October 18, 2012

US Nuclear Regulatory Commission Region 1

P3

Subject: Request for License amendment

03036438

Attn: Kathy Modes Marc Ferdas

Dear Sir or Madam

Request for license amendment NRC 37-30850-01, Attachment A list all documents and the number of pages with each, all documents are version D-2 dated 10/15/12. As per request from the NRC (Kathy Modes) I am sending the complete package the same as being sent to the NRC with exception of the request letter. All request from the PA DEP letter (from John Chippo) dated 10/2/2012 and the NRC Docket No. 03036438 License No 37-30850-01 Mail Control No. 579147 have been addressed and reviewed by my third party. If any other information is required please contact me .

Sincerely,

Doyle Terry Stout
Owner Radiation Safety Officer
Gamma Irradiator Service
License NRC 37-30850-01

579147

List of GIS submitted documents to the NRC and PA DEP

Attachment A

1. GIS-014 Procedure for Unloading/Loading Single source irradiators, 11 pages, version D-2 10/15/12
2. GIS Preventative Maintenance Procedure GMP 002, 4 pages, Version D-2 10/15/12
3. GIS REL-003 Procedure for Relocation and Preparation for Shipping 3 pages, Version D-2 10/15/12
4. Emergency Procedure GIS EMP 001, 17 pages, Version D-2 10/15/12
5. Third party review GIS cover letter dated 10/15/12 6 pages
6. Radiation Safety Manual, 18 pages, Version D-2 10/15/12
7. GIS-ALA-001. 3 pages, ALARA Procedure, Version D-2 10/15/12
8. Authorized Work GIS-AP-004, 1 page, Version D-2 10/15/12
9. Sample ALARA Document, 2 pages (and as many more is needed for job review) Version D-2 10/04/12
10. GIS 001A Transfer Shield and GIS 014 A Version D2 10/04/12 drawing
11. Source Stop Tool Version D-2 10/04/12 drawing
12. Signed request Letter NRC 10.18.12 or signed letter for PA DEP
13. Sample Service Report
14. List of submitted documents to the NRC and PA State Attachment A 10.15.12

Preventative Maintenance Procedure

PART 1: ANSI CATEGORY I:

The Irradiator make and models on which this license authorizes service work and that apply to this procedure are:

1. J.L. Shepherd Mark 1 Series (Registration Number CA 598-D-104-S)
2. J.L. Shepherd Model 484 (Registration Number CA 598-D-113-S)
3. J.L. Shepherd Model 89 (Registration Number CA 598-D-108-S)
4. J.L. Shepherd Model 143 (Registration Number CA-598-D-103-S)
5. J.L. Shepherd Model 109 (Registration Number CA 598-D-116-S)
6. CIS-US Model IBL 437 (Registration Number MA 0219-D-813-S)
7. Gammacell 40 (Registration Number NR-1307-D-101-S or NR-0169-D-132-U)
8. Gammacell 1000 & 3000 (Registration Number NR-1307-D-102-S or NR-0220-D-840-S)
9. Eberline 1000B (Registration Number NR-8105-D-805-S)
10. Gammacell 220 (Registration Number NR 0220-D-831-S or NR-8135-D-804-S)
11. Gammacell 200 (Registration Number NR-8003-D-802-S)
12. Gammator Model M, M34, M38, G50, G100, G150 and G 200 (Registration Number NR-0880-D-806-S)
13. J.L. Shepherd Model Gammacell 220R (Registration Number CA 598-D-118-S)
14. J.L. Shepherd Model 142-MA (Registration Number CA 598-D-131-S)
15. J.L. Shepherd Model 149 Series (Registration Number CA 598-D-109-S)
16. J.L. Shepherd Model Mark IV Dosimeter Irradiator (Registration Number CA 598-D-105-S)

Prerequisites:

1. Verify work procedure is authorized via AP-004.
2. Verify Irradiator make and model is authorized.
3. Determine identities of all personnel involved in the job.
4. Determine adequacy of training and experience.
5. Determine adequacy of dosimetry.
6. Determine availability of equipment and instrumentation. Wherever possible, replacement parts will be obtained from the manufacturer. 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.
7. Verify ready availability of GIS EMP-001 for use in emergency procedures.

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.

Preventative maintenance will be completed with the Irradiator Inspection/Performance Test Report. Test of all items listed in the specific Irradiator Inspection/Performance Test Report will be identified as OK with a yes or no. Any items that are deficient will be corrected and noted in the comment section. A typical procedure for preventative maintenance of Category I irradiators is outlined below:

1. Perform a dose rate survey with the highest contact and 30 cm reading.
2. Perform a leak test prior to working on the device.
3. 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.
4. Check mechanical components for wear and replace as needed. Drive motors, bearings, chains, sprockets and set screws will be checked, lubricated and or adjusted as needed.
5. Check pneumatic systems for leakage (internal and external); if multiple sources are used then system will be checked for unison.
6. Operate the device 35 times or sufficient amount of times to ensure proper operation.
7. Any 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 8.4 in the Radiation Safety Manual (10 CFR part 30.50) and 10 CFR 21.21 as applicable.
8. Upon completion of service visit, provide a copy of the Irradiator Inspection/Test Report to the customer. Communicate any problems or recommendations.

PART 2: ANSI CATEGORY II:

The irradiator make and models on which this license authorizes service work and that apply to this procedure are:

1. J.L. Shepherd Model 28 (Registration Number CA 598-D-106-S)

2. J.L. Shepherd Model 81-8, 81-8EXT, 81-10, 81-12, 81-12EXT, 81-14, 81-16, 81-18, 81-20, 81-22, 81-24, 81-26 (Registration Number CA 598-D-115-S)
3. J.L. Shepherd Model 142 (Registration Number CA 598-D-114-S)
4. J.L. Shepherd Model 78-2M (Registration Number CA 598-D-107-S)

Prerequisites:

1. Verify work procedure is authorized via AP-004.
2. Verify Irradiator make and model is authorized.
3. Determine identities of all personnel involved in the job.
4. Determine adequacy of training and experience.
5. Determine adequacy of dosimetry.
6. Determine availability of equipment and instrumentation. Wherever possible, replacement parts will be obtained from the manufacturer. 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.
7. Verify ready availability of GIS EMP-001 for use in emergency procedures.

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.

Preventative maintenance will be completed with the Irradiator Inspection/Performance Test Report. Test of all items listed in the specific Irradiator Inspection/Performance Test Report will be identified as OK with a yes or no. Any items that are deficient will be corrected and noted in the comment section. A typical procedure for preventative maintenance of Category II irradiators is outlined below:

1. Verify that the source is in the stored position (green light illuminated) then remove the key from the control panel; disconnect the air supply or electrical power to the source drive so the source cannot move.
2. 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.
3. Perform a leak test prior to working on the device.
4. Insert the beam plug; this shielding will remain in place until the service work is completed.

5. 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.
6. 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.
7. 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.
8. Check pneumatic systems for leakage (internal and external).
9. Reconnect the air or electrical supply and operate the device 35 times or sufficient amount of times to ensure proper operation.
10. 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 8.4 in the Radiation Safety Manual (10 CFR part 30.50) and 10 CFR 21.21 as applicable.
11. Upon completion of service visit, provide a copy of the Irradiator Inspection/Test Report to the customer. Communicate any problems or recommendations.

Emergency Procedures

Dislodged Source or exposed source:

1. Immediately exit the area.
2. Notify facility RSO and regulatory authorities as needed: Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50).
3. Keep others out of area, post area, verify dose rates, lock doors or post barricades to ensure that dose to members of the public do not exceed .002 rem in 1 hour in unrestricted areas (10 CFR 20.1301).
4. Evaluate worker dose received using dosimetry worn.
5. Develop a recovery plan in conjunction with facility RSO (evaluate the need for a Planned Special Exposure that may be needed in accordance with 10 CFR part 20.1206) with long reach tools, shielding and dose estimates; document actions.

Over Exposure Event:

1. Stop all work; immediately exit the area.
2. Evaluate dosimetry and make notifications per 10 CFR Part 20.2202.
3. Notify facility RSO and regulatory authorities as needed: Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50).
4. Keep over exposed individuals in areas that are not greater than background.

Alarming Dosimeter or Area Monitor:

1. Anytime there is an alarm from an area monitor, Electronic Dosimeter or an off scale self-reading dosimeter, work will immediately cease. All personnel will exit the area until all determinations are made as to the reason for such alarm.
2. If an off scale survey meter condition exists, exit the area until a determination can be made if the meter is faulty or there is a real problem.
3. Notify facility RSO and regulatory authorities as needed: Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50).
4. Keep others out of area, post area, verify dose rates, lock doors or post barricades to ensure that dose to members of the public do not exceed .002 rem in 1 hour in unrestricted areas (10 CFR 20.1301).
5. Evaluate worker dose received using dosimetry worn.
6. Develop a recovery plan in conjunction with facility RSO; document actions.

Medical Emergency:

1. Put work in safe condition if possible, then stop and assist injured individual if needed.
2. Contact facility RSO.
3. Follow site specifics for a medical emergency.

Fire:

1. Put work in safe condition, if possible.
2. Exit the area per site specifics, contact facility RSO.
3. If entering the area after a fire, monitor dose rates to verify that the source integrity has been maintained.

Flood:

1. Put work in safe condition, if possible.
2. Exit the area per site specifics, contact facility RSO.
3. If returning to an area that has been flooded, monitor for dose rates and contamination.

Irradiator Fails to function as designed:

1. Determine if the failure could cause a substantial safety hazard per 10 CFR part 21.21.
2. Notify facility RSO and regulatory authorities as needed: Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50) and 10 CFR 21.21 as applicable.
3. Repair if possible to restore to a safe operating condition. If repair cannot be made, remove the unit from service until it can be repaired.

Leaking Source:

1. If removable contamination in excess of .005 μCi is detected on a source, restrict access to the room, notify the facility RSO and the Gamma Irradiator Service RSO, and take additional area smears. Document locations and contamination level of each smear.
2. Request that facility RSO immediately lock and tag the irradiator out of service.
3. Develop a plan for decontamination, repair or disposal, in consult with the facility RSO.
4. Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50).

Device topples over or Rigging fails:

1. Immediately perform a dose rate survey to ensure the source has not been dislodged. If elevated dose rate other than what is anticipated or visual damage to the irradiator (that may cause the source to leak) immediately exit the area.
2. Notify facility RSO and regulatory authorities as needed: Make notifications per Table 8.4 in the Radiation Safety Manual (10 CFR part 30.50).
3. Keep others out of area, post area, verify dose rates, lock doors or post barricades to ensure that dose to members of the public do not exceed .002 rem in 1 hour in unrestricted areas (10 CFR 20.1301).
4. Evaluate worker dose received using dosimetry worn.
5. Secure the device from unwanted movement and verify that it cannot move any more.
6. If the dose rates are acceptable and visual damage is observed that may cause a source to leak, perform a smear survey for contamination.
7. Develop a recovery plan in conjunction with facility RSO.
8. If specialized equipment is needed, arrange to acquire equipment and recover as needed.

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.

The following is a ready reference to the points of contact in Agreement States, taken from the website at http://nrc-stp.ornl.gov/asdirectory.html.

Alabama

Agreement State Director	State Liaison Officer
James L. McNees, Director Office of Radiation Control Alabama Department of Public Health 201 Monroe Street The RSA Tower, Suite 700 P.O. Box 303017 Montgomery, AL 36130-3017 PH (334)206-5391 FX (334)206-5387 james.mcnees@adph.state.al.us	**James L. McNees**, Acting Director Office of Radiation Control Alabama Department of Public Health 201 Monroe Street The RSA Tower, Suite 700 P.O. Box 303017 Montgomery, AL 36130-3017 PH (334)206-5391 FX (334)206-5387 james.mcnees@adph.state.al.us

Alaska

Non-Agreement State Director	State Liaison Officer
Clyde E. Pearce, Chief Radiological Health Program Section of Laboratories State of Alaska/DH&SS 4500 Boniface Parkway Anchorage, AK 99507-1270 PH (907)334-2107 FX (907)334-2163 clyde_pearce@health.STATE.AK.US	**Doug Dasher**, Director Department of Environmental Conservation 610 University Avenue Fairbanks, AK 99709-3643 PH (907)451-2172 FX (907)451-5146 doug.dasher@alaska.gov

Arizona

Agreement State Director	State Liaison Officer
Aubrey V. Godwin, Director Arizona Radiation Regulatory Agency 4814 South 40th Street Phoenix, AZ 85040 PH (602)255-4845 ext. 222 FX (602)437-0705 agodwin@azrra.gov	**Aubrey V. Godwin**, Director Arizona Radiation Regulatory Agency 4814 South 40th Street Phoenix, AZ 85040 PH (602)255-4845 ext. 222 FX (602)437-0705 agodwin@azrra.gov

Arkansas

Agreement State Director	State Liaison Officer
Jared W. Thompson AR Department of Health Radioactive Materials Program 4815 West Markham, Slot H-30 Little Rock, AR 72205 PH (501)661-2173 FX (501)661-2849 jared.thompson@arkansas.gov	**Bernard Bevill**, AR Department of Health Radioactive Materials Program 4815 West Markham, Slot H-30 Little Rock, AR 72205 PH (501)661-2107 FX (501)661-2236 bernard.bevill@arkansas.gov

California

Agreement State Director	State Liaison Officer
Gonzalo Perez, Chief Radiologic Health Branch 1500 Capitol Ave., MS 7610 Sacramento, CA 95814 PH (916)440-7942 FX (916)440-7999 gonzalo.perez@cdph.ca.gov	**Robert Weisenmiller**, Chairman California Energy Commission 1516 Ninth Street Sacramento, CA 95814 PH (916)654-5036 FX (916)653-9040) rweisenm@energy.ca.gov

Colorado

Agreement State Directors	State Liaison Officer
Steve Tarlton, Director Hazardous Materials & Waste Management Division Department of Public Health and Environment 4300 Cherry Creek Drive South Denver, CO 80246-1530 PH (303)692-3423 FX (303)759-5355 steve.tarlton@state.co.us	**Steve Tarlton**, Unit Leader Radiation Management Program, HMWMD-B2 Hazardous Materials & Waste Management Division Dept of Public Health & Environment 4300 Cherry Creek Drive South Denver, CO 80246-1530 PH (303)692-3423 FX (303)759-5355 steve.tarlton@state.co.us

Connecticut

Non-Agreement State Director	State Liaison Officer
Edward L. Wilds, Ph.D., Director Radiation Division Bureau of Air Management Connecticut Dept. of Energy and Environmental Protection 79 Elm Street Hartford, CT 06106 PH (860)424-3029 FX (860)424-4065 edward.wilds@ct.gov	**Edward L. Wilds**, Ph.D., Director Radiation Division Bureau of Air Management Connecticut Dept. of Energy and Environmental Protection 79 Elm Street Hartford, CT 06106 PH (860)424-3029 FX (860)424-4065 edward.wilds@ct.gov

Delaware

Non-Agreement State Director	State Liaison Officer
Frieda Fisher-Tyler, Administrator Delaware Division of Public Health 417 Federal St., Jess S. Cooper Bldg. Dover, DE 19903 PH (302)744-4546 FX (302)739-3839 frieda.Fisher-Tyler@state.de.us	**Frieda Fisher-Tyler**, Administrator Delaware Division of Public Health 417 Federal St., Jess S. Cooper Bldg. Dover, DE 19903 PH (302)744-4546 FX (302)739-3839 frieda.Fisher-Tyler@state.de.us

District of Columbia

Non-Agreement State Director
Gregory B. Talley, Program Manager Department of Health Environmental Health Administration Radiation Protection Division 717 14th Street, NW, 6th Floor

Washington, DC 20005
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Greg.Talley@dc.gov

[redacted]	
Agreement State Director	**State Liaison Officer**
William A. Passetti, Chief Bureau of Radiation Control Florida Department of Health 4052 Bald Cypress Way, SE, Bin C21 Tallahassee, FL 32399-1741 PH (850)245-4266 FX (850)487-0435 bill_passetti@doh.state.fl.us	**William A. Passetti**, Chief Bureau of Radiation Control Florida Department of Health 4052 Bald Cypress Way, SE, Bin C21 Tallahassee, FL 32399-1741 PH (850)245-4266 FX (850)487-0435 bill_passetti@doh.state.fl.us

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Cynthia Sanders, Program Manager Radioactive Materials Program Department of Natural Resources 4244 International Parkway, Suite 114 Atlanta, GA 30354 PH (404)362-2675 FX (404)362-2653 csanders@dnr.state.ga.us	**Jim Hardeman**, Acting Chief Department of Natural Resources Environmental Protection Division- Air Protection Branch 4220 International Pkwy., Suite 100 Atlanta, GA 30354 PH (404)362-2675 FX (404)362-2653 jim.hardeman@dnr.state.ga.us

Hawaii

Non-Agreement State Director	**State Liaison Officer**
Jeffrey M. Eckerd, Supervisor Radiation Section HI Department of Health Indoor & Radiological Health Branch 591 Ala Moana Boulevard, Rm 133 Honolulu, HI 96813 PH (808)586-4700 FX (808)586-5838 jeffrey.eckerd@doh.hawaii.gov	**Lynn Nakasone**, Division Administrator Environmental Health Services Division Department of Health 1250 Punchbowl Street Honolulu, HI 96813 PH (808)586-4576 lynn.nakasone@doh.hawaii.gov

Idaho

Non-Agreement State Director	**State Liaison Officer**
Mark Dietrich Technical Services Administrator Idaho Dept. of Environmental Quality 1410 North Hilton Boise, ID 83706 PH (208)373-0204 FX (208)373-0143 mark.dietrich@deq.idaho.gov	**Mark Dietrich** Idaho Dept. of Environmental Quality 1410 North Hilton Boise, ID 83606 PH (208)373-0240 FX (208)373-0417 mark.dietrich@deq.idaho.gov

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Joseph G. Klinger, Assistant Director Illinois Emergency Management Agency Division of Nuclear Safety 2200 S. Dirksen Parkway Springfield,IL 62703 PH (217)785-9868 FX (217)558-7398 Joe.Klinger@illinois.gov	**Joseph G. Klinger**, Assistant Director Illinois Emergency Management Agency Division of Nuclear Safety 2200 S. Dirksen Parkway Springfield,IL 62703 PH (217)785-9868 FX (217)558-7398 Joe.Klinger@illinois.gov

Indiana

Non-Agreement State Director	State Liaison Officer
Mary Stiker Indiana Department of Homeland Security Indiana Government Center South 302 W. Washington Street-Room E208 Indianapolis, IN 46204 PH (317)605-7546 FX (317)234-7234 mstiker@dhs.in.gov	**Joan Duwve**, MD Chief Medical Officer Indiana State Department of Health 2 North Meridian Street Indianapolis, IN 46204 PH (317)233-7400 FX (317)233-7387 jduwve@isdh.in.gov

[redacted]

Agreement State Director	State Liaison Officer
Melanie Rasmusson, Chief Bureau of Radiological Health Iowa Department of Public Health Lucas Office Bldg., 5th Floor 321 East 12th Street Des Moines, IA 50319 PH (515)281-3478 FX (515)281-4529 mrasmuss@idph.state.ia.us	**Melanie Rasmusson**, Chief Bureau of Radiological Health Iowa Department of Public Health Lucas Office Bldg., 5th Floor 321 East 12th Street Des Moines, IA 50319 PH (515)281-3478 FX (515)281-4529 mrasmuss@idph.state.ia.us

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Agreement State Director	State Liaison Officer
Thomas A. Conley, RRPT, CHP, Section Chief Radiation and Asbestos Control KS Dept of Health & Environment 1000 SW Jackson, Suite 310 Topeka, KS 66612-1366 PH (785)296-1565 FX (785)296-0984 tconley@kdheks.gov	**Thomas A. Conley**, RRPT, CHP, Section Chief Radiation and Asbestos Control KS Dept of Health & Environment 1000 SW Jackson, Suite 310 Topeka, KS 66612-1366 PH (785)296-1565 FX (785)296-0984 tconley@kdheks.gov

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Agreement State Director	State Liaison Officer
Matthew W. McKinley KY Cabinet for Health Services Radiation Health Branch 275 East Main Street HS1C-A Frankfort, KY 40621-0001 PH (502)564-3700 ext 3701	**Matthew W. McKinley** KY Cabinet for Health Services Radiation Health Branch 275 East Main Street HS1C-A Frankfort, KY 40621-0001 PH (502)564-3700 ext 3701

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Agreement State Director	State Liaison Officer
Tim Knight, Administrator Emergency & Radiological Services Div. Environmental Compliance P.O. Box 4312 Baton Rouge, LA 70821-4312 PH (225)219-3624 FX (225)219-4044 tim.knight@la.gov	**Richard Scott Blackwell**, Environmental Scientist Supervisor LA Department of Environmental Quality Emergency & Radiological Services Division P.O. Box 4312 Baton Rouge, LA. 70821-4312 PH (225) 219-3639 richard.blackwell@la.gov

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Jay Hyland, Manager Radiation Control Program Division of Health Engineering 11 State House Station 286 Water St, Key Plaza, 4th Floor Augusta, ME 04333 PH (207)287-5677 FX (207)287-3059 jay.hyland@Maine.gov	**Jay Hyland**, Manager Radiation Control Program Division of Health Engineering 11 State House Station 286 Water St, Key Plaza, 4th Floor Augusta, ME 04333 PH (207)287-5677 FX (207)287-3059 jay.hyland@Maine.gov

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Roland G. Fletcher Environmental Program Manager III Radiological Health Program Air & Radiation Management Adm. Maryland Dept of the Environment 1800 Washington Blvd Suite 750 Baltimore, MD 21230-1724 PH (410)537-3300 FX (410)537-3198 rfletcher@mde.state.md.us	**Tom Levering**, Emergency Response Director Maryland Dept of the Environment 1800 Washington Blvd, Suite 7111 Baltimore, MD 21230-1720 PH (410)537-4460, 24 hour (443)721-7891 FX (410)537-3391 TLevering@mde.state.md.us

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Robert Gallaghar, Acting Director Radiation Control Program Department of Public Health Schrafft Center, Suite 1M2A 529 Main Street Charlestown, MA 02129 PH (617)242-3035, x2001 FX (617)242-3457 robert.gallaghar@state.ma.us	**John Giarrusso, Jr.**, Planning & Preparedness Division Chief Massachusetts Emergency Management Agency 400 Worcester Road Framingham, MA 01702-5399 PH (508)820-2040 FX (508)820-2015 John.Giarrusso@state.ma.us

Michigan (*Letter of Intent*)

Non-Agreement State Director	State Liaison Officer
Ken Yale, Acting Section Chief Radiological Protection Section Waste and Hazardous Materials Div. MI Dept of Environmental Quality 525 West Allegan Street PO Box 30241 Lansing, MI 48909-7741 PH (517)241-1278 FX (517)373-4797 yalek@michigan.gov	**Ken Yale**, Acting Section Chief Radiological Protection Section Waste and Hazardous Materials Div. MI Dept of Environmental Quality 525 West Allegan Street PO Box 30241 Lansing, MI 48909-7741 PH (517)241-1278 FX (517)373-4797 yalek@michigan.gov

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Agreement State Director	State Liaison Officer
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Missouri

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October 15, 2012

Mr. D. Terry Stout
337 Distillery Hill Rd
Benton, PA 17814

Dear Terry:

Per your request, I have reviewed all revised documents in preparation for your newest submission to the NRC and the PA Department of Environmental Protection. Specifically, these are:

-Radiation Safety Manual Version D-2
-ALARA Procedure GIS ALA-001 Version D-2
-Sample ALARA Document
-Authorized Work Activities Procedure GIS AP-004 Version D-2
-Emergency Procedures GIS EMP-001 Version D-2
-Preventative Maintenance Procedure GIS GMP-002 Version D-2
-Procedure for Relocation and Preparation for Shipping GIS REL-003 Version D-2
-Procedure for Unloading/Loading Single Source Irradiators GIS -014 Version D-2
-Source Transfer Shield GIS 014A pdf drawing
-Source Stop Tool pdf drawing
-Attachment A "List of GIS Submitted documents to the NRC"
-Sample Service Report

In addition, the emails from the NRC (Kathy Modes) dated 10-3-12 and the letter from the PA DEP (John Chippo) dated 10-2-12 were reviewed for outstanding information requested. Your revised documents were compared against all items of information requested, and my comments are listed in detail below. Note that the requested new edits are highlighted in red:

<u>First Email from NRC:</u>

1. All documents have been properly edited to reference this table as Table 8.4.
2. Edits were made to Section 6.1 of the Radiation Safety Manual and Prerequisites Item 6 of the GIS REL-003 document to reflect that "only authorized, licensed shippers" will be used for transportation of radioactive sources or devices. You may want to consider stating, for emphasis, that GIS will not be the shipper of any RAMQC sources, but will contract with an approved shipper.
3. AP-004 document has been changed to highlight the categories in each section, in order to differentiate Category I and II irradiators.
4. Edits to the Radiation Safety Manual:
   a. OSL has been added to the definition for Dosimetry.
   b. Non-Routine Maintenance definition has been changed to match the definition in NUREG 1556 Vol. 5 (for Category I irradiators). Since only

Routine Maintenance may be performed on Category II irradiators, the definition does not also have to include the text from Appendix I in Vol. 6 (for Category II irradiators), and this is sufficient. However, for the Routine Maintenance definition in item 19, you need to edit this so as to end the sentence when the definition for "routine maintenance" ends. It's not applicable to evolve into "non-routine maintenance", as it currently reads. You may also want to go beyond the definition given in NUREG 1556 Vol. 18 and state that "routine maintenance" can be any maintenance tasks that the manufacturer acknowledges can be performed by the customer in accordance with the instructions in the user's manual, and which do not involve the source, device shielding, or safety interlocks.

c. The Eberline survey instrument has been added to Section 7.4. However, please correct the capitalization in the word "Gamma".
d. The intent of this point is understood but additional text has not been added to the Radiation Safety Manual.
e. A clarifying statement has been added to Step 4 of Section 13.3 to indicate that, on pneumatic models, disconnecting the electrical power will cause the air solenoid to supply the air pressure to the air cylinder to maintain the source in a stored position. You will need to ensure that this text box does not block the underlying text. Note that this clarifying statement does not address the NRC's query on whether you have to enter the room to disconnect the air supply or electrical power. If you have to enter the room to perform these tasks, then need to place this as a separate step in the procedures, <u>after</u> Step 5.

5. Edits to GIS-014 Procedure for Unloading/Loading Single Source Irradiators:
   a. Boxes for technician initials have been added to all applicable steps in the procedures. Note that if you elect to insert an initials box at the step for "Be certain to turn off vacuum" (as in Part 2 Step 6) then you will also need to insert an initials box at Part 1 Step 16. "Caution" steps have all been reworded as "Proceed with "Caution"; however, delete the extra spaces at Part 4 Step 12.
   b. Clarifying language related to the potential for misalignment was added in Part 3 Step 11, as well as Part 4 Step 13. However, in order to fully address the NRC's concern, you will need to add text as suggested to account for the possibility of Emergency Procedures. Please replace, in both sections: "If any restrictions are felt, the source will be returned to the transfer shield (insert "NPI shipping cask" if Part 4) and steps will be repeated. (Typically the transfer cask and the shipping cask may have slight misalignment; repeat step 6 (insert "4" if Part 4.) If this occurs a second time, the source will be returned to the transfer shield (insert "NPI shipping cask" if Part 4) and the transfer will be stopped until the problem is resolved. Stop the process, check dose rates, step away to a low dose rate area, discuss status and next steps with GIS personnel and client RSO, and evaluate the need to apply the Emergency Procedures GIS EMP-001 document."

c. Part 4 Step 11 has been reworded to remove the term "upward dose rates".
d. Part 4 Step 15 has been separated into two steps, to MEASURE and record dose rates, and to STOP for a briefing.
e. Part 5 Step 2 has been reworded to clarify applicable irradiator models. However, in order to correct grammar errors, please insert this text instead: "Visually **VERIFY** the source tube is clean and that space pipe is in (Gamma Cell 40 only). Verify irradiator door is locked (Models Mark 1 and Gamma Cell 40 only) and attenuators are in (Model 89 only)." Note that this edit still has not addressed the NRC's concern, and so you will need to insert a new step after this step, with suggested text "**STOP** point: confirm the irradiator door is locked (if applicable) and attenuators are in place (if applicable). If not, then refer to GIS EMP-001 Emergency Procedures." Include an Initials Box for the technician to use. I'd suggest you retain the text box "No transfer will be completed unless the door can be secured closed" at this step, although please note the word "unless" has been misspelled.

Second Email from NRC:

1. I understand that you have already clarified your concerns with the NRC, and you concur that the specified documents can be removed from License Condition 15 of License No. 37-30850-01.
2. Although you have, as requested, now included a Sample Service Report, this report does not sufficiently illustrate the documentation required in the Radiation Safety Manual Section 6.1, second paragraph. Specifically, the text in this paragraph states "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." I recommend that the Sample Service Report be revised to reflect all documentation committed to.

Letter from PA DEP:

1. I do not recommend that you amend GIS AP-004 to add the J.L. Shepherd Model 78-2M irradiator (Category II), because all documents being sent to the NRC indicate that "routine maintenance only will be performed on ANSI Category II irradiators." This commitment is stated throughout your Radiation Safety Manual and other documents, and unless you want to rewrite an entire new set of documents for the State of PA, the revision to AP-004 cannot stand alone.
2. The spelling of "scaler" has been corrected in both locations.
3. Definition for Preventative Maintenance has been added. However, in order to correct spelling/grammar errors, please insert this text instead: **"Preventative maintenance = The task of inspection, testing, and/or replacement of worn parts to ensure the irradiator performs according to the**

Sealed Source and Device Registration and complies with the manufacturer's operating manual. When completed, this ensures that the irradiator performs in a radiologically-safe condition as designed."

4. Addition of instrument training element for measuring radiation field has been made in Section 5.2. However, for consistent reading, please insert this text instead:
   ***Radiation survey techniques for measuring fixed and removable contamination;**
   ***Radiation survey techniques for measuring radiation fields;**
5. Clarification of annual refresher training has been added to Section 5.3.
6. Correction of "should" to "shall" has been made in Section 6.2 regarding smear survey prior to service work.
7. Correction of "should" to "shall" has been made in Section 10.1 regarding dose rate survey prior to service work. Additionally, text has been added to reflect that notifications will include the Commonwealth of PA. However, in order to correct grammar errors and fit as a generic document, please insert this text instead:
   "If doses in excess of public dose limits in unrestricted areas are noted, then the site RSO, the Gamma Irradiator Service RSO, NRC Operations Center, and the Agreement State contact (if applicable) will be notified."
8. Clarification that surveys, leak tests, and inventories will pertain to all licensed sources has been made in Section 10.4.
9. Text in Section 10.5 has been added to reflect that notifications will include the Commonwealth of PA. However, in order to fit as a generic document, please insert this text instead:
   "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, NRC Operations Center, Agreement State contact (if applicable), and the shipper will be notified."
10. Text in Section 13.3 has been reworded so as to reflect that a leak test is performed prior to the beam plug insertion. However, for clarity, please insert this text for the first three paragraphs instead:

"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.

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.

Upon entering the irradiator room and prior to commencing service work on these devices, a dose rate survey and leak test will be performed. Following this, the beam port plug will be installed. If the beam plug is damaged or modified in any way, the customer shall request a replacement beam plug from the manufacturer.

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."

Additional observations:

- Attachment A has an incorrect title. It should be what the header currently reads, which is "List of GIS Submitted Documents to the NRC".
- Attachment A needs to include "Sample Service Report".
- You will want to do a review of the Radiation Safety Manual, after all new edits are made, to confirm that the listed page numbers in the Table of Contents matches the actual page numbers of each corresponding Section.

Following these edits, you should be able to submit all newest document revisions (Version D2) to the regulatory authorities at this time. Thank you for the opportunity to assist Gamma Irradiator Service. Please feel free to contact me if you have any questions or concerns with this review.

Best regards,

Cathy

Cathy Ribaudo,

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Health Physicist
301-460-6878
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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.

Table of Contents

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 scaler 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, OSL 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** = Section 8.10.8 of NUREG-1556 Volume 5 defines "non-routine maintenance" as any repair, removal, replacement, or alteration involving: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, any component that may affect safe operation of the irradiator, or any other activities during which personnel could receive radiation doses exceeding NRC limits.

19. **Routine Maintenance** = Section 8.10.9 of NUREG 1556 Volume 18 defines "Routine Maintenance" as cleaning, lubrication, changing batteries, relays or fuses. This can be any maintenance tasks that the manufacturer acknowledges can be performed by the customer in accordance with the instructions in the user's manual, and which do not involve the source, device shielding, or safety interlocks.

20. **Preventative maintenance** = The task of inspection, testing, and/or replacement of worn parts to ensure the irradiator performs according to the Sealed Source and Device Registration and

complies with the manufacturer's operating manual. When completed, this ensures that the irradiator performs in a radiologically-safe condition as designed.

21. **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).

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

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

24. **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.

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

26. **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.

27. **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
*Radiation survey techniques for measuring radiation fields;
*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 annually 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 licensed 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, 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, **shall** 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
Eberline	E-530	44-6/HP-270	Beta/Gamma
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 Scaler
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 shall 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, NRC Operations Center, and the Agreement State contact (if applicable) will be notified.

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 of any licensed source. (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 smear 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, NRC Operations Center, Agreement State contact (if applicable), and the shipper will be notified.

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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 ($\geq$ .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.

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.

Upon entering the irradiator room and prior to commencing service work on these devices, a dose rate survey and leak test will be performed. Following this, the beam port plug will be installed. If the beam plug is damaged or modified in any way, the customer shall request a replacement beam plug from the manufacturer.

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. **From the control room disconnect the air supply or electrical power to the source drive so the source cannot move.**

NOTE: on pneumatic model (design is fail safe) with no electrical power the air solenoid in the relaxed position (no power) supplies air pressure to the air cylinder for maintaining source in the shielded position.

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 8.4 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.

ALARA Procedure

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. The primary ALARA principles are use of time, distance, and shielding so as to minimize the radiation dose received by a worker. The ALARA Procedure is a formal review process to discuss details of a high risk job so that dose can be as low as achievable. This procedure is for jobs wherein the potential exists for exposure to an unshielded source (usually during source transfers). The items below list all the controls that should or can be utilized and will be considered in each task or step of the source transfer or any other high risk procedure.

1. Primary Shielding
2. Engineering controls
3. Training
4. Communication
5. Long reach handlers
6. Remote observation
7. Emergency conditions
8. Job task
9. Dose evaluation
10. Hold points
11. Verifications
12. Instrument Response check
13. Dosimetry
14. Documented pre job briefing
15. Mock up or dry run prior to source movement
16. Area radiation monitor and instruments for use

Additional Detail:

1. Primary shielding is typically lead or DU that is placed between the source and the device or transfer

shield exterior so as to minimize radiation levels at locations where personnel may be present.

2. Engineering controls are items such as temporary shielding, long reach tooling, alarming meters, and physical stops to prevent unwanted movement of the source.

3. Training shall consist of mock up or dry run, task authorization, engineering controls, Instrument response checks, hold points, communications, use of tooling, lessons learned and review of operating and emergency procedures.

4. Communications shall be discussed to address that each person involved in the transfer of sources shall have a clear understanding of each process in the procedure and limitations. **Use of pass-back communication required.** Understanding is communicated with all personnel that any perception of an unsafe condition is cause for any individual to voice a Stop command. Furthermore, understanding is communicated that all personnel have the opportunity to voice any questions, concerns, process improvements, etc.

5. Evaluate the need for long reach handlers.

6. Remote observation would discuss the use of bore scope, cameras or mirrors to keep dose as low as possible.

7. Evaluation and an emergency plan will be developed based on the type of transfer, location, room size, source size, type of transfer shield setup, etc.

8. Job task will be addressed in the pre job briefing and define who can do what and when.

9. Dose evaluation will be calculated for the various steps in the transfer procedure for whole body and extremities.

10. Hold points are places in the procedure where one person verifies that the preceding step has been completed and will give the thumbs up or repeat the steps until the process is complete. Use of pass-back communication required.

11. Verifications would be used after hold points to ensure that a step in the procedure has been completed successfully.

12. Evaluation of instrument response checks will be determined based on the transfer procedure e.g.: response test after securing a meter for proper operation if the instrument has an alarm, test the alarm function etc.

13. Dosimetry shall be evaluated for the type of transfer to be performed. Also, relocation of dosimetry may be required: the dosimeter may be worn on the shirt pocket, shirt collar, lanyard, belt, etc. so that the highest potential dose rate is recorded.

14. Pre job briefing will be conducted prior to the start of any transfer. The items discussed will be in the ALARA Document and will address all concerns prior to starting the job with the source transfer procedure.

15. A mock-up with all involved in the work or if a mock-up is not possible, then a dry run will be performed prior to moving any sources.

16. Area Radiation monitor will be evaluated: where to locate, how to response test, and actions to take when responding to an alarm.

The above items will be used to develop a Pre job discussion so a formal instruction can be provided prior to starting the job. The attachment "ALARA Document" will have a check off sheet after the final review of the Source Transfer Procedure.

This procedure is to govern licensed work activities within the scope of the license.

1. Verification of licensed activities will be verified by one or more of the following:
    a. Sealed Source and Device Registration
    b. Customer's license, personnel or licensee documentation
    c. Manufacturer's brochure
    d. Manufacturer's web site
    e. Manufacturer's Technical Manual or user's manual
    f. Verification from NRC Regulatory Authorities

No work will be performed unless work activities fall within the allowed licensed activities. After verification is completed work may be scheduled.

The Irradiator make and models on which this license authorizes preventive maintenance and service work and that apply to this procedure are:

Category I

1. J.L. Shepherd Mark 1 Series (Registration Number CA 598-D-104-S)
2. J.L. Shepherd Model 484 (Registration Number CA 598-D-113-S)
3. J.L. Shepherd Model 89 (Registration Number CA 598-D-108-S)
4. J.L. Shepherd Model 143 (Registration Number CA-598-D-103-S)
5. J.L. Shepherd Model 109 (Registration Number CA 598-D-116-S)
6. CIS-US Model IBL 437 (Registration Number MA 0219-D-813-S)
7. Gammacell 40 (Registration Number NR-1307-D-101-S or NR-0169-D-132-U)
8. Gammacell 1000 & 3000 (Registration Number NR-1307-D-102-S or NR-0220-D-840-S)
9. Eberline 1000B (Registration Number NR-8105-D-805-S)
10. Gammacell 220 (Registration Number NR 0220-D-831-S or NR-8135-D-804-S)
11. Gammacell 200 (Registration Number NR-8003-D-802-S)
12. Gammator Model M, M34, M38, G50, G100, G150 and G 200 (Registration Number NR-0880-D-806-S)
13. J.L. Shepherd Model Gammacell 220R (Registration Number CA 598-D-118-S)
14. J.L. Shepherd Model 142-MA (Registration Number CA 598-D-131-S)
15. J.L. Shepherd Model 149 Series (Registration Number CA 598-D-109-S)
16. J.L. Shepherd Model Mark IV Dosimeter Irradiator (Registration Number CA 598-D-105-S)

Category II

17. J.L. Shepherd Model 28 (Registration Number CA 598-D-106-S)
18. J.L. Shepherd Model 81-8, 81-8EXT, 81-10, 81-12, 81-12EXT, 81-14, 81-16, 81-18, 81-20, 81-22, 81-24, 81-26 (Registration Number CA 598-D-115-S)
19. J.L. Shepherd Model 142 (Registration Number CA 598-D-114-S)
20. J.L. Shepherd Model 78-2M (Registration Number CA 598-D-107-S)

The Irradiator make and models on which this license authorizes source loading/unloading and that apply to this procedure are:

Category I

1. J.L. Shepherd Mark 1 Series (Registration Number CA 598-D-104-S)
2. J.L. Shepherd Model 484 (Registration Number CA 598-D-113-S)
3. J.L. Shepherd Model 89 (Registration Number CA 598-D-108-S)
4. Gammacell 40 (Registration Number NR-1307-D-101-S or NR-0169-D-132-U)
5. Gammacell 1000 & 3000 (Registration Number NR-1307-D-102-S or NR-0220-D-840-S)

337 Distillery Hill Road , Benton, pa 17814

Gamma Irradiator Service

Phone 570-925-5681 Fax 570-925-5370

ALARA Document

Location/Customer

Device Model

Scope of work

Responsibilities

Items that have an Alara review are not limited to those listed below.

Procedure for this job

Steps in the procedure that require a ALARA review and any time a source is moved.

Hold points

When to use pass back communication

Training mock up and or dry run

Dosimetry required

Anticipated dose rates and exposure times

Emergency exits specific to location

Review of Emergency procedures

Required tools and source tooling

List of equipment needed to safely perform the job

Remote source handlers 6 to 10 feet

Area monitor location and alarm set points

Shielding requirements

Personnel locations and job task

Engineering controls to prevent unwanted source movement

337 Distillery Hill Road , Benton, pa 17814

Gamma Irradiator Service

Phone 570-925-5681 Fax 570-925-5370 NRC LIC # 37-30850-01 PA LIC # PA-1157

Service Report

Customer: **Contact:**

Address: **CAT: I or II**

telephone: **Service number:**

Service work to be performed: Preventative Maintenance

Service date: **P.O** **Device S.N.**

Model: AECL Gammacell 40

Parts replaced:

Service performed:

Recommendations:

Customer Comments:

All work has been performed to the satisfaction of the representatives signature below.

Service Work To Be Performed By:

G.I.S. Representative Signature | Date | Customer Representative Signature

Agreement for responsibilities between Customer and Gamma Irradiator Service

Customer retains possession of sources and maintains security in accordance with their license. Gamma Irradiator Service will maintain posting, labeling, and locking requirements for radiation protection of device when performing service work.