From: Williams, Matthew H
To: Gallaghar, Robert; Pearson, Reggie L
Cc: Gallo, Jody D
Subject: [External_Sender] RE: Second Request for Additional Information - Control No. 629452
Date: Thursday, March 17, 2022 9:07:38 AM
Attachments: image002.png
2022.01.13 RS003R01 Control Of Radioactive Material.docx

Hello Robert,

In our policy, we provide the proposed AU with a list of fulfillments required to become an AU. For 35.1000 Microspheres we follow what is NRC guidance on Y-90 microspheres.

Cheers,

Matt

From: Gallaghar, Robert <Robert.Gallaghar@nrc.gov>
Sent: Thursday, March 17, 2022 7:09 AM
To: Pearson, Reggie L <Reggie.L.Pearson@gunet.georgetown.edu>
Cc: Williams, Matthew H <Matthew.H.Williams@gunet.georgetown.edu>
Subject: [EXTERNAL] Second Request for Additional Information - Control No. 629452

License No. 08-30577-01
Docket No. 03035409
Control No. 629452

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

Mr. Pearson;

This message is in regard to your letter dated November 16, 2021 requesting renewal of License No. 08-30577-01. It is unclear in your application how new authorized users for 10 CFR 35.1000 uses will be approved. Please confirm that you commit to following the most current guidance on the NRC website for approving emerging technologies authorized by 10 CFR 35.1000.

We will continue our review upon receipt of the requested information.

Regards,

Robert L. Gallaghar
Health Physicist
Medical & Licensing Assistance Branch
U.S. NRC, Region I
2100 Renaissance Blvd.

King of Prussia, PA 19406
(610) 337-5182 office
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MedStar Georgetown University Hospital	Control of Radioactive Material	
	Radiation Safety Policy Number RS-003	
Radiation Safety Department Policies and Procedures	Effective Date: 2022.01.13	Areas Affected: MedStar Georgetown University Hosptial

1. Policy Statement

It is the policy of MedStar Georgetown University Hospital to provide information on procurement, receipt, transfer, inventory, and radioactive waste disposal of radioactive materials under a Nuclear Regulatory Commission or District of Columbia Department of Consumer and Regulatory Affairs license.

2. Objective

The objective of this policy is to:

- Detail the process for ordering, shipping, and receiving radioactive material
- Describe how to safely store and secure radioactive material
- Describe the safe use of radioactive material
- Explain how to respond to spills of radioactive material and minimize contamination
- Explain how radioactive material is disposed

3. Authorized User, Use Location, and Material Approval

3.1. New Material of Use

Any radioactive material that is to be used at MGUH must first be approved by the Radiation Safety committee and be listed on the NRC license. A proposed user may submit the desired isotope and amount to the RSC for review and approval. The RSO will maintain a complete list of all materials allowed at the location specified by the NRC license, including form and quantity.

3.2. New Location of Use

Prior to use in a new location a user must submit to the RSC the proposed location for approval. Once submitted the RSO will perform a risk assessment on the proposed location and provide a all requirements that must be in place. Prior to approval the RSO (or designee) will evaluate the area to ensure all safety and security requirements are met.

3.3. New Authorized User

Any user that would like to use radioactive material for any purpose (e.g. for research, calibration, or medical use) this user must be an authorized user for that material. Once the AU status is requested the RSC will provide the applicant with a list of supporting documentation required. Upon fulfillment the RSC will vote whether to approve the AU, the specific material requested, and the quantity allowed. If an existing AU would like additional materials for use, they must resubmit to the RSC.

3.4. Records

The RSO shall maintain internal licenses listing the AU, approved materials, and approved quantities and use. The RSO will also maintain all risk assessments, supporting documents for requests and approvals, and list of use locations within MGUH

4. Procuring Radioactive Material

Radioactive material shall only be ordered by an Authorized User (AU) or under the supervision of an AU. The isotope ordered shall only be the isotope for which the AU is approved to use by the Radiation Safety Committee (RSC).

4.1. Non-radiopharmaceuticals

Prior to radioactive material being ordered the AU must confirmed with the Radiation Safety Office that material request is in compliance with the MGUH NRC License (ensure MGUH is authorized to receive the isotope, activity level, and physical form). All non-radiopharmaceuticals shall be addressed and received by the radiation safety office at:

- Radiation Safety Office
  MedStar Georgetown University Hospital
  3800 Reservoir Rd, Room G2040
  Washington, DC 20007

4.1.1. Records

The AU shall provide a copy of the request to the Radiation Safety Office.

4.2. Radiopharmaceuticals

The Certified Nuclear Medicine Technologist of the Nuclear Medicine Department will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the MGUH NRC Radioactive Materials License. All radiopharmaceuticals shall be addressed and received by the Nuclear Medicine Department at:

- Nuclear Medicine Department
  MedStar Georgetown University Hosptial

3800 Reservoir Rd, Room G2014
Washington, DC 20007

4.2.1. Records

The Nuclear Medicine Department shall maintain a record that identifies the radionuclide, chemical form, and activity of all radiopharmaceuticals ordered. A request from the physician ordering the diagnostic scan and, if therapeutic, an order from the physician completing the procedure must be maintained.

5. Receiving Radioactive Material

During normal working hours, carriers will be instructed to deliver radiopharmaceuticals packages directly to the Nuclear Medicine Department. All other radioactive materials should be received at the Radiation Safety Office. During off-duty hours (5:30 pm – 6:00am) or on weekends/holidays the package shall be signed for by a Protective Services Officer and placed in the Nuclear Medicine Hot Lab (Gorman Room 2050)

If the package is damaged or appears to be leaking the receiver [Nuclear Medicine, Radiation Safety, or Protective Services] should stop the delivery personal and inform them the package could be leaking. The receiver should immediately contact the Radiation Safety Officer and perform a leak test on the package and its contents. If the contents are damaged the Radiation Safety Officer will isolate the package and contact the manufacturer and carrier.

Within 3 hours of delivery [or 1 hour the follow day if delivered after hours] A DOT certified shipper and receiver must complete a survey of the package

5.1. Package Evaluation

- Visually Inspect the package, if any damage if the package is damaged alert the RSO
- Measure the exposure at the surface of the package and at one (1) meter. If the measurement is above the trigger levels below contact the RSO

Label	Surface (mR/h)	1 m (mR/h)
White I	0.5	Background
Yellow II	50	1
Yellow III	200	10

- Wipe the outside and inside of the package for contamination evaluation.
- Verify the contents agree with the shipment packaging
- Visually inspect the source, when possible. If the seal is removed, vial cracked, or discoloration, wipe the source container for contamination evaluation.
- If any contamination measurement is above 6600 dpm/ 300 cm^2 contact the RSO.

5.2. Records

For all non-radiopharmaceuticals the Radiation Safety Office and for all radiopharmaceuticals the Nuclear Medicine Department, shall maintain a log of the all radioactive deliveries including:

- Date/Time received and evaluated
- Surveyor
- Visual Inspection and package type
- Exposure and contamination measurements
- Device used for evaluation

6. Storage and Security of Radioactive Material

All areas where radioactive materials are used and stored shall be locked when not attended by authorized personnel. All radioactive samples must be clearly labeled at all times with the pertinent information about the contents, such as name of isotope, its chemical form and the quantity of radioactive material. All areas where radioactive materials is used or stored should clearly be marked “Caution Radioactive Materials”.

6.1. Leak Testing and Inventorying

Prior to first use all seal sources, with half-life greater than 30 days (and in any form other than gas) shall be tested for leakage/contamination (unless leak testing was completed prior to the receipt and is accompanied by a certificate stating such). In addition all beta emitters will be test in an interval not exceeding 6 months and alpha emitters 3 months. If at any time leakage is suspected or the source has been damaged a leak test shall be completed. Exempt from leak testing are beta/gamma emitters with activity less than 100 µCi, alpha emitter with activity less than 10 µCi or any seal source which has been removed from service and is in storage or disposal or decay. All sources will be inventoried at the same interval based on the particle emission type.

6.2. Lost or Stolen Source

If a seal source has been lost or stolen contact the Radiation Safety Officer immediately. A search plan will be develop and executed. If the source is not found the RSO will notified the appropriate regulatory body

6.3. Records

The Radiation safety Office will keep, for the past 3 years, records off all required sealed sources leak test and inventorying. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

7. Safe Use of Radioactive Material

Prior to use of radioactive material ensure there is both approved operating and emergency procedures in place and available. Review the ALARA Policy and applicable subsections to ensure all risk mitigation has been set in place.

7.1. Administration of radiopharmaceuticals for diagnostic or therapeutic procedures

Authorized user or physician under the supervision of an authorized user will personally review the patient's case to establish that the medical use is indicated for the patient. Prior to administering a radiopharmaceutical, the authorized user or the physician under the supervision of an authorized user will personally make and date a prescription. If changes are required, they will be recorded in writing in the patient's chart or in another appropriate record, and will be dated and signed.

Prior to administering a radiopharmaceutical, the identity of the patient, the radiopharmaceutical, and the dosage will be confirmed by the person administering the radiopharmaceutical to establish agreement with the prescription. Any dose that differs from the prescribed dose by more than ten percent (10%) shall not be administered.

Assay, within 30 minutes before medical use, the activity of each radiopharmaceutical dosage that contains more than 10 μCi of photon emitting radionuclide.

7.1.1. Records

The Nuclear Medicine Department shall maintain a record of assays three (3) years. Additionally, the record shall contain the following:

- The patient’s name and identification number (if one has been assigned).
- The generic name or trade name, radiopharmaceutical abbreviation, lot number and expiration date of the radiopharmaceutical.
- The prescribed dosage and activity of the dosage at the time of assay, or a notation that the total activity is less than 10 μCi (370 kBq).
- The date and time of administration of the radiopharmaceutical.
- The initials of the individual who performed the assay.

For all therapeutic administration the Nuclear Medicine Department shall maintain written directives including:

- Patient name
- Radioactive drug
- Dosage
- Route of administration

7.2. Brachytherapy

Authorized users or the physician will personally review the patient's case to establish that the medical use is indicated for the patient's medical condition. Prior to administering the radionuclide, the physician will personally make and date a prescription. Before implanting the sealed sources, a

qualified person will verify that the radionuclide and source strength of the sources to be used are as prescribed.

Any change in the prescription will be recorded in the patient's chart or in another appropriate record and will be dated and signed by the physician or qualified individual.

After implantation, a qualified person under the supervision of an authorized user will update the patient's record to reflect the actual loading of the sealed sources and record any change in the prescription. Additionally, they will make, date and sign a written record in the patient's chart or in another appropriate record describing the administered dose; and this person will record the brachytherapy administration and the prescription.

Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.

Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

7.2.1. Records

For HDR Brachytherapy the Radiation Medicine Department shall maintain a record of source calibration including:

- The date of the calibration
- The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source.
- The source output or activity
- The source positioning accuracy within the applicators; and
- The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

Periodic inspection of the HDR system must be completed including:

For all manual and HDR brachytherapy The Radiation Medicine Department shall maintain written directives including:

- Patient name
- Radionuclide / Source Strength
- Treatment site
- Dose per fraction
- Number of fractions
- Total dose
- Additional if implanted:
    - Number of sources

- Exposure time (or total dose)

7.3. Release of Patient

Patients which have been administered or implanted with radioactive material and is likely to expose members of the public to 5 mSv (0.5 rem) or greater may not be released from the hospital. Any patient that was administered or implanted with radioactive material and is likely to expose members of the public to 1mSv (0.1 rem) shall be provided release instructions which contains recommended actions to reduce exposure to others.

Dose to public may be calculated based on activity administered or patient dose rate.

7.3.1. Records

Release records shall be maintained for 3 years are included:

- Patient identifier
- Radionuclide
- The administered activity
- Date administered
- The calculations used to determined dose to public

Following the completion of a therapeutic administration or implantation the AU and Radiation Safety Officer shall review the written directive and ensure a medical event has no occurred.

8. Radioactive Material Spill and Contamination Response

If a spill of contamination occurs contact the RSO immediately to develop a decontamination plan. To prevent the spread of contamination: This can be done by limit access into and out of the room. Only once personnel are cleared by the Radiation Safety personnel should they leave the area. If contamination:

- Is on skin or hands: wash your hands thoroughly with warm water and soap for 2- 3 minutes. Repeat and measure. Do not repeat more than 3 times as skin erosion may cause wounds
- Is on a wound: wash the wound with tap water for an extended time (4+ minutes) and, when possible, spread wound to permit flushing.
- Is ingested or injected: Ingest large quantities of water to flush out and dilute the radioactive material. Medicine which induces excretion may also be used.

8.1. Records

Radiation safety will document:

- The incident
- Location of contamination

- Readings before and after contamination clean up
- Detection equipment used
- Individuals involved
- Date/Time of the incident and decontamination
- Bioassays if applicable.

9. Radioactive Material/Waste Disposal

To minimize the amount of radioactive waste generated following an administration of unsealed radioactive material the administrator or Radiation Safety personnel should survey the area and isolate any waste which may contain radioactive material or have become contaminated. If there is contamination or radioactive waste identified contact the Radiation Safety Officer immediately.

9.1. Solid / Liquid Waste

All contaminated or radioactive materials which has a half life less than 120 days (including needles, absorbent pads, temporary seeds, vials containing radionuclide, etc) will be held be by Radiation Safety and allowed to decay in storage or until a licensed third party contracted by the hospital retrieves the material. Any waste with half life greater than 120 will be disposed of through a licensed contractor. Any release of liquid waste must first be evaluated to ensure the total activity is below NRC thresholds.

9.2. Biological Waste

Following administration biologics may be radioactive (blood, urine, fecal matter, sweat, etc). These biological products may be released to sewage.

9.3. Radioactive Material Disposal

Periodically radioactive sources will be exchanged. Prior to release these sources will be packaged and approved by the Radiation Safety Office in compliance with 10 CFR 71 and 49 CFR 170-189.

9.4. Records

Radiation Safety shall maintain records of the disposal of radioactive waste, for 3 years. The record must include:

- Date of the disposal
- Survey instrument used
- Background radiation level,
- Radiation level measured at the surface of each waste container,
- The name of the individual who performed the survey.

For liquid disposal (not excreted from a patient) a release must include:

- Date
- Radionuclide
- Estimate activity released
- Location
- The name of the individual releasing

10. <u>Medical Event</u>

Any department which expects a misadministration has occurred, according to the below criteria, should report this incident to the Radiation Safety Office. The Radiation Safety Office can then assist in determining if the incident qualifies as a reportable misadministration and, if so, reporting the incident to the proper agencies. Any administration of radioactive material to a patient that involves:

- The wrong patient;
- The wrong radiopharmaceutical;
- An administered dose that is 20% or more different than the prescribed dose; or
- An unintended dose to a pregnant woman or nursing child; or
- The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more
- The wrong route of administration; or
- The wrong mode of treatment; or
- A leaking sealed source.

All such incidents will be investigated by the Radiation Safety Office to determine the cause and any actions that can be taken to prevent a recurrence. If an incident is determined to be a misadministration the Radiation Safety Officer shall notify the NRC Operation Center by telephone within 24 hours after the discovery of the medical event

The referring physician must be contacted within 24 hours. The referring physician must decide who will notify the patient, or decide that notifying the patient would be harmful. If a physician cannot be reached within 24 hours the patient shall be notified as soon as possible thereafter. Appropriate medical care, including remedial care from the misadministration, must not be delayed due to notification delays.

The Radiation Safety Officer and Authorized User must submit a written report to the NRC regional office containing:

- The Hosptial license information
- Physician prescribing treatment
- Description off event
- Reasons for event occurrence
- The effect of the occurrence on the patient

- Planned preventative actions
- Proof of communication with patient, or statement on why the physician feels notification may be medically harmful.
- No information which may lead to the identity of the patient may be included in the report

10.1. Records

Radiation Safety shall maintain records of the medical event written report and NRC notification and correspondence.

Version History

Rev 0	**11/1/2019**	**The consolidation shipping and receiving, ALARA, and Survey polices**
Rev 1	**1/13/2022**	**Creation of required risk assessments for new use locations.**