UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

January 10, 2022

Michael M. Gottesman, M.D.
Deputy Director of Intramural Research
Department of Health & Human Services
National Institutes of Health
21 Wilson Drive, MSC 6780
Bethesda, MD 20892-6780

SUBJECT: DEPARTMENT OF HEALTH & HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH - NRC INSPECTION NO. 03001786/2021001 AND NOTICE OF VIOLATION

Dear Dr. Gottesman:

This letter refers to the inspection conducted on October 4 – 8, 2021 at your Baltimore, Bethesda, Frederick, and Rockville, Maryland facilities. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. After the onsite inspection additional information was supplied by you and your staff as needed to facilitate in office review which concluded on December 10, 2021. A virtual exit meeting was held on December 16, 2021.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. Specifically, in 2021, one physician was approved as a clinical authorized user for parenteral administration of radioactive drugs requiring a written directive; however, the physician did not have sufficient training and experience to be a clinical authorized user in accordance with 10 CFR 35.390(b)(1). The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation is cited in the enclosed Notice of Violation (Notice) because the violation was identified by the NRC.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket and include: immediately rescinding authorization for administration of parenteral radioactive drugs requiring a written directive by the physician and confirming that the physician had not performed the activities. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

If you have any questions regarding this matter, please contact Janice Nguyen of my staff at 610-337-5006 or via electronic mail at Janice.Nguyen@nrc.gov.

Thank you for your cooperation.

Sincerely,

Anne E. DeFrancisco

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Date: 2022.01.10 10:11:04 -05'00'

Anne E. DeFrancisco, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

Docket No. 03001786
License No. 19-00296-10

Enclosures:
1. Notice of Violation
2. Inspection Report

cc w/ enclosure:
Cathy Ribaudo, Division Director, Radiation Safety Officer
Michael Roberson, Associate Radiation Safety Officer
State of Maryland

DEPARTMENT OF HEALTH & HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH - NRC INSPECTION NO. 03001786/2021001 AND NOTICE OF VIOLATION DATED JANUARY 10, 2022

DOCUMENT NAME: https://usnrc.sharepoint.com/teams/Region-I-MLA/Inspection Reports/Inspection Documentation - Draft/NIH/L19-00296-10.2021001.docx

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NAME	ETindle-Engelmann / EDTE	RElliott / RLE	JNguyen/JEN	ADeFrancisco/AED	
DATE	12/10/2021	12/15/2021	12/16/2021	1/4/2022	

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Department of Health & Human Services
National Institutes of Health — Docket No. 03001786
Bethesda, Maryland — License No. 19-00296-10

During an NRC inspection conducted on October 4 – 8, 2021, with in office review through December 10, 2021, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> License Condition 22 of License No. 19-0026-10 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letter dated July 3, 2012.
>
> Item 7 of the letter dated July 3, 2012, requires, in part, that clinical authorized users (CAUs) meet the training and experience requirements in 10 CFR 35 and are approved by the Radiation Safety Committee (RSC).
>
> Contrary to the above, in 2021, one CAU did not meet the training and experience requirements in 10 CFR 35 and was approved by the RSC. Specifically, the RSC approved the CAU for activities described in 10 CFR 35.390(b)(1) and the physician did not have 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The licensee confirmed that, while inappropriately authorized, the physician was not involved with the use of unsealed byproduct material for which a written directive is required.
>
> This is a Severity Level IV violation (Enforcement Policy Section 6.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 10 day of January 2022

Department of Health & Human Services, National Institutes of Health

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001786/2021001
Docket No.	03001786
License No.	19-00296-10
Licensee:	Department of Health & Human Services National Institutes of Health
Location:	Baltimore, Bethesda, Frederick, and Rockville, Maryland
Inspection Dates:	October 4 – 8, 2021 In office review through December 10, 2021 Virtual Exit meeting December 16, 2021

Inspectors:

Janice E. Nguyen
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Janice Nguyen
Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Robin L. Elliott
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Robin Elliott
Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Elizabeth D. Tindle-Engelmann
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Elizabeth Tindle-Engelmann
Health Physicist
Material Inspection Branch
Division of Nuclear Material Safety

Approved By:

Anne E. DeFrancisco
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Anne DeFrancisco, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

EXECUTIVE SUMMARY

Department of Health & Human Services
National Institutes of Health
NRC Inspection Report No. 03001786/2021001

A routine announced inspection was conducted at the Department of Health & Human Services, National Institutes of Health (NIH) facilities located in Baltimore, Bethesda, Frederick, and Rockville, Maryland on October 4 – 8, 2021. The inspection was performed in accordance with NRC Inspection Procedures 87126, 87127, 87131, 87132 and 87134 and reviewed activities associated with the use of licensed materials authorized by License Number 19-00296-10.

The inspectors conducted interviews with NIH personnel, observed day-to-day operations, toured NIH's facilities, and reviewed documents and procedures. Based on the results of this inspection, one violation of NRC requirements was identified. License Condition 22 of License Number 19-00296-10 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the letter dated July 3, 2012. Item 7 of the letter dated July 3, 2012, requires, in part, that clinical authorized users (CAUs) meet the training and experience requirements in 10 CFR 35. In 2021, one physician was approved as a CAU for parenteral administration of any radioactive drug requiring a written directive (WD). While the physician had documented 700 hours of training and experience, the 200 hours of classroom and laboratory training were not obtained within the last seven years in accordance with 10 CFR 35.59, and the training and experience was not applicable to the medical use of unsealed byproduct material requiring a WD in accordance with 10 CFR 35.390(b)(1). The licensee confirmed that the physician had not used this material and issued a revised authorization rescinding this use. The physician was appropriately qualified for diagnostic uses of radiopharmaceuticals.

REPORT DETAILS

1. Organization, Oversight, and Scope of the Program

a. Inspection Scope

A routine announced inspection was conducted on October 4 – 8, 2021 at the following locations: NIH main campus in Bethesda, Maryland; Integrated Research Facility in Frederick, Maryland; Medical Center Drive facility in Rockville, Maryland; Triad facility in Baltimore, Maryland; and Baltimore Research Center (BRC) in Baltimore, Maryland. The inspection was performed in accordance with NRC Inspection Procedures 87126, 87127, 87131, 87132 and 87134, and reviewed activities associated with the use of licensed materials authorized by License Number 19-00296-10. The following focus areas were reviewed: (i) security and control of licensed material; (ii) shielding of licensed material; (iii) comprehensive safety measures; (iv) radiation dosimetry program; (v) radiation instrumentation and surveys; (vi) radiation safety training and practices; and (vii) management oversight. In addition, decommissioning activities, financial assurance (FA), and use of public health emergency (PHE) exemptions were reviewed.

The inspectors conducted interviews with NIH personnel, NIH contractors, observed day-to-day operations, toured NIH's facilities, and reviewed documents and procedures.

b. Program Scope and Management Oversight

NIH's radiation safety staff oversee the radiation safety program and are located within the Division of Radiation Safety (DRS) on the main campus of NIH. The staff consists of a Division Director/Radiation Safety Officer (RSO), a Deputy Division Director/Associate RSO, an Irradiator Program Manager, a Medical Physics Contract Coordinator/Executive Secretary to the Radiation Safety Committee (RSC), a Communications Manager/Communications Contract Coordinator, two Branch Chiefs, and a total of 24 support staff to carry out the functions of DRS. In addition, approximately 8.5 full time equivalent contract staff assist DRS in the conduct of routine surveys, package delivery, instrument calibrations, and waste processing. The licensee maintains an active RSC. The RSC is involved in the licensee's radiation safety program and meets monthly to discuss: (i) NRC licensing and regulatory matters; (ii) Radioactive Drug Research Committee (RDRC) activities; (iii) triennial reviews of permit renewals; (iv) laboratory use of radionuclides; (v) new license permit applications and users; (vi) new clinical protocol applications and users; (vii) personnel exposure monitoring; (viii) annual audit findings; (ix) any events; and (x) any corrective actions for items identified by DRS.

Several thousand regulatory compliance surveys were conducted by NIH staff and contractors since the last inspection. In 2020, there were approximately 577 posted laboratory modules where 429 authorized users (AUs) and 2,870 individual users conducted research activities. Most of the laboratory space and clinical facilities are located on the main campus in Bethesda, Maryland; however, the licensee has satellite facilities in Rockville, Baltimore, Poolesville, and Frederick, Maryland.

Approximately 24 laboratory protocols, 107 animal study proposals, and 94 clinical research protocols are reviewed each year by the RSC. DRS also performs triennial renewals of previously approved protocols. Approximately 75 percent of all protocols use Positron Emission Tomography (PET) radionuclides. Clinical protocols are reviewed

by the Institutional Review Board (IRB) and the RSC, as well as the RDRC, as necessary. Previously, there were 12 separate IRBs, but they have been consolidated into one IRB with different subcommittees that meet on different weeks. In addition, the licensee implemented a new database, iRIS by iMedRIS, which keeps tracks of all documentation and the various steps in the approval process.

The inspectors reviewed the training and experience approvals of six CAUs, two authorized nuclear pharmacists (ANPs), and nine research AUs performed by the RSC. With one exception, documented below, the approvals were found to be appropriately granted and documented. The inspectors confirmed that the RSC completed approvals and issued new authorization letters for all AUs to close out the previous violation of License Condition 22 of License Number 19-00296-10 for approving two CAUs for the parenteral administration of any radioactive drug requiring a WD that did not meet the training and experience requirements in 10 CFR 35. Based on the results of this inspection, one violation of NRC requirements was identified. Specifically, in 2021, one physician was approved as a CAU for the parenteral administration of any radioactive drug requiring a WD. While the physician had documented 700 hours of training and experience, the 200 hours of classroom and laboratory training were not obtained within the last seven years in accordance with 10 CFR 35.59, and the training and experience was not applicable to the medical use of unsealed byproduct material requiring a WD in accordance with 10 CFR 35.390(b)(1). The licensee confirmed that the physician had not used the material in question and issued a revised authorization immediately rescinding this use. The physician was appropriately qualified for the diagnostic uses of radiopharmaceuticals.

DRS staff responded to approximately 40 incidents since the last inspection, most of them were minor. The inspectors reviewed the following incidents: (i) fume hood with fixed contamination improperly sent to scrap yard; (ii) dust mop contaminated with Lutetium-177 following a therapy procedure; (iii) minor personnel Phosphorus-32 contamination; (iv) direct delivery of Lutetium-177 unit dose to molecular imaging clinic instead of to DRS; (v) Biosafety Level (BSL) IV suit contamination; (vi) Actinium-225 contamination in clinical research lab; (vii) suspected release of Carbon-11 during delivery; and (viii) minor Zirconium-89 spill. Corrective and preventative actions were reviewed for the above events with no concerns noted. Re-training of involved staff was conducted, as necessary. In addition, the events were confirmed to be below the regulatory reporting requirements and to have met the criteria in the NRC Enforcement Policy Section 2.3 for a minor violation, when applicable.

c. Medical Activities Scope

All medical activities at NIH are research related and are conducted in one of three areas: Nuclear Medicine (NM), PET, or the Molecular Imaging Program (MIP). All studies are conducted in accordance with the research protocol approved by the RSC and IRB. Written consents are signed by patients and include detailed information about the study as well as directions to follow to minimize exposure to others following release.

Currently, the NM staff includes six Nuclear Medicine Technologists (NMTs), one manager, one ANP, one pharmacy technician, and one physicist; in PET, there are seven NMTs; and in MIP, there are three NMTs. The NM facility currently includes a temporary radiopharmacy, one administration room, and five cameras. Patients who are not releasable or kept for observation following treatment are kept as in patients in one

of two shielded rooms. The PET facility includes: a radiopharmacy, two quiet/ administration rooms, and two cameras. The MIP facility includes one camera room with a hot lab and one quiet/administration room.

The cyclotron, licensed separately, produces various radionuclides for research. The inspectors watched the delivery of Fluorine-18 from the cyclotron to the PET radiopharmacy. The radiochemist uses current Good Manufacturing Practices during this process as well as a combination of robotics and remote handling tools to prepare the material. Delivery to the PET facility is accomplished using a "rabbit system." The ANP also uses a robotic system to draw up the dose and verifies it in the dose calibrator prior to administration. Once the dose is confirmed, the NMT injects the patient following agreement with the AUs direction. The NIH cyclotron produces Carbon-11, Fluorine-18, Nitrogen-13, and Oxygen-15 for research studies. In addition, unit doses are obtained from Cardinal Health, Sofie, and Novartis as needed.

NM conducts approximately 12 studies per day typically using Fluorine-18, Gallium-68, Iodine-123, Iodine-131 and/or Technicium-99m. In 2021, to date, there were five in-patient Iodine-131 therapies. The PET department typically conducts four-five studies per day using Carbon-11, Fluorine-18, Nitrogen-13, and/or Oxygen-15. MIP administers dosages to approximately three patients per day using Fluorine-18, Lutetium-177, and/or Radium-223. For Lutetium-177 therapies, all initial treatments are performed on an in-patient basis to assure the patients are able to tolerate the administration. The NMT is present throughout the infusion as well as a DRS Health Physicist (HP) and a nurse. In 2021, to date, 27 Lutetium-177 and 11 Radium-223 treatments have been performed. In 2019 and 2020, a study utilizing Thorium-227 occurred; however, the study has been terminated. WDs, room surveys, patient release criteria, and patient release instructions were reviewed for all therapies conducted and no concerns were noted. The inspectors also interviewed nursing staff and found them to be knowledgeable of radiation safety and associated risk in the therapies.

The high dose-rate remote afterloader (HDR) is in the radiation oncology department. The HDR was used to treat two patients since the last inspection: one in 2019, and one in 2021. Since the last inspection, a modification was made to the HDR vault to install glass doors inside the vault to allow for the heavy vault doors to be open during treatments. This change was made to improve the speed with which emergency response can be provided to patients. The licensee conducted an evaluation of the radiation levels outside the vault with the glass doors and verified that the public dose limits were not exceeded during operation of the HDR with no additional shielding required. The doors are interlocked to the operation of the HDR unit, and the inspectors verified that the radiation levels outside the door were within regulatory limits. The HDR is locked in a closet with keys controlled by trained individuals. Full calibrations, spot-checks, WDs, maintenance activities performed by the manufacturer, training records and treatment plans were reviewed with no concerns noted. The authorized medical physicists were conducting timer linearity over the maximum dwell time, rather than the typical range of use as required by 10 CFR 35.633(b)(5). This was determined to be acceptable since the HDR unit has independent timers.

A comprehensive audit of the HDR program was performed by DRS in August 2020, with all findings addressed by the radiation oncology staff. The audit addressed all requirements covered in 10 CFR Part 35 Subpart H related to HDR use. The inspectors reviewed the audit results and found the audit to be comprehensive.

d. Research Activities Scope

NIH research activities typically involve microcurie or millicurie quantities of radioactive material used on a bench top, in a fume hood, inside a plexiglass enclosure, or inside hot cell. A wide variety of radionuclides are used at NIH, including: Actinium-225, Americium-241, Astitine-211, Barium-133, Bismuth-207, Bismuth-213, Bromine-76, Cadmium-109, Calcium-45, Carbon-11, Carbon-14, Cesium-134, Cesium-137, Chlorine-36, Chromium-51, Colbalt-56, Colbalt-57, Colbalt-58, Cobalt-60, Copper-64, Europium-152, Fluorine-18, Gadolinium-153, Gallium-67, Gallium-68, Germanium-68, Gold-198, Hydrogen-3, Indium-111, Iodine-123, Iodine-124, Iodine-125, Iodine-129, Iodine-131, Iridium-192, Iron-55, Iron-59, Lutetium-177, Manganese-51, Manganese-54, Nickle-63, Nitrogen-13, Oxygen-15, Phosphorus-32, Phosphorus-33, Radium-223, Sodium-22, Strontium-90, Sulfur-35, Tantalum-182, Technicium-99m, Thallium-201, Thallium-204, Thorium-227, Thorium-229, Thorium-232, Uranium-238, Vanadium-48, Xenon-133, Yttrium-86, Yttrium-97, Yttrium-88, Zinc-65, Zirconium-88, and Zirconium-89.

Active research using radioactive materials has declined since February 2020 due to the PHE. The inspectors visited a sample of research laboratories in buildings 10, 21, 33, 49 and the Clinical Research Center on the main campus; the Integrated Research Facility in Frederick, Maryland; the Medical Center Drive facility in Rockville, Maryland; Triad facility in Baltimore, Maryland; and the BRC in Baltimore, Maryland.

Throughout all facilities, the scientists, researchers, and AUs were found to understand the hazards of radiation, radiation safety practices, and ALARA. Research facilities include graded safety systems, i.e. work generating airborne radioactive materials or aerosols is performed in a fume hood or glove box, operations generating radiation fields are performed in hot cells. Laboratory doors, freezers, and refrigerators are posted with the appropriate labels and hazard communication. Current copies of the NRC Form 3 are prominently posted lab areas. Radioactive use areas on the bench are clearly defined and absorbent paper is used to prevent contamination. The laboratories are equipped with portable survey meters and are calibrated as required by license commitments. Workers were observed using survey meters and demonstrated proper technique. Radioactive material users use appropriate shielding for the radionuclides they handle. In many laboratories, shielding was employed for benchtop use, as well as for waste and storage locations. Radioactive materials users that were interviewed stated they consistently perform daily surveys and proactively clean work areas at the conclusion of use of licensed material. Researchers were observed using personal protective equipment such as gloves and lab coats. The licensee has one operational iodination facility, which typically uses millicuries quantities of Iodine-125. Adequate engineering controls were utilized during iodinations and post iodination bioassays indicated there were no uptakes.

The Integrated Research Facility conducts COVID related research and other select agent research at BSL-IV. There are two AUs and two NMTs assigned to the facility for conducting imaging and an animal care manager. DRS has a HP permanently assigned to the facility to support the research activities. Both in-vivo and in-vitro research is performed involving animals. No animals are released, instead they are digested and processed through the effluent decontamination system. Radiopharmaceuticals are obtained from Cardinal Health in bulk doses of 100 mCi and unit doses of 2 mCi of Fluorine-18 for non-human primate studies involving PET/CT. Occasionally bulk Technetium-99m in units of 40 mCi are procured for instrument linearity checks. A

microPET machine was obtained since the last inspection for imaging of small animals. The inspector toured the cook and blend tank area and the areas outside the BSL-IV containment and interviewed the DRS HP and an AU. Only two HPs have the requisite training required to enter the BSL-IV containment. Radioactive material is stored for decay within containment, surveyed for release, and then disposed. Liquid waste disposal is normally though the cook tanks. A review of the records was conducted, including instrument calibration, surveys, effluent sampling, exposure, and waste records.

Benchtop and animal studies are also conducted at the BRC using a variety of radionuclides including but not limited to Carbon-14, Fluorine-18, Hydrogen-3, Phosphorus-32, Sulfur-35, and Technetium-99m. Benchtop research was conducted at the Triad facility using Hydrogen-3 and Phosphorus-32. Researchers were observed using appropriate radiation safety techniques including PPE, survey meters, dosimeters, labels, and shielding when needed. Researchers interviewed were knowledgeable about the hazards of the material they are working with and the precautions to take to reduce their exposure. Material was secured in locked storage locations inside laboratories.

At the time of the inspection, no NIH radioactive materials users were active at the Medical Center Drive facility. However, during the inspection, it was discovered that the Medical Center Drive facility is a leased space with multiple tenants. As such, the facility is not exclusive federal jurisdiction and other tenant(s) may have licenses from the State of Maryland. The NIH license lists the entire Medical Center Drive address as a location of use but since NIH does not control the entire address they prepared and submitted an amendment request to specify the areas of use as the areas that NIH controls through leases. The amendment request was received by the NRC on November 23, 2021.

Laboratory facilities are protected from other hazards associated with the research involving licensed materials. Sprinkler systems and fire extinguishers are present for protection from fire; eye wash units and safety showers are present to address splash or spill hazards; biosafety cabinets, infectious waste containers and biohazard labels are in use for biosafety concerns. Laboratory personnel were interviewed regarding hazards in the workplace, and all indicated they were aware and had been trained regarding these hazards; all indicated they would be willing to raise concerns if they arose. Safety appeared to be at the forefront of their activities indicating a positive safety culture.

2. Review of Program Areas

a. Material Receipt, Use, Transfer, Control and Transportation

The inspectors reviewed the material ordering, receipt, and control of radioactive materials at NIH. All materials used on the NIH campus are ordered and received through DRS, except for Fluorine-18 and Technetium-99m which are received directly at Fort Detrick and PET radionuclides which are received directly at the BRC by DRS staff. In 2020 DRS took over package receipt and delivery responsibilities; prior to the change they contracted with Clym Environmental for package receipt and delivery. In 2020, around 5000 packages were received by DRS, roughly half of which were for patient use and the other half for non-patient use. The number of packages received per year has held steady at an average of about 7,500 per year. Approximately 95% of the packages

received are used on the Bethesda campus with the remaining 5% used at the various remote locations.

Requests for purchase of radioactive material are completed by the researcher or clinician using a standard form. Once approved by DRS, purchasing agents place the orders, and the vendor ships the material to DRS. Prior to placing the order, the request is checked to ensure it is within the AU's authorization for the specific radionuclide and activity limit. Upon arrival, packages are surveyed for contamination, exposure levels, and the contents are verified against the packaging list and the order details. Vials are wipe tested to confirm there is no contamination present, and then re-packaged for transport to the AU by DRS personnel. The inventory system is also checked to confirm that the researcher does not exceed the quantity of material they are authorized for. If that occurs, then DRS holds the material until it decays, or the researcher reconciles their current inventory to remove disposed items. DRS verifies the electronic inventory annually. The researchers provide updates to their inventories as they use the material. The inspectors spot checked physical inventories against what was present in the laboratories.

Transfers to/from other licensees are managed by DRS. All the individuals that are involved with preparing radioactive material shipments are trained in accordance with the Department of Transportation (DOT) requirements and receive International Air Transport Association (IATA) training for shipments by air, as needed. A copy of the license from the institution receiving material is obtained prior to the shipment and reviewed to verify the recipient is appropriately authorized. Packaging, labeling, and shipping papers preparation for these shipments is performed by the DRS. The inspectors spot checked records of transfers and found no concerns. With regard to shipment of blood samples from patients administered licensed material, the licensee confirmed with NRC's Office of International Programs that they are exempt from needing an export license per 10 CFR 110.22. This applied to five international shipments of blood samples from patients treated with Thorium-227.

b. Security

On the main campus, security is restricted via the main gate where visitors are screened. Once on campus, some buildings have general access areas; however, access to laboratory areas requires additional measures. Access to radioactive material use areas is limited to only those who are authorized to be in that area. Within laboratory modules on the main campus, radioactive material stock vials are secure within the lab; waste is consistently secure in locked containers to prevent unauthorized access or removal. Security at the Integrated Research Facility, Triad, and the BRC include security guard access to the facility followed by secure laboratory areas. Laboratories at the Medical Center Drive were kept secure through appropriate means.

c. Radiation Surveys and Compliance Audits

The inspectors reviewed NIH's radiation and contamination survey process and performed confirmatory surveys. The inspectors noted the following:

(i) NMTs and ANPs, in NM and PET performed end of day surveys and weekly contamination surveys. MIP performed daily surveys and contracted Clym to

conduct weekly contamination surveys. The inspectors observed these surveys being performed.

(ii) DRS HPs conduct surveys of patient rooms prior to release after patients are released. The inspectors observed surveys being performed during an administration of Lutetium-177. Documentation of these surveys were reviewed.

(iii) Researchers performed adequate surveys. Some researchers utilized a contractor to perform their required surveys while others perform the surveys themselves which are then reviewed by one of the area HPs. The inspectors reviewed records of surveys performed in the labs by researchers as well as comprehensive surveys performed by NIH's contractor and noted that when removable contamination was detected, the areas were appropriately cleaned and resurveyed, with follow up surveys adequately documented.

(iv) In radiation oncology, surveys of the patient and remote afterloader unit were performed, as required, prior to patient release.

(v) Clearance surveys were performed prior to release of licensed facilities. The inspectors reviewed records maintained to support the release of facilities.

(vi) The licensee performs surveys on a daily basis and a more extensive weekly survey in the waste areas.

NIH uses a contractor to perform comprehensive compliance audits in all labs twice a year. As part of this survey, the contractor performs a contamination survey, a dose rate survey, and interviews of the AUs. The contractor collects information about material usage, training qualifications, and reviews the AU's survey records. The contractor also reviews postings, calibrations of survey equipment, the flow on ventilation, shielding, and confirms that there is no eating, drinking, or smoking in the restricted area. The inspectors accompanied a contractor while he performed a monthly survey and a comprehensive survey. The inspectors found the activity to be very thorough and noted that the surveys could be modified for labs where no work has been conducted to free resources for higher risk activities. The laboratories and departments are also audited by a member of the radiation safety staff annually. DRS streamlined these audits from a 32 page form to a 5 page form focusing on items that are more likely to change or require additional follow-up. Audit records were reviewed, with no concerns noted.

d. Instrumentation

Calibration of instrumentation is performed onsite, as well as offsite. The contractor performs the onsite calibrations for count rate meters. Dose rate meters are sent offsite to AM Calibrations or the specific manufacturers such as Ludlum. The inspectors observed the contractor perform an on-site calibration and interviewed him regarding his process. The individual was knowledgeable, and no concerns were noted. The inspectors also reviewed a sample of the off-site calibrations and found them acceptable. DRS schedules the meter calibrations to be done every eleven months and leaves December to address those that were not calibrated within that time frame. All meters checked during the inspection were current with their calibration. AUs are accountable for calibrating their own liquid scintillation and gamma counters. Typically, they perform an annual calibration and daily constancy checks. The inspectors reviewed

calibration and counting statistics performed on survey instruments, liquid scintillation and gamma counters and noted that they appeared satisfactory and in accordance with the manufacturer's recommendations.

e. Occupational Exposure

External exposure is monitored by personnel dosimeters and the dosimetry issuance policy is based on a millicurie per hour nuclide specific schema that is documented in the license application. Cyclotron engineers and radiochemists are issued whole body dosimeters and extremity dosimeters for each hand. The extremity dosimeters are exchanged weekly. When personnel have incidents that result in skin contamination Varskin is used by DRS to calculate the skin dose.

Internal dose is assessed by bioassay. The bioassays that are performed are thyroid scans, whole body scans, and urinalysis. The thyroid monitoring equipment used is a Canberra Accuscan II system which has a dual calibration to allow monitoring of Iodine-125 and Iodine-131 uptakes. The Canberra Fastscan system is used for whole body counting. Based on the records reviewed and information provided by the DRS, there were no personnel doses in excess of the regulatory limits specified in 10 CFR 20.1201.

In addition, the licensee has developed a comprehensive procedure for addressing fetal and nursing child protection for occupationally exposed workers. The procedure is reviewed during initial radiation safety training. A review of the records for declared pregnant workers indicated that none of the women had received a fetal dose greater than specified in 10 CFR 20.1208.

f. Effluent Monitoring

In laboratories using licensed material produced by NIH's cyclotron, air effluent is sampled and analyzed by the licensee. The licensee uses a combination of plastic scintillator coincidence detectors to continuously monitor for effluent releases and filters that are counted using appropriate analytical equipment.

The licensee also performs air sampling in the ducts of some laboratories to quantify releases during iodinations and other processes that are high risk for effluent releases. The air sampling data is corrected based on the total effluent volume and wind rose data. Then it is converted to dose utilizing the values in 10 CFR Part 20, Appendix B. This data provides the basis for estimating the releases of radionuclides in effluents for comparison to the regulatory limits. The remaining site inventory, less waste disposals, is combined to establish the source term for the EPA's COMPLY computer program to determine the dose to the maximally exposed member of the public.

During the inspection it was determined that the licensee omits certain radionuclides from the COMPLY calculation due to continuous monitoring. However, through discussion it was determined that the calculations used to determine dose from the continuous monitoring assumes all emissions are Fluorine-18. This is not the case; some emissions have more restrictive limits than Fluorine-18. Additionally, the licensee was removing some short-lived radionuclides from the COMPLY calculation based on filter samples. However, the filters are analyzed on a monthly basis therefore the short-lived radionuclides may not be detected depending on the date of the emission. The licensee reperformed the annual effluent assessment and determined that the initial

calculation was still valid. For 2020, the result was 1.688 mrem. Therefore, the results indicated compliance with the constraint rule in 10 CFR 20.1101(d).

g. Radioactive Waste Management

The radioactive waste program is managed by a member of DRS and supported by Clym Environmental contractors. The licensee has a radioactive waste facility and mixed waste facility. Radioactive waste streams are segregated. Radioactive waste containers are labeled, bar coded for tracking of contents, and data is put into a database. Laboratory researchers and clinical users track the activity per container and call for a pickup or place a request online. Waste collections occur daily. A three-ply waste tag is used on each container. One copy of the tag is kept in the laboratory/clinical area, one stays on the waste, and one is used to enter the material into the database. NIH infrequently compacts radioactive waste. NIH maintains an ultraviolet processing system designed to treat aqueous mixed waste; however, it is infrequently used. Liquid scintillation vial wastes are segregated based on regulated and non-regulated constituents. Regulated vials are disposed through a waste broker. Non-regulated vials are shredded on site. The scintillation fluid is bulked in a drum and disposed of as flammable liquid. The shredded vials are discarded as dry active radioactive waste and disposed of accordingly. Medical/pathological waste (MPW), mixed organic liquids and animal carcasses with a half-life less than 120 days are held for decay-in-storage. The waste is surveyed using an appropriate survey instrument to identify any waste that has not reached background level. If the survey indicates anything above background, it is held for further decay. A resurvey is performed to demonstrate that the waste is indistinguishable from background before disposing as either MPW or hazardous waste. Any waste identified with half-life greater than 120 days, such as waste contaminated with Lutetium-177m, is transferred to the radioactive waste stream. All radioactive dry active waste is shipped as low specific activity material.

The waste facility is equipped with nine 2,250-gallon fiberglass tanks that hold aqueous non-hazardous radioactive waste. The licensee made one batch release from the tanks to the sanitary sewer during the inspection period. The licensee appropriately quantified the concentration of radioactive material present in the tanks prior to release into the sanitary sewer in accordance with 10 CFR 20.2003.

Waste manifests are prepared by the various waste brokers that NIH works with and are signed by a DRS staff member. Inspectors reviewed the radioactive waste manifests, receipt records, and final disposal records over the inspection period. All of the workers involved with packaging and labeling radioactive waste or transporting the radioactive waste between sites receive hazardous material training in accordance with DOT requirements.

Survey instruments are present in the radioactive waste processing area and the mixed waste processing area. Personnel are required to survey themselves as they exit the area. The facilities are well designed with sloped floors and dykes to contain leaks and prevent the spread of contamination. The inspectors made independent measurements of the waste facilities and did not identify contamination or elevated exposure rates.

h. Posting and Labeling

The inspectors toured the various clinical areas and multiple research facilities. All areas of use and storage were properly posted, and radioactive materials were properly labelled in accordance with NRC requirements.

i. Radiation Safety Training

The licensee requires all personnel to obtain training prior to working with radioactive material. Individual users and AUs take online training that includes verification by exam. Refresher training is also required and is available in person and online. DRS offers several online radiation safety modules designed for over 30 different user types with topics tailored to each individual's needs, such as irradiator use, animal handler, PET use, cyclotron use, and others.

In addition to online training, DRS continues to conduct in person refresher training. The sessions are typically conducted by HPs to targeted groups including hot cell users and therapy nurses, and auxiliary groups such as police, fire fighters and housekeepers. Approximately 100 of these sessions are conducted annually. The DRS staff and researchers involved in shipping radioactive materials off-site obtain DOT and IATA training, where applicable, every three years. The inspector evaluated a sample of training records of laboratory and medical personnel and found all training up to date.

j. FA and Decommissioning

The inspectors reviewed the FA submittals prior to the site visit and determined that adequate instruments and certificates were on file for the materials currently licensed. The licensee had recently amended their FA to accommodate the alpha program with the addition of byproduct material with atomic numbers 93-96 and reductions in the plutonium radionuclide quantities. The new Certification of FA was approved on August 13, 2020, and the Decommissioning Funding Plan (DFP) was approved on July 31, 2021. The FA package is up to date for all materials currently licensed.

Decommissioning activities of three facilities have been performed since the last routine inspection. The NIH license was amended on February 26, 2020, to release the facilities at Twinbrook I and II in Rockville, MD. The license was amended again on February 1, 2021, to remove the Gaithersburg, MD location. The buildings underwent decommissioning using the MARSSIM technique with oversight by Clym Environmental. These projects were submitted and approved by the Region I office. The inspectors reviewed the process NIH uses to release laboratories and buildings, and no concerns were noted. The inspectors reviewed records of active laboratories that demonstrate the licensee is maintaining information important to decommissioning.

Inquiries from the licensee about decommissioning of buildings on the Bethesda Campus and possible release of two 10,000-gallon abandoned waste storage tanks located under Building 21 were referred to the Region I Decommissioning Branch. Additionally, NIH was in the midst of a multiphase project to renovate Building 10. During a recent phase of the project DRS was notified that the construction team identified old piping that was labeled as radioactive liquid and a liquid waste storage tank located under Building 10. These discoveries are presumed to be from the 1970s. DRS surveyed the piping and did not identify any radioactive material. At the time of the

inspection, the licensee was working to gain access to the holding tank in order to perform surveys and sampling activities. NIH will continue to pursue this effort and will document all findings, as well as submit a revised FA and DFP if required.

k. Independent Radiation Measurements

Independent radiation surveys were conducted at the inspected facilities. The survey results were consistent with the licensee's postings, the licensee's results, and applicable regulatory limits.

Instrument type:	Model: Ludlum 6 Serial Number: PF001744 Calibration Expiration: March 25, 2022
Instrument type:	Model: RadEye G Serial Number: 30846 Calibration Expiration: October 12, 2021
Instrument type:	Model: Ludlum 2401-P Serial Number: 281353 Calibration Expiration: April 12, 2022
Instrument type:	Model: Ludlum 2401-P Serial Number: 344918 Calibration Expiration: December 9, 2021

3. Review of Other Items

a. PHE

By letter dated April 8, 2020 (ML20101K327) and e-mail dated April 14, 2020 (ML20105A456), and in accordance with 10 CFR 20.2301, 30.11(a), and 37.11(a), NIH requested multiple temporary exemptions from regulations and license conditions of its NRC Materials Licenses 19-00296-10 (ML20091G555); 19-00296-17 (ML19277F172); and 19-00296-21 (ML17048A006). In its request, NIH stated that it is seeking these exemptions because strict conformance with the regulations and license conditions would be unavoidably incompatible with facility access restrictions and social distancing protocols implemented by NIH in response to the PHE. NIH noted that few labs were using radioactive material during this time, and even fewer labs had staff present on a daily basis, because lab visits had been curtailed as much as possible. On April 23, 2020, NIH was granted 15 temporary exemptions, 14 of which were specific to the medical broad scope license. These exemptions were authorized for up to 90 days.

The inspectors determined that out of the 14 exemptions, only six were actually utilized during the PHE. These involved 10 CFR 35.61(a) (survey instrument calibration), License Condition 22.C. (annual instrument calibration, comprehensive compliance surveys, monthly contamination surveys, and personal dosimetry exchange), and License Condition 22.F. (renewal of research protocols every two years). In addition, it was determined that the licensee had resumed normal operations before the 90-day time period lapsed.

b. Limited Scope Inspection

The NRC conducted a limited scope inspection on November 5 - 6, 2020, which focused on a review of DRS's analytical laboratory. During the inspection, one severity level IV violation of NRC requirements was identified. The violation involved the failure to implement corrective actions for programmatic weaknesses that were identified in an audit report dated January 29, 2019. Specifically, the audit identified that the licensee should update all Standard Operating Procedures (SOPs) and create new SOPs for operation of analytical equipment currently present in the Analytical Lab. At the time of the limited inspection, the licensee was relying on a SOP from November 2008 and the experience of the laboratory manager to conduct operations in the Analytical Lab. The procedure did not reflect the current operations and therefore contributed to inconsistencies in reports from the Analytical Lab during the COVID-19 PHE. This was a violation of Condition 22 of NRC License Number 19-00296-10. For corrective actions, as of February 22, 2021, the licensee updated and implemented ten SOP's. In addition, they identified and updated ten additional SOP's. This violation is now closed.

4. Conclusions

During this inspection one violation of NRC requirements was identified. Specifically, in 2021, one physician was approved as a CAU for the parenteral administration of any radioactive drug requiring a WD and the physician's training and experience was not applicable to the medical use of unsealed byproduct material requiring a WD in accordance with 10 CFR 35.390(b)(1) and the license. In addition, the classroom and laboratory training exceeded seven years preceding the date of the application as specified in 10 CFR 35.59. Corrective actions were taken by NIH as documented above.

5. Exit Meeting

At the conclusion of the onsite inspection on October 8, 2021, a summary of the inspection and the open items were discussed with NIH's senior management at an inspection exit briefing. Upon completion of in office review a virtual exit meeting was held on December 16, 2021 with the licensee.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Licensee

+^ Mark Ahlman, M.D., CAU, Nuclear Medicine Dept
* Allen Anthony, DRS Health Physicist
*^ Kwamena Baidoo, Ph.D., Staff Scientist, NCI Molecular Imaging Branch
* Cheryl Beegle, J.D., CRA, Administrative Supervisor, Nuclear Medicine
* Lang Best, Health Physicist Manager, Clym LLC
+* Alan Boudreau, DRS Health Physicist
* Charles Boxill, DRS Admin Team
* Andrew Cabot, DRS Health Physicist
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+ Jason Cheng, Ph.D., Medical Physicist, Radiation Oncology Branch
+* Ken Cheng, Ph.D., BCNP, Nuclear Pharmacy Manager and Radiopharmacist
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*^ Newbegin Devaraj, DRS Health Physicist
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+*^ Freddy Escorcia, M.D., Ph.D., CAU, NCI Molecular Imaging Branch & Radiation Oncology Branch
* Michelle Evans, Dr.P.H., Clinical Center Safety Officer
+ Leah Fahnbulleh, NIH DRS Amin Team
+*^ Teresa Fisher, DRS Health Physicist, RSC Exec Sec, Chair, RDRC
+ John Gallin, M.D., CAU, PET Dept
+* Ahmed Gharib, M.D., Chief, Biomedical and Metabolic Imaging Branch, NIH RSC Deputy Chair
* Dustin Gibbs, DRS Health Physicist
+ James Gilman, M.D., Chief Executive Officer, Clinical Center
+* Jennifer Gutierrez, DRS Health Physicist
+* Peter Herscovitch, M.D., Chief, PET Department
* Elizabeth Jones, M.D., MPH, MBA, Chief, Radiology and Imaging Sciences Dept
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^ Rosemary Miller, Supervisory Nurse Manager
+* Sidni Moore, DRS Health Physicist
* John Musachio, Ph.D., Chief, Radiopharmaceutical Production and Quality Control

+* Laurenti Ngutter, DRS Health Physicist, Branch Chief, RSOB
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* Tara Norouzi, B.S., Chief, Quality Assurance & Radiopharmacy
+*^ Olumide Owoade, DRS Health Physicist
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* Kim Powers, DRS Health Physicist
+*^ Cathy Ribaudo, DRS Health Physicist, NIH Radiation Safety Officer
+*^ Mike Roberson, DRS Health Physicist, NIH Associate RSO
+* Wendy Rubin, DRS Health Physicist
+*^ Babak Saboury, M.D., MPH, CAU, Nuclear Medicine Physician
+ Kilian Salerno, M.D., CAU, Radiation Oncology Branch
+*^ Alfredo Sancho, Ph.D., Office of Intramural Research, RSC Management Rep
+^ Margaret Sanders, R.N., NIH Office of Human Subjects Research Protections
* Tim Tosten, Office of Research Services, Acting Associate Director, Scientific Resources
+*^ Victor Voegtli, DRS Health Physicist, Branch Chief, MCAB
+*^ Brad Wood, M.D., Chief, Interventional Radiology, NIH RSC Chair
+* Richard Wyatt, M.D., Director, Office of Intramural Research
Various medical staff, researchers, contractors, and support staff

+ Present at entrance meeting
* Present at exit briefing
^ Present at exit meeting

INSPECTION PROCEDURES USED

IP 87126, Industrial/Academic/Research Programs
IP 87127, Radiopharmacy Programs
IP 87131, Nuclear Medicine Programs, Written Directive Required
IP 87132, Brachytherapy Programs
IP 87134, Medical Broad-Scope Programs

LIST OF ACRONYMS USED

ALARA – As Low As Reasonably Achievable
ANP – Authorized Nuclear Pharmacist
AU – Authorized User
BRC – Baltimore Research Center
BSL – Biosafety Level
CAU – Clinical Authorized User
CFR – Code of Federal Regulation
DFP – Decommissioning Funding Plan
DOT – Department of Transportation
DRS – Division of Radiation Safety
EPA – Environmental Protection Agency
FA – Financial Assurance
HDR – High Dose Rate Remote After Loader
HP – Health Physicist
IATA – International Air Transport Association
IRB – Institutional Review Board
MPW – Medical/pathological waste
MIP – Molecular Imaging Program

NIH – Department of Health & Human Services National Institutes of Health
NM – Nuclear Medicine
NMT – Nuclear Medicine Technologist
NRC – Nuclear Regulatory Commission
PET – Positron Emission Tomography
PHE – Public Health Emergency
RDRC – Radioactive Drug Research Committee
RSC – Radiation Safety Committee
RSO – Radiation Safety Officer
SOP – Standard Operating Procedure
WD – Written Directive