DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
1095 Willowdale Road
Morgantown, WV 26505-2888

Randolph C. Ragland, Jr.
Division of Radiological Safety and Security
U. S. Nuclear Regulatory Commission, Region I
475 Allendale Road, Suite 102
King of Prussia, PA 19406-1415

March 10, 2025

SUBJECT: DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTER FOR DISEASE CONTROL, NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH, LICENSE RENEWAL, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 642368

Mr. Ragland:

This is reference to your March 4, 2025, letter asking for additional information for Item 5, page B-1 for potentially volatile materials, Item 5, page B-2, Item6 page B-2, Items 8 and 9 on page B-3, Item 10 on pages B-4, B-5 and B-6.

1. In accordance with items 5, **Radioactive Material**.

Source Material	**Form**	**One Time Possession Limit**
Carbon 14	Any	50 millicuries total
Hydrogen 3	Any (free / bound)	350 millicuries total

Hydrogen 3 used in free (volatile and bound) forms. Requirements are specified in the Radiation Safety Manual excerpt is provided below:

D. All potentially exposed personnel involved in tritium-labeling procedures will be subject to a regular program of urinary monitoring performed by the principal investigator. The PI will provide copies of the bioassay results to the RSO as required on a quarterly basis.

Table 2.d.1.: 3-H Levels requiring Monitoring by Bioassay

Location or Use Area	**Tritiated Water or Tritiated Compounds (Ci)**	**Tritium Gas in Sealed Vessels (Ci)**	**Tritiated Water Mixed with More than 10 kg of inert water or other substance (Ci/kg)**
In open room with possible escape of tritium	0.01 (10 Millicuries)	10	0.001
Within fume hood of adequate design	0.10 (100 millicuries)	100	.010
Within glove box	1.00 (1000 millicuries)	1000	0.100

2. In accordance with item 6, **Purpose for which license material will be used**:

Radioisotope	Chemical/physical form	Max. Possession Limit	Proposed Use
H-3	Unbound/ volatile	300 millicuries	Labeling of compounds
H-3	Bound/ non-volatile	50 millicuries	In Vitro studies in small animals
C-14	Any	50 millicuries	Was used for Vitro studies, labeling compounds. CURRENTLY only in waste storage.

3. In accordance with item 8, **Training for Individuals working in or frequenting restricted areas**.

All users are required to complete the New User Training before they are badged and allowed to work with radionuclides. Private Investigator's receive special training detailing their responsibility to maintain their individual program's along with specific instruction on common program violations and how to avoid them. All current users are required to attend a yearly refresher training to keep them up to date on change in program requirements. Any personnel working in laboratories that use radionuclides but do not necessarily work with materials must receive basic instructions to recognize the possible hazards they may encounter and understand the Radiation safety Office policies they may encounter. Service personnel (warehouse, facilities, security, animal quarter personnel) are given periodic instructions on their responsibilities under the site Radiation Safety Program.
The following is an individual breakdown of all training courses offered by the Radiation Safety Office and a description of the course content.

Training Courses

Principle Investigator – Sealed Source (required annually)
Principle Investigator – Unsealed Source (required annually)
New User Sealed Source
New User Unsealed Source
Sealed Source Refresher (annual)
Unsealed Source Refresher (annual)
Animal Quarter Personnel (annual)

Maintenance/Warehouse Personnel (annual)
Security Personnel (annual)
Radiation safety Awareness (periodic)

4. In accordance with Item 9, **Facility and Equipment**.

The facility is a closed campus with security guards and restricted access. Security conducts rounds every two hour and monitor cameras of the facility. Laboratory wings are secured with PIV card access within the facility. Laboratories are designed with a laboratory specific entry card to limit employee entrance. Radiation signs are posted at laboratories entrances which house radionuclide. Radionuclide not in use are placed in locked containers within the laboratory or warehouse.
There is a radioactive waste holding area on site. The room is outside of the main facility in the facilities parking garage. Security makes rounds every hour and monitors cameras of the area. The room has a locked door with a metal strap across the door secured with two pad locks, the only key is held by the RSO.
The warehouse is a closed facility with restricted access. Security makes timed rounds of the facility. Radionuclide are stored in original packaging from the manufacture and stored in a specific area of the warehouse. Radioactive signs are posted on stored equipment.

5. The following are responses according to item 10 **Radiation Safety Program**.

a) 10.1 **Audit program**
The site radiation program was audited yearly by outside auditors (using RSO from other CDC location). The current state of government employment does not allow for this activity to take place, so we will need to reconfigure the audit program. We considering following Appendix H of the NUREG-1556, volume 7, Revision 1, customizing it to fit our specific needs.

b) 10.2 **Radiation Monitoring Instruments**
We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG – 1556, vol. 7, Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, dated 2018. We reserve the right to upgrader our survey instruments as necessary.

The following is a description of the instruments used at NIOSH. All laboratories are provided with the appropriate instruments to complete their required surveys. The RSO provides for the proper calibration of the instruments annually. Instruments for counting low energy beta emitters are provided and maintained by the laboratory divisions. The RSO has an instrument for its own survey work, and it is calibrated annually.

<u>Radiation Meters</u>

Ludlum Model 3	general purpose survey meter with a G-M, pancake detector
Ludlum Model 3 98	alpha, beta and low energy gamma survey, internal pancake G-M. External low energy gamma scintillator (sodium iodide)
Ludlum Model 12SA (MicroR meter)	low level gamma survey, sodium iodide scintillator
Eberline ASP-1	general purpose analog survey meter
Eberline RO20	portable ion chamber

Ludlum 2221 floor meter scaler/ratemeter, single channel analyzer with an Alpha/beta suevey detector

c) 10.3 **Material Receipt and Accountability**
All orders must be placed with the Radiation Safety Office. All orders are delivered to the RSO's attention only. The warehouse personnel are trained to release radiation packages to the RSO only. If a package must be left unattended a lockable cabinet is provided at the loading dock until the RSO can retrieve the package. No afterhours deliveries are accepted unless they are approved in advance.
Physical inventories are conducted at intervals not exceeding 6 months, to account for all sealed sources and devices received and possessed under this license.

d) 10.4 **Occupational Dose**
Currently all radiation users working with materials that may be detected by dosimetry, wear radiation dosimeters. If a dosimeter is not needed but requested, it shall also be provided. We monitor individuals in accordance with the criteria in the section entitled 8 Contents of an Application – Occupational Dose in NUREG – 1556, vol 7, dated 2018.

e) 10.5 **Public Dose**
We do not submit public dose information during the licensing phase. However, we prepare for NRC inspections by ensuring that our public dose management practices comply with NRC regulations. This includes having records and demonstrating our measures to protect the public from radiation exposure.

f) 10.6 **Safe Use of Radionuclides, Security, and Emergency Procedures**
Procedures for the safe use, including security of materials, and emergencies have been developed an are part of the NIOSH Radiation Safety Manual.
Procedures may be revised only if 1) the changes are reviewed and approved by the license management and the RSO in writing; 2) the license staff is provided training in the revised procedures prior to implementation; 3) the changes are in compliance with the NRC regulations and the license; and 4) the changes do not degrade the effectiveness of the program.

g) 10.7 **Surveys and Leak Test**
We conduct required leak tests on sources at intervals approved by the NRC or an Agreement state. We take the samples according to the manufacture's recommendations and the kit supplier's instructions. We choose to use an authorized service provider to ensure accurate and reliable results. Leak test records are maintained for compliance verification.

h) 10.8 **Transportation**
We do not transport ECDs or XRFs; however, if done in an emergency, we adhere to U. S. Department of Transportation regulations. Radioactive waste is packaged and transported according to NRC and DOT requirements. Requirements for transporting licensed material within the facility is currently being revised to include a "chain of custody" for all moves. The revision will be updated in the radiation safety manual. Disposal of waste shall have the appropriate documentation, as specified in Appendix G.

6. In accordance with item 11 **Waste Management**
We currently use the model waste procedures published in Appendix P in the NUREG. The facility has a designated Decay-in-Storage area. Disposal of radiation source or radioactive material shall be by transfer to a licensee specifically authorized to possess the waste.

The point of contact for this memorandum is the undersigned and can be reached at qma5@cdc.gov or 304-285-6331.

Shane L. Rogers -S

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Date: 2025.03.13 08:36:18 -04'00'

Shane Rogers, SMS, RSO
Occupational Health and Safety Manager
Facilities Management Office (FMO)
National Institutes for Occupational Safety and Health (NIOSH)
Center for Disease Control and Prevention (CDC)
Physical Address: 1095 Willowdale Rd., Building L – Room 1107, Morgantown, WV 26505
Mail Address: 1000 Frederick Lane, Morgantown, WV 26508
Desk: (304)-285-6331
Mobile: (304) 282-0993

Management Representative:

Brance L. Mccune Jr -S

Digitally signed by Brance L. Mccune Jr -S
Date: 2025.03.25 08:31:33 -04'00'

Brance L. McCune, Jr., MBA
Deputy Associate Director
Facilities Management Office (FMO)
Office of the Deputy Director for Management (ODDM)
National Institute for Occupational Safety and Health (NIOSH)
Centers for Disease Control and Prevention (CDC)
Physical Address: 1095 Willowdale Road, Building L – Room 1109, Morgantown, WV 26505
Mailing Address: 1000 Frederick Lane, Morgantown, WV 26508
Desk: (304) 285-5882
Mobile: (304) 376-6684