta and gamma radiation.

7.4. Following is a partial list of Health Physics instruments available for use:

| Manufacturer | Model | Detector | Radiation detected |
|---|---|---|---|
| Ludlum | 14-C | 44-6/HP-260 | Beta/Gamma |
| Ludlum | 2241-2 | 44-6/HP-210T | Beta/Gamma |
| Eberline | E-520 | HP-270/260/210 | Beta/Gamma 2 each |
| Eberline | ESP-2 | various | Alpha/Beta/Gamma |
| Eberline | RO-2A | ion chamber | Beta/Gamma |
| Eberline | SRM-100 | Various | Digital Scalar |
| Eberline | PIC-6A | ion chamber | Gamma 3 each |
| Eberline | MP-2 | n/a | pulse generator |
| Eberline | SPA-3 | Scintillation probe | Gamma |
| Bicron | RSO-500 | ion chamber | Beta/Gamma |
| Victoreen | 570 | ion chamber | Condenser R-meter set |
| Radcal | 2025 | 3cc/180cc ion chamber | Gamma (NIST traceable) |
| Xetex | 305B | GM | Beta/Gamma |
| Eberline | RM-14 | | Frisker/cpm |
| Eberline | RO-4 | Ion Chamber | Beta /Gamma |
| Eberline | Teletector 6112B | GM | Beta/Gamma |

| | | |
|---|---|---|
| Various (approx. 40) Self-reading dosimeters | Ion Chamber | Gamma (ranging from 200 mR to 600R) |

Gamma Irradiator Service reserves the right to upgrade survey instruments as necessary.

## Audit Program

8.0. An audit of license compliance will be performed on an annual basis. Audits will include the ALARA program to ensure that personnel receive the lowest exposure possible. The Auditor will note any recommendations or deficiencies on all audits performed; corrective actions will immediately be taken to correct any violation of the license, NRC orders, NRC or State of PA regulations, NRC Confirmatory Action letter, or any other Regulatory Authority commitments. Audit should follow guidance in NUREG-1556, Vol. 18, Appendix I.

## Occupational Dosimetry

9.0. A TLD, OSL, or film badge shall be worn at all times when performing service work. The customer facility may also require their dosimetry to be worn. Additionally, a calibrated PIC or ED shall be worn while performing service work; the self-reader should not be more than 25% of full scale at start of the job. Dosimeter readings shall be noted prior to the start and after the finish of each job. High risk jobs such as source transfers additionally require the use of extremity monitors.

9.1. Records of all occupational doses shall be maintained for any personnel that are monitored.

9.2. Individuals will be monitored in accordance with the criteria in the section entitled "Occupational Dose" in NUREG-1556, Vol. 18, "Consolidated Guidance about Materials License: Program-Specific Guidance about Service Provider Licenses" dated November 2000. Only a NVLAP-approved dosimetry provider will be used.

9.3. When working with devices containing neutron sources such as J.L. Shepherd model 149, neutron dosimetry will be issued and worn. A calibrated working survey meter capable of detecting and calibrated for neutrons will be used while working with any neutron source. Dose for neutron exposure will be calculated based on the neutron dose rate and the time in that dose field. This calculated exposure will be recorded on the dosimeter dose data sheet.

## Radiation Surveys and Leak Test

10.0. A leak test **shall** be taken prior to start of the job **(and specifically when servicing portions of the device with the potential for contamination)** to determine if the source is leaking. Smears or swabs shall be taken in the area most likely to show contamination if the source was leaking **per manufacturer's recommendation.** This smear or swab will be checked with a detector/instrument capable of determining if the source is leaking (a leaking source has greater than 0.005 uCi or 185 Bq).

10.1. Dose rate surveys at contact and 30 cm should be taken on each device and recorded on the "Irradiator Inspection/Test Report" sheet per specific procedure or on the survey sheet. If doses in excess of public dose limits in unrestricted areas are noted, then the site RSO, the Gamma Irradiator Service RSO, and the NRC Operations Center will be notified. Access will be posted and restricted. Dose assessments will be performed on potential members of the public.

10.2. Any smear or swab that shows greater than 1000 dpm will be followed up with area smears to assess the situation. If the follow up smears indicate contamination, the RSO for the facility shall be notified as well as the RSO for Gamma Irradiator Service.

10.3. All leak test smears shall be returned to the Gamma Irradiator Service shop to be counted on a digital counter if not counted on a digital meter in the field. The results will be recorded and a leak test certificate issued to the facility (if requested) stating the results (or recorded on the Inspection Test Report). Leak tests involving source exchange will be taken prior to and after completion of transfer. (This is a PA-regulated activity)

10.4 Radiation surveys of the shop for contamination and dose rates surveys should be quarterly but in no case greater than 6 months as this survey also includes leak test and inventory. (This is a PA-regulated activity)

10.5. Surveys on incoming radioactive material packages shall comply with all aspects of 10 CFR 20.1906 and will have smears taken on outer and inner surfaces. A dose rate survey shall be performed prior to opening package to ensure the dose rates at contact and 1 meter (or TI) on the package are consistent with markings on the label. All packages will be monitored for contamination and radiation levels, and shall be inspected for degradation of package integrity. All information on the shipping document and/or bill of lading shall be reviewed prior to opening package. If the smears show activity in excess of 4Bq/cm2 (49 CFR 173.443) then package shall be closed back up and RSO for the job site, RSO for the service provider, final delivery carrier, the NRC Operations Center and the shipper will be notified.

If any package damage is noted that leads to elevated radiation levels or other potential abnormality with DOT compliance, then the facility RSO, service provider RSO, final delivery carrier, the NRC Operations Center and the shipper will be notified. Package may still be accepted for delivery after consultation with affected parties.

## Maintaining Records

11.0. All records for devices and work performed shall be maintained for review by regulatory authorities and customers. Gamma Irradiator Service will maintain a history for each device serviced including radiation surveys, leak tests, performance test and check-off sheets. All calibration documents will be maintained for review by regulatory authorities or customers. Gamma Irradiator Service will maintain a history of all employees, including personnel dose records for all employees that have been monitored by Gamma Irradiator Service. Initial training records will be kept for the lifetime of the worker as part of their employee record. Authorized Work Procedure (AP-004) documentation will be maintained for 5 years. Audit records will be maintained for 3 years.

## Notifications

12.0. Gamma Irradiator Service will maintain records of repairs that use replacement parts. All replacement parts used will conform to the parts that are listed in the SS&DR and also with the manufacturer's recommendation. GIS will inform the customer licensee, prior to beginning, that they are performing work and if any failure needs to be reported (10 CFR Part 21.21, Notification of failure to comply or existence of a defect and its evaluation). After maintenance or repair is completed, the irradiator or calibration device will be tested and determined to function as designed before being returned to routine use. The site will be provided with a copy of the completed Inspection/Performance Test report.

12.1. The following table lists a summary of required notifications: "Table 8.4 Typical NRC Incident Notifications Required for Service Provider Licensees" and/or Agreement State Regulators; this notification will be made by the service provider RSO.

**Table 8.4 Typical NRC Incident Notifications Required for Service Provider Licensees.**

| Event | Telephone Notification | Written Report | Regulatory Requirement |
|---|---|---|---|
| Theft or loss of material | immediate | 30 days | 10 CFR 20.2201(a)(1)(i) |
| Whole body dose greater than 0.25 Sv (25 rems) | immediate | 30 days | 10 CFR 20.2202(a)(1)(i) |
| Extremity dose greater than 2.5 Sv (250 rems) | immediate | 30 days | 10 CFR 20.2202(a)(1)(iii) |
| Whole body dose greater than 0.05 Sv (5 rems) in 24 hours | 24 hours | 30 days | 10 CFR 20.2202(b)(1)(i) |
| Extremity dose greater than 0.5 Sv (50 rems) in 24 hours | 24 hours | 30 days | 10 CFR 20.2202(b)(1)(iii) |
| Whole body dose greater than 0.05 Sv (5 rems) | none | 30 days | 10 CFR 20.2203(a)(2)(i) |
| Dose to individual member of public greater than 1 mSv (100 mrems) | none | 30 days | 10 CFR 20.2203(a)(2)(iv) |
| Defect in equipment that could create a substantial safety hazard | 2 days | 30 days | 10 CFR 21.21(d)(3)(i) |
| Filing petition for bankruptcy under 11 U.S.C. | none | immediately after filing petition | 10 CFR 30.34(h) |
| Expiration of license | none | 60 days | 10 CFR 30.36(d) |
| Decision to permanently cease licensed activities at entire site | none | 60 days | 10 CFR 30.36(d) |
| Decision to permanently cease licensed activities in any separate building or outdoor area that is unsuitable for release for unrestricted use | none | 60 days | 10 CFR 30.36(d) |
| No principal activities conducted for 24 months at the entire site | none | 60 days | 10 CFR 30.36(d) |
| No principal activities conducted for 24 months in any separate building or outdoor area that is unsuitable for release for unrestricted use | none | 60 days | 10 CFR 30.36(d) |
| Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits | immediate | 30 days | 10 CFR 30.50(a) |
| Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits | 24 hours | 30 days | 10 CFR 30.50(b)(2) |
| Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material | 24 hours | 30 days | 10 CFR 30.50(b)(4) |

*Note:* Telephone notifications shall be made to the NRC Operations Center at (301) 816-5100 or (301) 951-0550.

## ADDENDUM TO Radiation Safety Manual

**Operating and Emergency Procedures Relating to Service Work on Panoramic or open air collimated devices** (ANSI Category II)

13.0. Service work may be provided on panoramic or open air collimated irradiator devices (ANSI Category II). Examples of these devices include J.L. Shepherd Models 81, 28, 78-2M and 142. Verification of Authorized Work Procedure: reference Document AP-004. No work will be performed unless work activities have been confirmed to fall within the allowed licensed activities.

13.1 Responsibilities of customer and service provider

Devices that are serviced at the customer's facility will be serviced under the Gamma Irradiator Service license. Gamma Irradiator Service will comply with facility's rules for maintaining control of radioactive material and security while service work is being performed, and will also comply with all facility requirements for safety including postings. In addition, Gamma Irradiator Service may use additional locks or tag outs to control use while service is being provided. Any degradation of the safety system or any part of the device that could cause failure will be identified and recommendations made to the customer. An agreement between Gamma Irradiator Service and the customer will be established that specifies all aspects of the work provided including individual responsibilities, licensed activity responsibilities, safety commitments, and site decontamination or cleanup if necessary. This document will be maintained for inspection.

13.2. Instructions for handling and use of radioactive material (all devices)

All personnel working under the Gamma Irradiator Service license will be monitored for radiation exposure using a self-reading dosimeter or electronic dosimeter and NVLAP approved dosimetry. Personnel working on a routine basis providing service under the Gamma Irradiator Service license shall have completed the 40 hour health physics class (refresher training annually) and be monitored for radiation exposure with a TLD or OSL or film badge, and a self-reading dosimeter or electronic dosimeter. Extremity dosimeters will also be worn. Operation and use of devices shall be consistent with the manufacturer's recommendations and Emergency Procedures in the manual for the device for which service is being provided. Personnel working on all devices shall use a calibrated and operational survey meter in the area at all times. ALARA will be practiced when servicing all devices. Personnel shall comply with the customer's security of licensed material when service is being performed. A smear survey of portions of the device (per manufacturer's recommendation) most likely to show if a source is leaking, should be taken prior to service work if applicable. If smear results **are greater than 0.005 µCi (185 Bq), follow the guidance in GIS EMP-001, Emergency Procedures**. Determine if the smears are the same isotope as in the device by using absorbers or a single or multi-channel analyzer. If a source is determined to be leaking (≥ .005 µCi) immediately remove from service, develop a plan for decontamination, repair or disposal with the customer.

13.3 Operating and Emergency Procedures

The types of service work that may be performed on ANSI Category II irradiators includes routine preventive maintenance, service repair work, testing/inspection of irradiators, leak test performance, and irradiator relocation or removal. The manufacturer's procedures for inspection, maintenance, and test of safety systems, if applicable, shall be followed. Upon entering the irradiator room and prior to commencing service work on

these devices, the beam port plug will have been installed. If the beam plug is damaged or modified in any way, the customer shall request a replacement beam plug from the manufacturer.

Procedures required to perform routine maintenance on these irradiators includes but is not limited to the following: leak test, check of all interlocks and safety systems, pneumatics, drives, cables, lubrication per manufacturer's recommendation, micro switches, relays, timers, and mechanical wear on parts. Replacement parts will be in conformance with the parts that have been identified in the sealed source and device registration and in agreement with the manufacturer's recommendation. Any non-manufacturer supplied replacement components or the use of materials (e.g, lubricants) other than those specified or recommended by the manufacturer will be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration before they are used.

A dose rate survey of the device will be recorded along with the results of the leak test. The Irradiator Inspection/Performance Test report acts as the procedure for guidance to ensure all components are tested as needed for all irradiators. Service will not be completed until after an Inspection/ Performance Test List is completed and after operating the unit more than 35 times or sufficient times to ensure proper operation of the safety system and interlock system. In addition, all functions listed in 10 CFR 36 will be tested for proper operation, such as scram switches or emergency stop switches, door interlock switches, time delay relays, audible and visual alarms. At all times a calibrated and operational survey meter will be used to detect radiation fields. No entry into areas > 100 mR/hr is permitted unless all ALARA principles have been exhausted and instructions and dose estimates have been calculated and proper instructions are followed.

If these operations are not performed properly with attention to radiation safety principles, the irradiator may not operate as designed and personnel performing these tasks could receive lethal radiation doses. Only personnel with documented training on the Category II model being serviced can perform work on the device; personnel will follow appropriate procedures consistent with the manufacturer's written instructions and recommendations that address radiation safety concerns at all times.

The following procedures will be followed in the general order as listed:

1. Service provider personnel will wear all required dosimetry including extremity monitors. A calibrated PIC or ED shall also be worn while performing service work; the self-reader should not be more than 25% of full scale at start of the job. Dosimeter readings shall be noted prior to the start and after the finish of each job.

2. Use only those survey meters that have been verified to be appropriately working and calibrated.

3. Operate the device in normal mode to define if the device is operating properly following the instructions in the operation manual.

4. Verify that the source is in the stored position (green light illuminated) then remove the key from the control panel and disconnect the air supply or electrical power to the source drive so the source cannot move.

5. Perform a dose rate survey as the irradiator room is entered; the survey instrument will be kept on while in the area at all times.

6. Perform a leak test, prior to working on the device, of the area most likely to show contamination (per manufacturer's recommendation); see Section 13.2.

7. Insert the beam plug; this shielding will remain in place until the service work is completed.
8. Test all electrical components for tight connections and relay operability. Test switches independently to ensure switches used in the safety system have not failed closed. Check timers against a calibrated stopwatch for accuracy.

9. Test all safety interlocks independently to ensure proper operation such as scram switches, set-up switch, photo-cells, door switches, audible and visual alarms, etc.
10. Check mechanical components for wear and replace as needed. Cables, drive motors, bearings, chains, sprockets and set screws will be checked, lubricated and or adjusted as needed.
11. Check pneumatic systems for leakage (internal and external).
12. Reconnect the air or electrical supply and operate the device 35 times or sufficient amount of times to ensure proper operation.
13. Any inspection items that cannot be corrected will be noted. If failed items are part of the safety system, the device will be tagged out of service until the problem is corrected. Determine if the failure could cause a substantial safety hazard per 10 CFR part 21.21. Notify facility RSO and regulatory authorities as needed: Make notifications per Table 8 in the Radiation Safety Manual (10 CFR part 30.50) and 10 CFR 21.21 as applicable.
14. Upon completion of service visit, provide a copy of the Irradiator Inspection/Test Report to the customer. Communicate any problems or recommendations.

## 13.4 **EMERGENCY PROCEDURES**

Gamma Irradiator Service Document EMP-001 will be readily available and accessible to GIS staff at all times.

Panoramic or open air collimated units: Emergency Procedures will follow the recommendation in the manufacturer's operator's manual for normal service work.

To help prevent a source unintentionally becoming unshielded during non-routine service (such as irradiator relocation), the ALARA Review Document will address the specific precautions based on the steps in the type of transfer involved, location and/or room design, and training. Personnel will follow the requirement to wear all required dosimetry including extremity monitors.

An emergency situation may be one of the following examples, although this is not a comprehensive list:

- The irradiator device falls or topples over
- An alarm from an area monitor, Electronic Dosimeter, or an off scale self-reading dosimeter or PIC
- An over-exposure event takes place, including public dose limits in unrestricted areas
- A source unintentionally becomes unshielded or dislodged and a safe setting is unattainable
- A source becomes stuck in an unshielded position

Anytime there is an emergency, work will immediately cease. Follow the guidance in the GIS Emergency

Procedures Manual (EMP-001), which includes a ready reference to the points of contact in Agreement States, taken from the website at http://nrc-stp.ornl.gov/asdirectory.html.