



GE Healthcare

Tracy L. Gale
Radiation Safety Officer

GE Precision Healthcare
219 Sugartown Rd
Apt N104
Wayne, PA 19087

T 518-859-6426
F 518-218-9311
tracy.gale@ge.com

United States Nuclear Regulatory Commission
Region I
475 Allendale Road – Suite 102
King of Prussia, PA 19406-1415

August 18, 2022

RE: Radioactive Material License No. 06-32815-01

Dear Mr. Ayala

This letter is in response to your letter dated July 22, 2022, for additional information needed for our amendment request.

1. Item 5: On your application, you listed Co-57 as a new isotope you would like to add to your license. In accordance with NUREG-1556, Volume 18, Revision 1 "Consolidated Guidance About Materials Licenses, Program-Specific Guidance About Service Provider Licenses," (NUREG-1556, Vol. 18, Rev. 1), Section 8.5.1, "Sealed Sources," please provide the manufacturer(s) name(s) and model number(s) for the Co-57 sealed source(s) requested, including the Sealed Source and Device Registration (SSDR) number for those source(s), and the purpose of use. Please note that the source models listed on the license will be limited to those sources listed in the SSDR certificates submitted with the application for the devices you intend to service.

The manufacture name for the Co-57 sealed source requested is Eckert & Ziegler Isotope Products dba Isotope Products Laboratories Model Number PHI-0124 and Sealed Source and Device Registration (SSDR) number CA-0406-S-118-S.

For use incident to installation, relocation, removal from service, repair, source replacement, calibration, testing and radiation surveys of sealed and their devices which have been registered pursuant to 10 CFR 30.32(g) or equivalent Agreement State regulations as a service to customers at customers facilities.

2. Item 7: In accordance with NUREG-1556, Vol. 18, Rev. 1, Section 8.7.1 "Radiation Safety Officer," confirm that the RSO will be available for emergencies and can be on site within 24-48 hours, if applicable.

We confirm that the RSO (Tracy Gale) will be available for emergencies and can be on-site within 24-48 hours.

3. Item 10.1: In accordance with NUREG-1556, Vol. 18, Rev. 1, Section 8.10.1, "Operating and Emergency Procedures," provide the following:

- a. Procedures that govern handling/use of sources, damaged sources, remote handling tools, and access control including security of the area where work is performed.

Appended is the current revision of our Nuclear and PET Scanner Radioactive Material Guidelines, Revision 20, dated April 5, 2022. These procedures include handling/use of sources, damaged sources, and remote and remote handling tools.

We maintain security of the areas where work is performed, obtain authorization from the customer prior to accessing sources and follow the customers site-specific radioactive material handling procedures including adherence to customer site-specific emergency procedures.

- b. Procedures for obtaining an agreement with customers outlining the responsibilities of both the customer and service provider, when performing service operations at a customer's facility.

Our general service agreement between the customer and GE Healthcare includes written customer responsibilities to 'maintain licenses, permits and any other approvals required to receive or use radioactive sources and provide the sources needed for calibration and performance checks'. In addition, 'GE Healthcare may stop work due to safety concerns. Customer must comply with GE Healthcare's EHS requirements, provide a safe environment for GE Healthcare personnel, thoroughly clean Product before Servicing, provide radioactive materials required for testing Products, and dispose of waste related to Products.

- c. Condition 15.C of your current license lists procedures and other commitments for activities to be performed. The list includes the procedures, "Nuclear and PET Scanner Radioactive Material Guidelines, Technical Publication Direction 2346591 DRS, Revision 9" and "Source Pin Handling Techniques, dated June 29, 2011." Confirm if these documents continue to be a required part of your radiation safety program. If so, state if these revisions remain in effect or have been superseded by a newer revisions. If newer revisions exist, please provide the revised documents.

We confirm that Nuclear and PET Scanner Radioactive Material Guidelines, Technical Publication Direction 2346591 DRS, Revision 9 has been superseded by a new revision; Nuclear and PET Scanner Radioactive Material Guidelines, Revision 20, dated April 5, 2022. This newer revision is appended.

We confirm that Source Pin Handling Techniques, dated June 29, 2011 is no longer required to be part of our radiation safety program.

If you have any questions or concerns, please do not hesitate to contact me.

Sincerely

A handwritten signature in cursive script, appearing to read "Tracy L. Gale".

Tracy L. Gale
RSO
GE Healthcare Field Service

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US Services Nuclear and PET Scanner Radioactive Material Guidelines

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REVISION HISTORY

Revision #	Rev Date	Author Name	Sections Affected
13	04/02/2015	Tracy L. Gale	Annual review conducted
14	06/29/2015	Colin Bender	Updated Program Format
15	04/01/2017	Tracy L. Gale	Annual review conducted
16	04/05/2018	Tracy L. Gale	Annual review conducted Removed <ul style="list-style-type: none"> • “The replacement or handling of radioactive material for use in GE products will be handled under the direction of the customers site RSO.” • “GEHC Field Service Engineers shall not physically prepare mix or transport (drive) liquid radioactive materials. Field Service Engineers are allowed to transport shielded pin sources (not PET phantoms) within the facility under the site’s radioactive material handling guidelines.” • “GEHC employees CAN NOT service or activate as part of servicing, the source assembly on OEM equipment (such as ADAC, Siemens, etc).” Added F-18 to Section 3.10 Updated GEHC-EHS-HCS37055078, State Notification and Radiation Survey Meter Training for Field Service to GE-EHS-574 Radiation Surveys Renumbered outline and made minor clarifications. Updated section 5
17	04/01/2019	Tracy L. Gale	Updated section 5

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18	04/06/2020	Tracy L. Gale	Added Co-57 to section 2.2.2, 3.3.3
19	05/10/2021	Tracy L. Gale	Made clarifications and simplifications to improve intent of procedure. Removed references to exempt sources. Reformatted sections and numbering. Moved detail for product training, emergency procedures and skin contamination to appendices.
20	04/12/2022	Tracy L. Gale	Annual review conducted

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1. SCOPE/PURPOSE

- 1.1 This document provides guidance to Field Engineers for the handling of radioactive sources during installation, replacement and service of Nuclear Medicine and PET imaging equipment.
- 1.2 Licenses for equipment operation, FDA approval, and patient or equipment user qualifications are not addressed in this document.

2. DEFINITIONS

- 2.1 **Radioactive material** means any solid, liquid, or gas that undergoes the process of spontaneous transformation of the nucleus, through the emission of alpha, beta particles, x-ray or gamma rays.
- 2.2 **Radiation Safety Officer (RSO)** means the qualified individual designated to implement and manage the radioactive materials program. In this procedure, customer RSO refers to the individual designated by the customer; Field Service RSO refers to Tracy Gale, the USCAN radiation safety officer for GE Healthcare.
- 2.3 **Sealed source** means any radioactive material that is permanently encased in a capsule designed to prevent leakage or escape of the radioactive material. These include the Pin sources (Germanium-68), attenuation correction sources (Gd-153), and button sources (Co-57).
- 2.4 **Technologist** means the customer's authorized user for radioactive materials. Typically, a nuclear medicine technologist or other representative.
- 2.5 **Unsealed source** means radioactive material that is not encapsulated or contained. The radioactive material, if not controlled, can move around and cause contamination. These include liquid sources used to calibrate SPECT imaging equipment (Tc-99m, In-111, Ga-67) and liquid filled phantoms used to calibrate PET imaging equipment (F-18, Ga-68).

3. TRAINING

- 3.1 Before using radioactive materials, complete assigned training. GE Learning courses include:
 - 3.1.1 GE-EHS-575, Radiation Safety
 - 3.1.2 GE-EHS-574, Radiation Surveys
- 3.2 Refer to Appendix 1 for Product and On-The-Job Training courses

4. WORKING WITH RADIOACTIVE MATERIAL

- 4.1 We do not receive, transport, or ship radioactive material for customers. Advise customers that we are not authorized to perform these activities.
- 4.2 Obtain authorization from the customer RSO prior to accessing sources from their hot lab or system.
- 4.3 Understand and follow the customer site-specific radioactive material handling procedures.
- 4.4 Handle pin sources using the approved handling tool specified for the service activity.
- 4.5 Do not fix or attempt to fix bent/damaged Pin sources.

- 4.6 Advise the customer to return bent/damaged Pin sources to the supplier. If necessary, use a dummy Pin source until a new Pin source is available.
- 4.7 Whenever a Pin source appears damaged or cannot be properly inserted into a transport container, or it becomes exposed/unshielded and/or stuck:
 - 4.7.1 Stop what you are doing and shield the source to the best of your ability
 - 4.7.2 Immediately contact customer RSO
 - 4.7.3 Immediately report event to the Field Service RSO, Tracy Gale. (Report suspected damage to sealed radioactive sources, regardless of whether leakage or contamination has occurred.)
- 4.8 Handle radioactive PET phantoms (*e.g.*, F-18) within the PET scanner room, under the supervision of the customer RSO or trained technician. Understand and follow any site-specific radioactive material handling rules (*e.g.*, decay in storage waste).
- 4.9 Use the concepts of ALARA (time and distance), which means planning to eliminate unnecessary time spent around the source and using remote handling tools.
- 4.10 If a radioactive Pin source needs to be removed from the source shield and temporarily stored while service is being performed, store in an approved shielded container.
- 4.11 Refer to Appendix 2 for detailed Emergency Procedures.
 - 4.11.1 Notify the customer RSO and immediately adhere to any site-specific emergency procedures.
 - 4.11.2 Report incidents and unusual situations involving radioactive materials, *e.g.*, radioactive material spills, personal contamination, suspected damage to sealed sources, suspected unplanned exceedances of ALARA levels.
 - 4.11.3 Contact your EHS Specialist or Field Service RSO, immediately for assistance with incident investigation, customer site follow-up, corrective actions, and determine any reporting requirements.

5. UNDERSTANDING CUSTOMER PROCEDURES

- 5.1 Customers hold the NRC or state radioactive materials license authorizing them to receive, transport and ship (*i.e.* FedEx) their radioactive materials. GEHC does not hold any licenses to perform these activities as a service to our customers.
- 5.2 When service is performed after hours, on weekends, or holidays when customer staff is limited, ensure to have customer's emergency contacts (*e.g.* a customer RSO or technologist may not be physically present, not on site or must leave the site), phone number or pager in case of an emergency.
- 5.3 Obtain permission to access, remove and return shielded radioactive sources from the customer's hot lab or source storage location.
- 5.4 Place decayed or spent radioactive sources in the properly shielded storage location designated by the customer.

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- 5.5 Request customer's technologist to physically prepare, mix, handle, or transport unsealed sources in (*i.e.*, Tc-99m, Ga-67, In-111, F-18) used for calibration. Inform the customer that Field Engineers are not authorized to prepare these calibration sources.
- 5.6 Request the appropriate source activity be delivered in the configuration (*i.e.*, vial in a nitrile glove) required for the calibration activity. The customer should transport and position where necessary for the calibration. Limit your own handling of the source.
- 5.7 Request the customer to prepare and deliver PET phantoms to the PET scanner.
- 5.8 Contamination level surveys (wipe and source leak tests) are the customers obligation in accordance with the conditions of their radioactive materials license and site-specific procedures.
- 5.9 Obtain storage containers for Pin sources from the customer as necessary for the service activity.

6. GENERAL RULES FOR WORKING SAFELY WITH RADIOACTIVE MATERIALS

- 6.1 Wear your radiation dosimeter at the neck/collar area during all work-related activities.
- 6.2 Post "radiation service" signs (PN: 2282043 or equivalent) when conducting service or initiating calibration scans, if not in direct view of the scan room.
- 6.3 Always wear the required personal protective equipment while working at the customer site.
- 6.4 Never eat, drink, smoke or put fingers in mouth while working with radioactive materials.
- 6.5 Always monitor hands, feet, and clothing for contamination after handling unsealed radioactive materials and wash your hands thoroughly.
- 6.6 Report to your EHS Specialist or Field Service RSO any instances of personal contamination.
- 6.7 The Field Service RSO will determine additional regulatory reporting requirements and will make internal notifications to GE Healthcare.
- 6.8 A 'spill' or contamination containing radioactive material can originate from the following: a damaged or leaking sealed source, liquid sources or phantoms, other radioactive materials on the customer premises. Follow the emergency procedures in Appendix 2 and 3.

7. U.S. STATE NOTIFICATION OF SERVICE

- 7.1 Notify the state regulatory agency of source handling activities at least 3 days PRIOR to any source service event (*i.e.*, installation, replacement, and service where sources are removed/replaced).
- 7.2 See [State Notification Procedure](#) for refresher information.

8. RADIATION SURVEYS

- 8.1 A radiation survey is required following the handling of Pin sources (Ge-68) and attenuation correction sources (Gd-153).
- 8.2 A survey with a calibrated survey meter needs to be completed after handling Pin sources or ATC option sources. This includes initial installation, source exchanges and service calls when sources are removed or replaced.

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- 8.3 Field Engineers authorized to handle Pin sources are provided with annually calibrated radiation survey meters provided by GE Healthcare. Use of a customer meter is permitted if GE Healthcare meter is not available or not functioning properly.
- 8.4 Survey meter/equipment must be within calibration date and in working order.
- 8.5 Submit the required survey information within one week to the Field Service RSO via the Radiation Survey Report Form (which is a part of the State Notification process). See [Radiation Survey Meter Training](#) for refresher information.

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Attachment 1

Product and On-The-Job Training

1. Employees formally trained in radioactive material handling and who attended the PET Advance/NXi training (no longer offered), may work on the PET Advance, PET Advance NXi and DLS systems but are not authorized to work on the DST/DSTE/DSTRx/DVCT systems or the PET/CT 500, 600, 700 Series Scanners.
2. Employees formally trained in radioactive material handling and who attended the DST/DSTE/DSTRx/DVCT systems training only, are not authorized to work on the DLS, PET Advance/NXi or the PET/CT 500, 600, 700 Series Scanners.
3. Only employees formally trained in radioactive material handling and who attended the PET Advance or PET Basic or PET Proficient course at the Healthcare Institute will be authorized to use solid radioactive materials to service PET scanners. We not provided training in the use of liquid radiation sources.
4. Courses include practical hands-on experience with handling Pin sources which may be included in Service Qualification Standards (SQS) training, In-Resident Learning (IRL) or other applicable training.
5. If you have been PET Basics trained after November of 2008, you may work on all GE PET, GE PET/CT systems to date. This was the date that training on the PET/CT 500, 600, 700 series systems began.
6. The PET Basics course instructs students on the basic service for all GE PET, PET/CT scanners. The student then returns for the specific system/s courses needed for service level training. Note: The PET Basic, DST/E Full Service, and D600 ILT classes will be retired in 2018. The PET/CT Proficient ILT course is the replacement for these courses.
7. There is no In-Residence Learning (IRL) training course for just the DLS system. In the PET Advance/NXi In-Residence Learning (IRL) training course, students are taught the differences between the PET Advance/NXi and the DLS. The PET Advance/NXi and DLS have the same 3 Pin sources (Ge-68 at the same activities: 2 sources at 10 mCi and 1 source at 1.5 mCi).

Note: The single DST/DSTE/DSTRx/DVCT Pin source (Ge-68 at 1.5 mCi) is physically longer and the Source Loader Assembly is different than the one on the PET Advance/NXi / DLS.

Note: The single PET/CT 500, 600, 700 Series Pin source (Ge-68 at .27 mCi for BGO detectors and .5 mCi for LYSO/LGSO detectors) are physically the same as the DST/DSTE/DSTRx/DVCT Scanners but the Source Loader Assembly is different.

8. A new course has been introduced in March 2018 called PET/CT Proficient. This instructor led course covers the DST/DSTE/DSTRx/DVCT/D500, 600, 700, DIQ, DMI-DR Series. It includes practical hands-on experience of handling Pin sources and annulus phantom sources. It does not authorize employees to work on DLS or PET Advance/NXi series of scanners.

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Note: The DIQ and DMI-DR Series do not use Pin sources and are excluded from State Notification requirements as in previous products.

Note: The Discovery 690 Elite has plans to eliminate the use of Pin sources and convert to the annulus phantom (1.5 mCi (55 MBq)).

9. A new course was introduced in Jan 2017 for the Discovery MI. This product uses the annulus phantom and is exempt from state notification reporting. It is an instructed led course that requires the student to have proficient equivalent training in the D500, 600, 700, DIQ products as a prerequisite to enrollment.

**Attachment 2
Emergency Procedures**

Radioactive Spill Control

- Notify others in the area that a spill has occurred
- Vacate the immediate area of the spill to avoid any unnecessary exposure to yourself while limiting the spread of contamination
- Call for assistance
- Restrict access to the area and take actions to avoid any further exposure to others
- Remove and replace any contaminated outer protective clothing
- Monitor hands, feet and clothing for contamination and wash hands thoroughly

Personal Contamination

Report to your EHS Specialist or Field Service RSO any instances of personal contamination and be prepared to provide information (radiation source type, activity, survey meter results, area of skin contaminated). The Field Service RSO will assist with follow up of personal contamination events with the customer RSO to investigate, assess potential skin dose, and initiate any needed corrective actions.

Suspected Damage to Sealed Sources

Whenever a sealed source appears damaged or cannot be properly inserted into a container, or it becomes exposed/unshielded and/or stuck, Authorized users are instructed to:

- 1) Stop and shield the source. Immediately contact the customer RSO
- 2) Immediately report event to the Field Service RSO.

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- 3) Report suspected damage to sealed radioactive sources, regardless of whether leakage or contamination has occurred.

Unplanned exceedances of ALARA levels

Each exceedance of an Investigation Level (100 mrem) is investigated to determine factors that led to the elevated reading and, where possible, implement controls to reduce further exposure.

Attachment 3

Skin Decontamination

1. If contamination event to the skin occurs, immediately flush the contaminated area with water. Gently clean the skin with soap and warm water.
2. If some contamination remains, clean the skin with mild abrasive soap. Use a soft brush or towel if necessary and flush with water. Never scrub the skin to the point where irritation occurs. Never use chemicals or caustic cleaning agents on skin.
3. If after repeated washing the contamination persists, begin the survey and recordkeeping as detailed below.

Notify the customer RSO and/or the Field Service RSO.

Initial Survey: In a low radiation level background area, survey the contaminated area by placing the detector directly above the area of skin contamination to achieve the highest reading.

Use your Ludlum Model 2401-EW Survey Meter or a customer owned contamination-monitoring meter with display preferably in counts per minute (cpm). If you are unsure, ask the customer's Radiation Safety Officer.

4. Record all the following available:
 - Site, building, and/or room where the contamination occurred
 - Date that the skin contamination occurred.
 - Estimated time of day that the initial skin contamination occurred.
 - Details to identify the location and area of the contaminated skin. Use a small volume detector such as your Ludlum Model 2401-EW Survey Meter or customer survey meter to "pinpoint" contamination to estimate the area in cm² of contiguous contamination. If more than one area of contamination is detected, record all areas.
 - The radionuclide (e.g. F-18, Tc-99m, Ga-67, etc.) causing the contamination.
 - Manufacturer, model and serial number of the calibrated meter (i.e., meter calibrated in cpm)
 - Results of the survey meter readings. In a low radiation level background area, survey the contained area by placing the detector directly above the area of skin contamination to achieve the highest reading. Record the meter reading, units, date, and time.
 - Perform repeated measurements over time at frequent intervals (~ 1 hour) as activity is removed through radioactive decay (for short-lived nuclides) and/or skin exfoliation. Record the time interval between consecutive surveys, as necessary.
5. Provide all information to the Field Service RSO to complete the dose assessment.