U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001786/2011001, 03008478/2011001, 03017872/2011001 03037773/2011002
Docket No.	03001786, 03008478, 03017872, 03037773
License No.	19-00296-10, 19-00296-17, 19-00296-20, 19-00296-21
Licensee:	Department of Health & Human Services National Institutes of Health
Location:	Bethesda, Rockville, Baltimore, and Frederick, Maryland
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EXECUTIVE SUMMARY

Department of Health & Human Services
National Institutes of Health
NRC Inspection Report Nos.
03001786/2011001, 03008478/2011001, 03017872/2011001, 03037773/2011002

A routine, unannounced team inspection was conducted at the National Institutes of Health (NIH) facilities located in Bethesda, Rockville, Frederick, and Baltimore, Maryland on April 4-8, 2011. Additional information, contained in correspondence from NIH on April 11 and May 9, 2011, was also reviewed. The inspection was performed in accordance with NRC Inspection Procedures 87122, 87125, 87126, 87127, and 87133 and reviewed activities associated with the use of licensed materials associated with License Numbers 19-00296-10 (medical broad scope), 19-00296-17 (irradiator), 19-00296-20 (irradiator), 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, four violations of NRC requirements were identified. Specifically,

- NIH did not determine their remote afterloader unit's timer linearity over the typical range of use as required by 10 CFR 35.633(b)(5). Specifically, in 2010, the timer linearity was measured over 200 seconds; however, the typical treatment time was approximately 500 seconds. In addition, on August 11, 2010, timer linearity was not determined during the full calibration, as required.

- The NIH Radiation Safety Committee (RSC) approved an authorized user (AU) for the use of a remote afterloader unit under 10 CFR 35.600 without obtaining a written attestation, signed by a preceptor AU who meets the requirements in 10 CFR 35.690. Specifically, Condition 11.B. of License No. 19-00296-10 requires, in part, that individuals designated in writing by the licensee's RSC to work as an AU, as defined in 10 CFR 35.2, shall meet the training and experience requirements in 10 CFR Part 35; which requires a preceptor attestation, when applicable.

- NIH did not dispose of licensed material by decay in storage or transfer to an authorized recipient, as required by 10 CFR 20.2001. Specifically, on May 4 and June 28, 2010, NIH personnel inadvertently placed nanocurie quantities of bromine-76/77 and nanocurie quantities of zirconium-88/89 into the normal trash prior to decay, which caused local landfill radiation detectors to alarm.

- NIH did not post a room adjacent to the cyclotron area with a "Caution Radiation Area" sign, as required by 10 CFR 20.1902. Specifically, a room located adjacent to the cyclotron charcoal exhaust filter room had a measurable reading of 12 milliRoentgen per hour 20 minutes following a transfer of carbon-11 and 5 milliRoentgen per hour 45 minutes following the transfer. Since the area met the definition of radiation area in 10 CFR 20.1003 (i.e., greater than 5 millirem in 1 hour), posting pursuant to 10 CFR 20.1902 was required.

REPORT DETAILS

I. Organization, Oversight, and Scope of the Program

a. Inspection Scope

A routine, unannounced team inspection was conducted at the NIH facilities located in Bethesda, Rockville, Frederick, and Baltimore, Maryland on April 4-8, 2011. Additional information, contained in correspondence from NIH on April 11 and May 9, 2011, was also reviewed. The inspection was performed in accordance with NRC Inspection Procedures 87122, 87125, 87126, 87127, and 87133 and reviewed activities associated with the use of licensed materials associated with License Numbers 19-00296-10 (medical broad scope), 19-00296-17 (irradiator), 19-00296-20 (irradiator), 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.

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 in Bethesda, Maryland. The staff consists of a Division Director/Radiation Safety Officer (RSO), three Branch Chiefs/Team Leads, and a total of 27 support staff to carry out the functions of DRS. In addition, 30 contract staff assist the radiation safety office in the conduct of routine surveys, package delivery, instrument calibrations, and waste processing.

Approximately 5000 compliance surveys were conducted by NIH staff and contractors in 2010. Currently, the licensee has approximately 750 authorized users spread among approximately 20 institutes and 1500 laboratories. Most of the laboratory space and clinical facilities are on the main campus in Bethesda, Maryland. However, the licensee has several leased facilities in Rockville, Maryland and Baltimore, Maryland. In addition a new facility in Frederick, Maryland has recently opened with limited use of licensed material.

Approximately 60 new research protocols per year are reviewed by the Radiation Safety Committee (RSC) with an estimated 100 active clinical protocols on-going 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.

The inspectors reviewed a sampling of new clinical protocols approved by the RSC and noted that NIH's "Application for Authorization to Use Radiation in Research Involving Human Subjects Form NIH 88-23(a)," requires documentation of the FDA approved investigational new drug (IND), to demonstrate compliance with 10 CFR 35.6, with a copy of the approval letter attached. Based on a review of 14 clinical protocols and discussions with the Clinical Protocol Administrator, the inspectors identified the following concerns: (i) the RSC relies on each institute's IRB to confirm the IND status, without confirmation by the RSC; and (ii) the RSC approved an iodine-131 (I-131) MIBG therapeutic protocol with a documented maximum thyroid dose of 1000 rads, even though the research protocol and informed consent indicated that the accumulated dose to the thyroid would be well in excess of 1000 rads. The inspectors contacted the National Cancer Institute's IRB and confirmed that the institute maintains copies of all FDA approval letters and confirms that each clinical research protocol has an active IND prior to IRB approval. Following the on-site inspection, NIH contacted the remaining 11 IRBs and confirmed that IND approval status is confirmed by each institute prior to IRB approval. With regards to the I-131 therapy protocol, the inspectors confirmed that the research protocol had not been started and the Clinical Protocol Administrator indicated that the concerns noted by the inspectors would be addressed prior to initiation of the protocol.

The inspectors reviewed four clinical authorized user (AU) approvals by the RSC. The inspectors noted that one radiation oncologist, approved for the use of the remote afterloader had not provided a properly signed preceptor form. Specifically, documentation provided to the RSC for review included a board certificate and a preceptor form signed by an authorized medical physicist. 10 CFR 35.690 requires that the written attestation be signed by a preceptor AU who meets the requirements in 10 CFR 35.690. Also, Condition 11.B. of License No. 19-00296-10 requires, in part, that individuals designated in writing by the licensee's RSC to work as an AU, as defined in 10 CFR 35.2, shall meet the training and experience requirements in 10 CFR Part 35. NIH took corrective actions which included having a preceptor AU review the training and experience of the proposed AU and document, on a preceptor form, that the proposed AU had satisfactorily completed the requirements in 10 CFR 35.690 and had achieved a level of competency sufficient to function independently as an AU. The inspectors determined that this was a violation of Condition 11.B. of License No. 19-00296-10. In addition, the inspectors noted that the RSC generally approved AUs for all licensed material in 10 CFR 35.300, even though AU's would not have been able to meet the fourth category of use listed in 10 CFR 35.390. This concern was discussed with the RSO.

The inspectors reviewed the following incidents that DRS staff responded to since the last inspection: (i) two landfill alarms in 2010 (see Radioactive Waste Management Section for further information); (ii) leaking nickel-63 chemical agent detector (reported to the NRC's general licensing tracking system); (iii) use of microcurie quantities of carbon-14 by a student with supervisor oversight, but without the required NIH approval; (iv) spill of 330 gallons of contaminated mixed waste from the UV peroxidation treatment system;

(v) skin infiltration of carbon-11 during injection of a healthy volunteer with no detrimental effect noted; (vi) fluorine-18 (F-18) contamination event in the PET/cyclotron facilities; and (vii) copper-64 contamination events.

The inspectors also reviewed the NIH training program and noted that initial radiation safety training of workers is performed in the classroom by radiation safety staff. Periodic training is performed by computer based training. All supervisors are responsible for ensuring that their personnel have had the appropriate training. Approximately 3500 employees were trained in 2010.

Medical Activities Conducted under License Number 19-00296-10

The nuclear medicine facility includes a radiopharmacy, two injection rooms, two quiet rooms, and four cameras. Patients treated with greater than 33 millicuries of I-131 are housed in one of two shielded rooms. All iodine patients are issued written instructions on methods for controlling exposures to member of the public. The PET research facility includes a radiopharmacy, quiet rooms, two PET cameras and a high resolution tomograph for brain scans. A remote afterloader is located in radiation oncology.

The nuclear medicine department receives a three curie molybdenum/technetium generator weekly. The authorized nuclear pharmacist (ANP) is responsible for eluting the generator, analyzing the molybdenum-99 concentration, preparing the technetium-99m kits (Tc-99m), and assaying all doses prior to administration by the nuclear medicine technologists (NMT). Unit doses of other radiopharmaceuticals (F-18, I-131, samarium 153, etc.) are delivered directly to the radiopharmacy by various vendors. Tc-99m and F-18 are the primary radioisotopes used in the nuclear medicine department.

The PET research facility uses F-18, carbon-11 (C-11), and oxygen-15 (O-15) for human and animal research protocols. F-18 and C-11 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.”

In 2009, NIH performed 27 I-131 therapies, 12 samarium-153 therapies, and three yttrium-90 therapies. In 2010, 44 I-131 therapies, six samarium-153, and 19 yttrium-90 therapies were performed. The licensee also possesses a remote afterloader that was used to treat three patients in 2010 and no patients in 2011. The remote afterloader is used for gynecologic procedures using either a vaginal cylinder or tandem and ovoid. The inspectors reviewed full calibration testing of the unit. The inspectors noted that the timer linearity was not being performed over the typical range of use and on one occasion the timer linearity was not performed, as required by 10 CFR 35.633. Timer linearity was routinely verified out to approximately 200 seconds, which appeared less than the typical range of use. The inspectors requested that NIH determine the typical range of use based on the previous patient treatments and verify the timer linearity over that range. On April 11, 2011, the results of the timer linearity were provided to the NRC. The AMP determined that the typical treatment time was 496 seconds and verified the timer linearity out to 600 seconds. The inspectors determined that this was a violation of 10 CFR 35.633 (b)(5).

Research Activities Conducted under License Number 19-00296-10

Research activities primarily encompass the use of microcurie quantities of carbon-14, tritium, phosphorus-32, sulfur-35, chromium-51, iodine-125, F-18, O-15, and nitrogen-13. Research activities are conducted in approximately 1500 laboratories in several buildings located in Bethesda, Rockville, Frederick, and Baltimore, Maryland.

The inspectors reviewed the security of radioactive material, and noted that NIH's policy requires radioactive material to be secured when not attended. Most researchers utilize locked refrigerators and waste containers to accomplish this task. The inspectors noted that, in general, buildings are secured by proximity card access or security personnel. Buildings that required general public access, such as the hospital, control access by both personnel and keypad entry. The inspectors identified two instances where radioactive material contained in waste was unsecured. Specifically, an unattended laboratory contained an unsecured waste container with small amounts of licensed material. In both cases, the amount of radioactive material involved was less than 10 times the quantities listed in 10 CFR Part 20, Appendix C. Therefore, the inspectors determined that this was a minor violation of 10 CFR 20.1801 and discussed the concern with DRS.

The inspectors also reviewed safety measures instituted in each laboratory and noted that the facilities: (i) were equipped with sufficient shielding; (ii) had appropriate fire protection capability; and (iii) used contained hoods, where needed, to perform experiments. The inspectors noted that most research was performed on the benchtop using microcurie quantities of radioactive material; however, a few locations where millicurie quantities of radioactive material are used were also noted. These facilities were noted to be equipped with additional effluent and breathing zone controls.

The inspectors also reviewed the use of survey instruments in laboratories. The inspectors noted that there was ample availability of radiological instrumentation and the type of instrumentation being used by individual researchers was appropriate for the radioisotopes being used. However, three instruments located in laboratories were noted to be out of calibration and one instrument was noted to be only partially calibrated. The inspectors determined that no violations had occurred, however, some NIH personnel did not demonstrate the proper checks prior to use of portable survey instruments. The issues were discussed with DRS.

Cyclotron Activities Conducted under License Number 19-00296-21

NIH operates three cyclotrons to produce PET isotopes. The cyclotrons are located within two rooms which are located behind a large shielded door. Access to the area was properly maintained. Material is generally discharged to hot cells to prepare the material for use. The facility was built in the mid 1980's and currently includes a CS-30 Cyclotron Corp. unit and 2 GE PETtrace units. The facility also includes six hot cells, four mini-cells, three laboratories, a machine shop, an analytical counting lab, and an exhaust filter unit. Several protocols govern the cyclotron/hot cell/target handling activities and include Protocol #354-0 (cyclotron vaults, hot cells, etc) and 345 (target handling in lab, hot cell).

Irradiator Activities Conducted under License Numbers 19-00296-17 and 19-00296-20

NIH possesses irradiators at various locations. The inspectors noted that all sources were properly leak tested and inventoried and all irradiator users were appropriately trained. In addition, NIH personnel discussed the 10 Part 36 exemptions described in NUREG-1556, Volume 20, with the inspectors and as a result, submitted an amendment request dated March 25, 2011 to clarify the necessary exemptions.

Material Receipt, Use, Transfer, and Control

The inspectors reviewed the receipt, use, and transfer of radioactive material at NIH. Nuclear medicine packages are received in the nuclear medicine department. All packages of radioactive materials used in research are delivered to DRS. Each AU submits a request for materials to their responsible health physicist, who verifies that the requested material is authorized. When packages are received, they are surveyed by radiation safety staff and opened to check for contents. After the survey results and the package contents are reviewed, the packages are then resealed and delivered to the respective AU. The licensee utilizes the services of a contractor to handle the receipt and delivery of packages. The inspectors confirmed that the transport of licensed material, including methods for securing packages and presence of shipping papers during transport, was in accordance with 49 CFR.

Radiation Surveys

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

i. Nuclear medicine technologists 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 utilize a contractor to perform their required monthly 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. The inspectors noted that the survey meter used and the results of the surveys were not always noted on the patient release surveys. The inspectors discussed this concern with NIH staff, who immediately updated the forms to include a prompt for the data.

iv. Surveys in the Cyclotron area and the waste management areas were performed weekly. In addition, the O-15 transfer lines through the parking garage were

monitored by area dosimeters. Based on these surveys the inspectors concluded that the area maintains less than the required 2 millirem in any one hour, in compliance with 10 CFR 20.1302, and that due to the low occupancy in this area, the public dose limit of 100 millirem/year would not be exceeded.

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

NIH uses a contractor to perform comprehensive surveys in all the 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 AU. 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.

Calibration of instrumentation is performed onsite as well as offsite. The calibration of one instrument 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.

Effluent Monitoring and Radiation Protection

In 2010, NIH collected over 4000 air samples, including environmental samples, personal breathing zone samples, and restricted area samples. Iodinations were performed about six times a year. Air sampling is performed in the air and effluent during iodinations. All results were noted to be less than the regulatory limits.

The inspectors reviewed the air samples performed in the cyclotron and PET production areas and noted that NIH samples the air effluent releases locally using charcoal. Previously, NIH used an Eberline PING3B air monitor to measure air effluents; which has been taken out of service. A new stack monitoring system is planned to be installed late in 2011. Gases are collected in holding bags in the vaults and are released to holdup tanks that are released thru carbon filters to the air. NIH relies on the samples to determine the concentration of the material being discharged. NIH uses a default factor of 0.25 from NCRP 123, to support their assumption that only 25% of the concentration would be to any one sector. NIH also uses Regulatory Guide 4.20 methodology to perform effluent calculations. NIH also runs the COMPLY code annually.

For the calculation of the effluents resulting from activities conducted under the broadscope license, the licensee takes a conservative approach by utilizing ANSI N13.1-1999 values for estimating airborne radioactive material on the basis of form. The licensee uses the entire inventory of material possessed, excluding packaged waste, stored waste, and shipped materials. In 2010, NIH calculated a public dose of 1.0 millirem from effluent using the COMPLY code. The inspectors reviewed the assumptions utilized by the code and noted that:

i. The discharge location in two sectors of the COMPLY code run were incorrect. A closer distance should have been used since full time residents live on site.

ii. The amount of tritium used in the calculation was incorrect due to inappropriately subtracting the amount contained in waste.

iii. Decay daughters for some radionuclides should be added to the input.

The inspectors discussed these issues with NIH staff, and NIH recalculated the COMPLY code value to include all concerns noted except the decay daughters. A value of 1.1 millirem was calculated. To confirm this value, the inspectors obtained a summation of all the effluent samples taken by NIH and calculated a dose of 3.24 millirem, as compared to Appendix B, 10 CFR 20 values. Using the conversion factor of 1/4 from NRCP 123 for Appendix B values, a value of 0.81 millrem was calculated; which is similar to the COMPLY code value of 1.1 millirem. NIH is continuing to review the contribution from decay daughters; however, the inclusion is not expected to increase the calculated dose significantly.

The inspectors reviewed dosimetry badge readings, bioassay results and the calibration of the whole body counter. All results were less than the regulatory limits and most results were less than the licensee's established ALARA levels.

Radioactive Waste Management

NIH currently stores dry active waste (DAW) for decay in storage (DIS) (short lived) or burial (long lived). Although compactors are available, NIH has not performed compacting of waste in recent years. An extensive system for DIS waste storage and tracking is implemented. Liquid wastes and mixed wastes may be treated by oxidation prior to transfer to one of the nine 2250 gallon hold-up tanks, for eventual sewer disposal. The licensee discharged 4489 gallons of treated water for sewer disposal in 2010. The inspectors determined that sewer releases were well within regulatory limits.

Solid waste and liquid waste is picked up by NIH's contractor from the individual labs. The lab sends an electronic mail request to schedule pickup. The personnel performing waste collection activities receive hazardous packing and shipping training every 2 years. This training is a combination of classroom and computer based training.

The inspectors reviewed the 2010 shipping manifests. Most shipments were Radioactive LSA II or limited quantity shipments. There were 872 millicuries of waste shipped in 2010, with no concerns identified by the inspectors. During the last inspection, it was noted that NIH had several drums of waste stored at Allied Technology Group's Richland, Washington facility. The current owner, PermaFix Northwest Richland, certified in a letter dated November 6, 2008, that all radioactive waste had been properly treated and dispositioned as of July 30, 2008.

DIS waste is stored for a minimum of 10 half lives before being monitored for release. The inspectors reviewed disposals via DIS and noted that disposals were generally in accordance with the requirements. However, two events occurred since the last

inspection involving improper disposal of licensed material. Specifically, on May 4, 2010, NIH lab personnel improperly placed nanocurie quantities of bromine-76/77 in the regular trash without performing a survey and on June 28, 2010, NIH lab personnel placed nanocurie quantities of zirconium-88/89 into the normal trash without performing the proper surveys to ensure the waste had properly decayed. In both incidents, the radioactive waste caused local landfill radiation detectors to alarm. NIH personnel retrieved the radioactive material from the landfill, placed the material into its decay in storage waste, and re-instructed involved staff on proper disposal procedures. The inspectors determined that NIH did not dispose of licensed material by decay in storage or transfer to an authorized recipient as required by 10 CFR 20.2001.

Posting and Labeling

The inspectors toured the research facilities, nuclear medicine department, cyclotron facilities, and PET areas; and reviewed the posting and labeling in these areas. The inspectors noted that after a C-11 transfer from the cyclotron on April 5, 2011, the charcoal exhaust filter area was reading 40 milliRoentgen per hour. This area was properly posted as a radiation area with shielding added on one wall of the room to control dose rates in an adjacent room. The inspectors noted that two walls did not include shielding, and made measurements in areas adjacent to these two walls. The inspectors measured 12 milliRoentgen per hour at 10:25 AM, approximately 20 minutes after transfer of the C-11 in one of the adjacent areas. The inspectors noted that this area was not posted as a radiation area. The inspectors resurveyed the area at 10:50 AM and measured 5 milliRoentgen per hour. Therefore, the inspectors determined that the calculated dose in any one hour exceeded 5 millirem, which required posting. NIH subsequently posted this area, but in a letter dated May 9, 2011, indicated that the radiation area was not accessible to individuals, as defined in 10 CFR 20.1003. In their letter, NIH also implied that the radiation area met the exemption requirements for posting in 10 CFR 20.1903, since the area may have been constantly attended. Pursuant to discussions with the RSO and other DRS staff on May 17, 2011, the inspectors confirmed that the area was accessible since: (i) the tank preventing access was on wheels and could be moved; and (ii) even without moving the tank, an individual would be able to place their head in the radiation area. The inspectors also confirmed with the RSO and other DRS staff that the area was not constantly attended by personnel trained to take the precautions necessary to prevent the exposure of other individuals accessing the area. The inspectors determined that this was a violation of 10 CFR 20.1902(a).

c. Conclusions

Based on the results of this inspection, four violations of NRC requirements were identified. Specifically,

- NIH did not determine their remote afterloader unit's timer linearity over the typical range of use as required by 10 CFR 35.633(b)(5). Specifically, in 2010, the timer linearity was measured over 200 seconds; however, the typical treatment time was approximately 500 seconds. In addition, on August 11, 2010, timer linearity was not determined during the full calibration, as required.

- The NIH Radiation Safety Committee (RSC) approved an AU for the use of a remote afterloader unit under 10 CFR 35.600 without obtaining a written attestation, signed by a preceptor AU who meets the requirements in 10 CFR 35.690. Specifically, Condition 11.B. of License No. 19-00296-10 requires, in part, that individuals designated in writing by the licensee's RSC to work as an AU, as defined in 10 CFR 35.2, shall meet the training and experience requirements in 10 CFR Part 35; which requires a preceptor attestation, when applicable.

- NIH did not dispose of licensed material by decay in storage or transfer to an authorized recipient, as required by 10 CFR 20.2001. Specifically, on May 4 and June 28, 2010, NIH personnel inadvertently placed nanocurie quantities of bromine-76/77 and nanocurie quantities of zirconium-88/89 into the normal trash prior to decay, which caused local landfill radiation detectors to alarm.

- NIH did not post a room adjacent to the cyclotron area with a "Caution Radiation Area" sign, as required by 10 CFR 20.1902. Specifically, a room located adjacent to the cyclotron charcoal exhaust filter room had a measurable reading of 12 milliRoentgen per hour 20 minutes following a transfer of carbon-11 and 5 milliRoentgen per hour 45 minutes following the transfer. Since the area met the definition of radiation area in 10 CFR 20.1003 (i.e., greater than 5 millirem in 1 hour), posting pursuant to 10 CFR 20.1902 was required.

II. Exit Meeting

At the conclusion of the on-site inspection on April 8, 2011, the inspection findings were discussed with NIH's senior management. NIH acknowledged the inspectors' findings and immediately initiated corrective actions.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

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