UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

September 4, 2015

Docket No. 03001786
03037773

License No. 19-00296-10
19-00296-21

Michael M. Gottesman, M.D.
Deputy Director for Intramural Research
Department of Health and Human Services
National Institutes of Health
Building 1, Room 103
1 Center Drive, MSC0140
Bethesda, MD 20892-0140

SUBJECT: NRC INSPECTION REPORT NOS. 03001786/2015001 AND 03037773/2015001, DEPARTMENT OF HEALTH AND HUMAN SERVICES, NATIONAL INSTITUTES OF HEALTH, BETHESDA, BALTIMORE, FREDERICK, AND ROCKVILLE, MARYLAND

Dear Dr. Gottesman:

On July 20-23, 2015, Tara Weidner, Janice Nguyen, Robin Elliott, and Dennis Lawyer of this office conducted a safety inspection of the National Institutes of Health facilities at the above addresses of activities authorized by the above listed NRC licenses. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspectors, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with Richard Wyatt, M.D., Deputy Director, Office of Intramural Research and other members of your organization at the conclusion of the onsite inspection. The enclosed report presents the results of the inspection.

Within the scope of this inspection, no violations were identified.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** then **Enforcement Policy (Under 'Related Information').** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

No reply to this letter is required. Please contact Tara Weidner at 610-337-5272 if you have any questions regarding this matter.

Sincerely,

for James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Inspection Report

cc:
Nancy E. Newman, Radiation Safety Officer
State of Maryland

DOCUMENT NAME: G:\WordDocs\Current\Insp Letter\L19-00296-10.2015001.doc
Friday, September 4, 2015 12:46:18 PM

SUNSI Review Complete: TWeidner

After declaring this document "An Official Agency Record" it **will** be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI	N	DNMS/RI	N	DNMS/RI	N
NAME	TWeidner		KNguyen		RElliott		DLawyer	
DATE	9.4.15		9.4.15		9.4.15		9.4.15	

OFFICE	DNMS/RI
NAME	JDwyer PL for
DATE	9.4.15

OFFICIAL RECORD COPY

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001786/2015001 03037773/2015001
Docket No.	03001786 03037773
License No.	19-00296-10 19-00296-21
Licensee:	Department of Health and Human Services National Institutes of Health
Location:	Bethesda, Baltimore, Frederick, and Rockville, Maryland
Inspection Dates:	July 20-23, 2015

Inspectors:

Tara Weidner — date 9/4/15
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

for Robin Elliott — date 9/4/15
Health Physicist
Medical Branch
Division of Nuclear Materials Safety

for Janice Nguyen — date 9/4/15
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

for Dennis Lawyer — date 9/4/15
Health Physicist
Commercial, Industrial, R&D, and
Academic Branch
Division of Nuclear Materials Safety

Approved By:

for James P. Dwyer, Chief — date 9-4-15
Medical Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Department of Health and Human Services
National Institutes of Health
NRC Inspection Report Nos. 03001786/2015001 and 03037773/2015001

A routine, unannounced team inspection was conducted at the National Institutes of Health (NIH) facilities located in Bethesda, Baltimore, Frederick, and Rockville, Maryland on July 20-23, 2015. The inspection was performed in accordance with NRC Inspection Procedures 87125, 87126, 87127, and 87134 and reviewed activities associated with the use of licensed materials authorized by License Numbers 19-00296-10 (medical broad scope) and 19-00296-21 (cyclotron production).

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 no violations of NRC requirements were identified and five previous violations were closed. The corrective actions taken by the licensee are discussed in Section 1.

REPORT DETAILS

1. Organization, Oversight, and Scope of the Program

a. Inspection Scope

A routine, unannounced team inspection was conducted July 20 through 23, 2015, at the NIH main campus in Bethesda, Maryland; the Integrated Research Facility, 8200 Research Plaza, Fort Detrick, Frederick, Maryland; the Behavioral Biology Research Center, 251 Bayview Boulevard, Baltimore, Maryland; and 9800 Medical Center Drive, Rockville, Maryland. The inspection was performed in accordance with NRC Inspection Procedures 87125, 87126, 87127, and 87134, and reviewed activities associated with the use of licensed materials authorized by License Numbers 19-00296-10 (medical broad scope) and 19-00296-21 (cyclotron production). 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, releases to the environment, and financial assurance were reviewed.

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

b. Observations and Findings

Program Scope and Management Oversight

NIH's radiation safety staff oversees the radiation safety program and is 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), an Assistant Director, two Branch Chiefs, a Team Leader for the cyclotron activities, an Executive Secretary, Radiation Safety Committee (RSC), and a total of 26 support staff to carry out the functions of DRS. In addition, 18 contract staff assist DRS in the conduct of routine surveys, package delivery, instrument calibrations, and waste processing.

A total of 3,811 regulatory compliance surveys were conducted by NIH staff and contractors in 2014. This reflected a 1% decrease from 2013. In 2014, there were approximately 966 posted laboratory modules where 578 authorized users and 4,273 individual users conducted research activities. Most of the laboratory space and clinical facilities are on the main campus in Bethesda, Maryland; however, the licensee has several satellite facilities in Rockville, Baltimore, Poolesville, Gaithersburg, and Frederick, Maryland.

Approximately 120 new research protocols per year are reviewed by the RSC with an estimated 131 on-going clinical protocols which use radioactive material in humans. Approximately 90 percent of all protocols use Positron Emission Tomography (PET) radioisotopes. Clinical protocols are reviewed by one of the 12 Institutional Review

Boards (IRB) and the RSC, as well as the Radioactive Drug Research Committee (RDRC), as needed. The RSC is actively involved in the licensed program and meets monthly to discuss: (i) NRC licensing and regulatory matters; (ii) 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. During the previous inspection, it was identified that the RSC membership did not include an authorized user (AU) for each type of use, in violation of 10 CFR 35.24(f). Specifically, an AU from radiation oncology was not a member of the committee. Since that time, an AU from radiation oncology and a back-up AU has been assigned to the RSC. This violation is closed.

During the 2011 inspection, the inspectors noted that NIH's RSC no longer required documentation of the identifier for the Food and Drug Administration approved investigational new drugs (IND), to demonstrate compliance with 10 CFR 35.6. The RSC relied on the IRBs for confirmation of this information and requested that each IRB confirm that this was being done. At the time of the 2013 inspection, 7 of the 12 IRBs had provided confirmation. Following the 2013 on-site inspection, NIH contacted the remaining five IRBs and requested written confirmation that IND approval status is confirmed by each institute prior to IRB approval. Inspectors determined, during the July 2015 inspection, that these confirmations were obtained from the five remaining IRBs.

The inspectors reviewed the training and experience approvals of two clinical AUs and 17 research AUs performed by the RSC, and found them to be appropriately documented. During the last inspection, the inspectors noted that the RSC had approved an AU and an authorized medical physicist (AMP) for clinical use of the remote afterloader based on board certificates that were not recognized by the Commission, in violation of License Condition 11.B. of License No. 19-00296-10. NIH took immediate corrective actions which included rescinding the approvals of the AU and AMP. Subsequently, the AU and AMP reapplied for AU status, documenting their training and education on the appropriate NRC Form 313A. The RSC reviewed the preceptor forms for both individuals and reinstated their authorizations in July 2013. This violation is closed.

NIH DRS staff responded to 43 incidents since the last inspection, most of them minor. The inspectors reviewed the following incidents: (i) technetium-94m, less than 10 times the quantity in Appendix C to 10 CFR Part 20, detected in dumpster at off-site transfer station; (ii) radiochemist contamination of hand with fluorine-18 (F-18); (iii) cyclotron gasket failure resulting in worker contamination with F-18; (iv) copper-64 spill in the microPET facility; (v) wrong package containing technetium-99m (Tc-99m) picked-up by courier; and (vi) carbon-11 (C-11) gas release at cyclotron. 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.

Medical Activities Conducted under License Number 19-00296-10

The nuclear medicine facility currently includes a temporary radiopharmacy, two injection rooms, two quiet rooms, and five cameras (two of which are PET/CTs). Patients treated with greater than 33 millicuries of iodine131 (I-131) are housed in one of two shielded rooms. All I-131 patients are issued written instructions on methods for controlling exposures to members of the public. The PET research facility includes: a radiopharmacy, quiet rooms, one PET camera, one PET/CT unit, and a high resolution tomograph for brain scans. A high dose rate (HDR) remote afterloader is located in the radiation oncology department.

The nuclear medicine department typically receives a single 4 curie molybdenum-99/technetium-99m generator weekly. However, the nuclear medicine department is currently in the process of relocating its hot lab, so only unit and bulk doses are being used while the hot lab is in its smaller, interim location. Appropriate close out surveys were performed of the old hot lab prior to releasing it for renovations. The new hot lab will consist of multiple rooms for waste storage, dose preparation, and a clean room, and is estimated to be ready by December 2015. The authorized nuclear pharmacist (ANP) is responsible for eluting the generator, analyzing the molybdenum-99 concentration, preparing the technetium-99m (Tc-99m) kits, and assaying all doses prior to administration by the nuclear medicine technologists (NMT). Unit doses of short-lived radiopharmaceuticals (F-18) are delivered directly to the radiopharmacy by various vendors. All other doses go to DRS, are checked in, and then delivered to nuclear medicine. Tc-99m and F-18 are the primary radioisotopes used in the nuclear medicine department. In 2013, NIH performed 32 I-131 therapies (27 inpatient and five outpatient), 12 diagnostic studies with I-131, and five yttrium-90 (Y-90) radioimmunotherapy treatments. In 2014, NIH performed 16 I-131 therapies (10 inpatient and six outpatient), six diagnostic studies with I-131, and three Y-90 radioimmunotherapy treatments. The inspectors reviewed written directives, patient release criteria, and patient release instructions and found them to be acceptable.

The PET research facility uses F-18, C-11, nitrogen-13 (N-13), manganese-51 (Mn-51), and oxygen-15 (O-15) for human and animal research protocols. F-18, C-11, N-13, and Mn-51 are delivered from the cyclotron to the radiopharmacy via a "rabbit system." The ANP uses a robotic system for drawing up the doses and assays them prior to injection by the NMT. Because of the short half-life of O-15, it is delivered directly from the cyclotron to the scan room via a "water on the wall system." Since the protocols are all research studies, a signed informed consent form is on file for each patient prior to the dose administration.

The licensee also possesses a remote afterloader unit that was used to treat four patients over 12 fractions in 2013 and two patients over five fractions in 2014. The remote afterloader is used for gynecologic procedures using a vaginal cylinder, tandem and ovoid, or tandem and cylinder. They are looking to start a HDR prostate program within the next six months. During the previous inspection, one violation was identified in the HDR program. NIH had upgraded their HDR unit to a newer Nucletron version on January 15, 2013, without amending License Condition 9. L. of their NRC license. NIH submitted an amendment request to the NRC on June 21, 2013, to update the HDR unit

on the license to the current device, and the amendment was issued on September 20, 2013. This violation is closed.

During the last inspection, the inspectors reviewed the written directives for treatments conducted with the remote afterloader unit. It appeared that all of the information required by 10 CFR 35.40 was not being captured in the written directives but instead was being documented in the patient's charts. NIH updated the written directive form on July 2, 2013, to document all required information in one place. All current written directives are complete.

The inspectors observed the AMP perform daily spot check procedures for the remote afterloader unit. All required tests were performed and documented.

For audits of the remote afterloader program, an AMP does an internal review of records and procedures. It was recommended during the last inspection that a member of DRS perform a regulatory audit to ensure that all requirements are being met. An audit by DRS is currently in progress.

Research Activities Conducted under License Number 19-00296-10

Research activities typically involve microcurie quantities of radioactive material used on the bench top, or in fume hoods involving the following radioisotopes: tritium, N-13, C-14, O-15, F-18, sodium-22, phosphorus-32, phosphorus-33, sulfur-35, calcium-45, chromium-51, zirconium-89, iodine-125, and astatine-211. Iodination facilities typically use millicurie quantities of licensed materials. In 2014, there were 966 posted laboratory modules where 578 authorized users and 4,273 individual users conducted research activities. DRS made a significant effort to reduce the numbers of posted lab modules where licensed material was no longer being used and this number reflects approximately a 37% decrease in posted lab modules over the last inspection. The number of authorized users also decreased by approximately 16%; however, the number of individual users increased by 45.5%.

The inspectors visited a sampling of research laboratories in buildings 10, 21, 35, 37, and 50 on the main campus; the Behavioral Biology Research Center in Baltimore, Maryland; the Integrated Research Facility at Fort Detrick in Frederick; Maryland, and 9800 Medical Center Drive in Rockville, Maryland. Security is restricted to the campus via the main gate which screens visitors. Once on the campus, some buildings have general access areas; however, access to laboratory areas requires additional measures such as card access, security guard clearance, or key control. Access to radioactive material use areas is limited to only those who are authorized to be in that area. Additionally, not all DRS staff have access to all radioactive material use areas. Within laboratory modules, radioactive material stock vials were secured within locked refrigerators or freezers, and waste was consistently secured in locked containers to prevent unauthorized access or removal. Security at the Integrated Research Facility and the Behavioral Biology Research Center was similar. The buildings had a main security entrance and escorts were required. Laboratories were either key carded or the material was locked in a separate location.

Overall, the scientists were found to be exercising good practices for radiation safety and ALARA. The NIH has appropriate facilities for conducting the research being performed on site; i.e. work generating airborne radioactive materials or aerosols was done in a fume hood or glove box, operations generating radiation fields were performed in hot cells, etc. Laboratory doors, freezers, and refrigerators were posted with the appropriate warning labels. One instance was found where one door to a laboratory space was not posted with a Radiation Area posting; however, the other door leading to the same space was posted. The licensee took note and corrected it. Current copies of the NRC Form 3 were prominent in the lab areas. Radioactive use areas on the bench were clearly demarcated and absorbent paper was consistently used in an effort to prevent fixed contamination. The laboratories were consistently equipped with survey meters that were functional and calibrated. Workers were asked to demonstrate use of the survey meters and showed proper technique. When a scientist was using a material requiring shielding, proper shielding was available at the work station and the radioactive waste was also stored in shielded containers. Surveys are conducted each day that work is performed with radioactive material and wipe tests are performed weekly. Researchers were observed using personal protective equipment such as gloves, and lab coats. Higher risk areas, such as the iodination facilities and the alpha lab, instituted higher levels of protection, such as booties, hair nets, sleeve covers, and dust masks. Remote handling devices and breathing zone and room air sampling are performed as well.

Scientists interviewed in the labs were knowledgeable regarding their use of radioactive material. They exhibited good awareness regarding personal protective equipment, emergency procedures, hazards associated with the material they were working with, security requirements, and surveying their work area after completing an assay or before leaving the laboratory.

The areas inspected appeared to have fire protection in place (sprinklers and fire extinguishers) that were being inspected on a regular basis, emergency lighting, and eye wash stations and safety showers. In addition, there were appropriate receptacles in place to collect infectious waste and sharps consistent with the OSHA Blood Borne Pathogen (BBP) program requirements. All personnel interviewed, that were working with BBPs, stated they had received the required training and were familiar with emergency evacuation routes. Without exception all personnel interviewed stated they were comfortable raising safety concerns and did not express any safety concern with their current work environment.

The Integrated Research Facility utilizes one unit dose of F-18 each day for imaging and Tc-99m as needed for linearity checks. The material was received from a vendor rather than from the NIH main campus. The inspectors observed the material receipt, instrumentation availability, and survey practices of the facility. Air samplers and portable meters were within calibration. The inspectors toured areas outside the containment and observed worker radiation safety practices within the containment. The procedures implemented for radioactive contamination and biological hazard controls, including hot/cold working areas for imaging suites, tissue digester and biological holdup tanks for animals and animal waste, specialized animal rooms, autoclave, specialized air control and monitoring systems were discussed. Material is stored for decay, surveyed

for release, and then disposed before leaving the containment. Disposal is normally though the cook tanks. The sampling methods for the cook tanks were reviewed. The cook tanks receive the waste from the containment areas which has the most chance of radioactivity. When the cook tank is filled, it is heated to remove biological hazards. The tank cannot be recirculated but, the heating will cause a circulation within the tank. The tank is sampled shortly after heating.

In the 2013 inspection, an NIH researcher did not make an adequate survey of a work area, to evaluate residual radioactivity and potential radiological hazards in accordance with 10 CFR 20.1501(a). The researcher conducted a survey at the end of radioactive material use; however, the survey was not adequate because it failed to detect approximately 35,000 counts per minute (cpm) [109,000 disintegrations per minute (dpm)] on the floor located directly below the work area. Subsequent to this incident, the researcher satisfactorily cleaned the location and DRS conducted training with the group on survey requirements. In addition, during the 2015 inspection all the research areas inspected were surveyed and found to be clear of contamination. This violation is closed.

Cyclotron Activities Conducted under License Number 19-00296-21

NIH operates three cyclotrons to produce radioisotopes. The cyclotrons are located within two vaults which are located behind two heavily shielded doors. Access to the area is controlled and appropriate warning signs are posted. Radioactive material, that is produced in the cyclotrons is either piped directly to hot cells or transferred manually using heavily shielded and labeled containers. Lines that are used to transfer the radioisotope from the cyclotrons to the hot cells are marked with the appropriate warning labels as well as a phone number to be contacted in the event of an emergency or the need to perform a line break. The cyclotron facility utilizes a dumb waiter for transporting radioactive material between floors. Therefore, minimizing handling time and personnel exposure. Material production is managed by schedule and relates to the amount of material produced. Material production was compared to the license limits with no concerns noted. Material transfer to the broad scope license is done by a Form 88-1. Normally the researcher that intends to receive the material completes the form and electronically submits it to DRS. DRS uses the information on the Form 88-1 to update the inventory.

Both of the cyclotron vaults and the hot cells are equipped with collection bags to trap volatile radioactive material and minimize the concentrations of radioisotopes in air effluent. In addition, exhaust ducts are equipped with a HEPA filter and a charcoal filter. When there is an unexpected release in the cyclotron vault or a hot cell, the charcoal filters are effective at trapping the activity and minimizing the release to the environment. However, the filters themselves can become a significant source of radiation for a limited period of time. The charcoal areas are posted as radiation area for normal routines. If a large amount of volatile material is released within a hot cell, DRS is prepared to post the affected area as a high radiation area and control it in accordance with 10 CFR 20.1601(b).

One of the transfer lines from the cyclotron that is used to transfer O-15 travels through a parking garage. The transfer line is clearly labeled and the junction boxes are closed and secured with padlocks to prevent tampering. The inspectors measured a radiation reading of 1.3 millirem per hour on the line during a transfer. The licensee posts area dosimetry in the area to monitor long term doses in the area to ensure public dose limits are not exceeded. NIH has designed additional shielding enhancements for the O-15 lines. They plan to install the enhancements after a decision is made as to whether or not C-11 will be transferred through the same line. If C-11 is used, additional shielding may be necessary.

The cyclotron vaults and the hot cells are maintained under negative pressure. The ventilation system has a redundant back-up exhaust motor in the event that the primary motor were to fail to provide the proper exhaust. There is an electronic readout of the pressure differential and ventilation performance is tied into the Siemens monitoring system to assure that the cyclotron engineer would be alerted of a ventilation problem or malfunction. Since the last inspection, there was an issue with maintaining negative pressure at all times in the vaults. Some of the linkages to ventilation dampers had slipped resulting in positive pressure in the vault. Maintenance was done to correct the positions and maintain negative pressure. The licensee has scheduled an upgrade to the system which is expected to be completed in July 2016.

Contamination at the cyclotron is controlled several ways. Individuals that enter the cyclotron vault don bootie shoe covers that are removed upon exiting. The licensee has deployed a "sticky" step-off pad in an effort to control the potential spread of contamination. Portable survey meters are available at the vault exit for personnel to frisk themselves and survey their shoes. All the meters present were checked and were operational and had been calibrated within the last twelve months. All employees are required to use the Berthold hand and foot monitor prior to leaving the cyclotron restricted area and the inspectors observed this practice.

The cyclotron facility and associated hot cells are also equipped with a hold-up tank to capture any radioisotopes prior to release to the sanitary sewer. Radioisotopes are held in the tank and allowed to decay. A health physicist stated that the hold-up tank has not been released to the sanitary sewer for several years and certainly not since the last inspection. Most liquid is placed into a container and transferred to Building 21.

The inspectors toured the new cGMP hot cell facility which will have direct transfer capability from the cyclotron. Equipment is currently being installed to make it operational. The shielded transfer lines and hot cells were installed. The licensee had installed a portal monitor for exiting the facility. These hot cells utilize a small carbon filter at each hot cell prior to exhausting through the exhaust line.

Radiation Safety Training

DRS requires all personnel to obtain training prior to working with radioactive material. Individual users and AUs take on-line training that includes verification by exam. Prior to receiving approval, AUs are required to participate in practicum and round-robin sessions followed by a proctored final exam, with a pass rate of 80%. Refresher training

is also required and is available via on-line sessions. In 2014, 1,166 radioactive material users participated in on-line refresher training. DRS offers many other on-line radiation safety courses on a variety of topics such as Irradiator refresher, PET refresher, etc. In 2014, they offered a total of 37 on-line courses and trained 3,490 students.

In addition to on-line training, DRS continues to conduct face-to-face training. The sessions are typically conducted by health physicists to targeted groups including: hot cell users and I-131 therapy nurses, etc., and auxiliary groups such as police, fire fighters and housekeepers. In 2014, a total of 89 sessions on these specialized topics with 1,095 individuals were held. The DRS staff and researchers involved in shipping radioactive materials off-site obtain Department of Transportation (DOT) and International Air Transport Association training, where applicable, every three years. The inspector evaluated a sample of records of laboratory personnel and found all their training records to be up to date.

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, with the exception of F-18, which is received directly in nuclear medicine, and a cocaine derived compound, which is received directly in the pharmacy. Requests for purchase of radioactive material are completed by the researcher and submitted to the purchasing department and DRS simultaneously. Purchasing agents place the orders, and the vendors ship the material to DRS. Upon arrival, packages are surveyed for radiation levels and contamination and the contents are verified against the packaging list and the order. Vials are wipe tested to confirm there is no contamination present, and then re-packaged for transport to the AU by contract personnel. Lastly, the AU's inventory is checked to verify the material is within their limits. The licensee utilizes the services of a contractor to handle the receipt and delivery of packages.

Transfers to/from other licensees are managed by health physicists within DRS. All the individuals that are involved with preparing radioactive material shipments are trained and tested in accordance with the DOT requirements. Licenses from the institution receiving material are obtained prior to the shipment and reviewed to verify the recipient is authorized. Packaging, labeling, and preparing shipping papers for these shipments is performed by the health physics staff. The inspectors reviewed a sample of records of transfers and licenses from other institutions and found no concerns.

DRS utilizes their contract personnel to verify the electronic inventory by performing a physical inventory of licensed material on the NIH campus annually. This is currently done by conducting the inventory in sections due to the large number of locations, rather than all locations at one time. This method provides a challenge to the contractors when multiple AUs store the same compounds in the same storage location. In an effort to improve the ability to conduct the physical inventories given this scenario, the inspectors made two recommendations: (i) to conduct the inventories for all users in a given area at the same time, and (ii) to include lot numbers on the inventory record to aid in identifying specific vials of the same compound. The manager of this area and the contractor who performs the inventories agreed with these recommendations.

The inspectors reviewed the forms and database for maintaining the inventory and purchasing the research materials. The package receipt process in DRS was observed. The inspectors also observed the process for picking up and preparing an off campus shipment from 9800 Medical Center Drive, Rockville, Maryland. No concerns were noted. The procedure for on-campus shipments was also in order; DOT requirements do not apply since the NIH Bethesda Campus roads are privately used.

From the 2013 inspection, NIH was issued a violation of 10 CFR 20.1906(b)(1) and (c) related to shipping of packages off the main campus. NIH shipped packages with DOT Yellow II labels on public roadways to the NIH Baltimore campus and the licensee did not monitor the external surface of the package for contamination when the package was received, as required. The corrective actions implemented included changing their procedure to require surveys to be performed of all labelled packages transported on public roadways to other NIH campus locations. Researchers at the NIH Baltimore and Frederick site were questioned with regard to their procedure when receiving a labelled package containing radioactive material shipped from the Bethesda campus. They indicated that they perform a survey of the package and provide the results to the main campus to include with paperwork for the shipment. It is now their practice to attach a copy of the survey results to the package manifest kept on file. The inspectors reviewed the files for all shipments made since the last inspection and found that surveys were performed for all of them. This violation is closed.

Radiation Surveys

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

(i) NMTs and radiopharmacists, in both the nuclear medicine area and the PET areas, performed end of day surveys and weekly contamination surveys. NIH personnel were able to adequately demonstrate these surveys to the inspectors.

(ii) 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 health physicists. 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 re-monitored, with follow up surveys adequately documented.

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

(iv) Surveys in the cyclotron area and the waste management areas were performed weekly. In addition, the O-15 transfer line through the parking garage was monitored by area dosimeters. The inspectors reviewed records maintained of these surveys, with no concerns noted.

(v) Clearance surveys were performed prior to release of licensed facilities. The inspectors reviewed records maintained to support the release of facilities, with no concerns noted.

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 wipe and dose rate survey, as well as interviews with 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 hoods, shielding in use, and confirms that there is no eating, drinking or smoking in the restricted area. The inspectors reviewed the contractor's audits, with no concerns noted. The laboratories and departments are also audited by a member of the radiation safety staff at least every two years. This AU audit is more comprehensive, and reviews protocols, inventory, and use. Audit records were reviewed, with no concerns noted.

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 Ludlum. The calibration of one instrument by the contractor was observed by the inspectors and found to be in accordance with ANSI N323A-1997. AUs are accountable to calibrate their own liquid scintillation counters. The inspectors reviewed calibration and counting statistics performed on survey instruments and liquid scintillation counters and noted that they appeared satisfactory and in accordance with the manufacturer's recommendations.

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, the Varskin software is used by a member of DRS to calculate the skin dose.

Internal dose is assessed by bioassay. The bioassays that are performed are thyroid scans, body scans, and urine sample analysis. The thyroid monitoring equipment used is the Canberra Accuscan II system which is calibrated using an iodine-129 reference standard and a neck phantom. The Canberra Fastscan system is used for whole body counting. Based on the records reviewed and information provided by the health physicist from 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. There are currently three declared pregnant workers. A review of the records indicated that none of the women had received a fetal dose greater than 500 millirem during the gestation period, in accordance with 10 CFR 20.1208.

Effluent Monitoring

In the cyclotron area, a PING monitor measures the effluent data from the EF-1 line coming from Vault 1 and is captured and analyzed. It also has the ability to obtain a grab sample for analysis. The EF-2 exhaust line from Vault 2; the EF-3 line from the NIMH/NIBIB and general areas of the cyclotron offices; and the EF-4 exhaust line from the IPDC and future cGMP areas each has a plastic scintillator coincidence detector on each line. The licensee collects data from the detectors and performs effluent calculations. The licensee also performs air sampling in the ducts of the laboratories to quantify releases during iodinations. The data from the EF-1 through EF-4, and the air sampling data is corrected based on the total effluent volume and wind rose data and converted to dose utilizing the data 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 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.

The results were as follows:

- 2013 – 9.50 mrem
- 2014 – 4.12 mrem

Therefore, the results indicated full compliance with the constraint rule in 10 CFR 20.1101(d).

Radioactive Waste Management

The radioactive waste program is managed by a member of DRS and supported by contractors who are employees of Clym Environmental. Radioactive waste streams are segregated, radioactive waste containers are well labeled, bar coded when appropriate, and tracked in a database. The compactors for radioactive waste have not been used for years and there are no plans to use them routinely in the future. The ultraviolet processing system that was used to treat aqueous mixed waste has also been shut down since the last inspection.

All liquid scintillation vial wastes are handled as radioactive and they are currently deregulated per 10 CFR 20.2005(a)(1). No liquid scintillation waste is held for decay-in-storage. Some non-RCRA (hazardous wastes governed by the Resource Conservation and Recovery Act) vials are shredded by a vyleater on site. The fluid is bulked in a drum and shipped for disposal. The shredded vials are discarded as dry active radioactive waste to a disposal facility. All other vials are directly shipped to a waste vendor.

Medical/pathological waste 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 meter and, according to the records, the licensee periodically identifies a container that has not decayed to background levels. In those cases, the waste is decayed longer and re-surveyed to demonstrate that it is indistinguishable from background. The licensee re-cycles their lead waste. Prior to re-cycling, the lead is surveyed with a pancake GM counter and a sodium iodide crystal detector and smears are collected and analyzed.

All radioactive dry active waste is shipped as low specific activity (LSA) material. The shipment is considered "exclusive use" and the transport vehicle is placarded. Instructions pertinent to the exclusive use shipment are provided to the driver. All of the workers involved with packaging and labeling radioactive waste or transporting the radioactive waste between sites have received hazardous material training and have been tested in accordance with DOT requirements.

The waste facility is equipped with nine 2,250 gallon fiberglass tanks that hold aqueous non-RCRA radioactive waste. The licensee made two batch releases from the tanks to the sanitary sewer on February 7, 2014, and November 4, 2014. The total activity was approximately 300 millicuries mostly of tritium. The licensee was in compliance with 10 CFR 20.2003.

Contamination control in the waste area appeared effective. The inspectors made independent measurements of the area and did not identify contamination on the floors or surfaces. The licensee performs surveys on a daily basis and a more extensive weekly survey in the waste areas. A hand and foot monitor was located in the area and personnel were observed using it. The facility was well designed with sloped floors and dykes to contain leaks and prevent the spread of contamination. A detailed audit of radioactive waste operations was performed in March 2015 with no concerns noted.

Posting and Labeling

The inspectors toured the nuclear medicine department, PET areas of use, the radiation oncology department, research facilities, cyclotron facilities, and Building 21 (DRS). All areas of use and storage were properly posted and radioactive materials were properly labelled.

Financial Assurance and Decommissioning

The inspectors reviewed the financial assurance submittals prior to the site visit and determined that adequate instruments and certificates were on file for the materials currently licensed. Decommissioning activities had been performed since the last inspection and were approved for release in license amendments for the Gerontology Research Center in Baltimore, 5 Research Court and 5516 Nicholson Lane in Rockville.

The inspectors reviewed records of active laboratories that demonstrate the licensee is maintaining information important to decommissioning.

c. Conclusions

Based on the results of this inspection, no violations of NRC requirements were identified for License Nos. 19-00296-10 and 19-00296-21.

2. Exit Meeting

At the conclusion of the onsite inspection on July, 23 2015, the inspection findings were discussed with NIH's senior management.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

*Richard Wyatt, M.D., Deputy Director, Office of Intramural Research
*Alfred Johnson, PhD, Director, Office of Research Services (ORS)
*Lisa Coronado, Deputy Chairman, Radiation Safety Committee
*Larry Chloupek, Management Representative, Radiation Safety Committee
+*Nancy Newman, RSO and Director, Division of Radiation Safety (DRS)
*Peter Herscovitch, M.D., Chief, PET Department
*Ronald Neuman, M.D., Chief, Nuclear Medicine Department
+*Cathy Ribaudo, Assistant Director, DRS
*Michael Roberson, Team Leader, Cyclotron and PET, DRS
+*Wendy Rubin, Chief, Materials Control and Analysis, DRS
+*Laurenti Ngutter, Chief, Radiation Safety Operations, DRS
*Israel Putnam, Supply Management Officer, DRS
*Larry Koenig, Health Physicist, DRS
*Neena Patel, Health Physicist, DRS
*Allen Anthony, Health Physicist, DRS
*Doug Carter, Health Physicist, DRS
*Keith Ball, Team Leader, DRS
*Alan Boudreau, Health Physicist, DRS
*Teresa Fisher, Health Physicist, DRS
*Daniel McDonald, Health Physicist, DRS
*John Jacobus, Health Physicist, DRS
*Andrew Cabot, Health Physicist, DRS
*Stephen Guarino, Health Physicist, DRS
Dustin Gibbs, Health Physicist, DRS
Eric Munger, Health Physicist, DRS
Adella Francis, Health Physicist, DRS
*Lang Best, Surveyor, Contractor, DRS
*F. Watts, Clym

Various medical staff, researchers, contractors, and support staff

+Present at entrance meeting
*Present at exit meeting