UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-

January 23, 2105

Mr. Mark Shaffer, Director
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region IV
1600 E. Lamar Blvd.
Arlington, TX 76011-4511

Subject: SNM-362 License Annual Audit Results – CY 2014

Dear Mr. Shaffer,

Pursuant to the requirements in EA-09-142, Confirmatory Order (CO) issued to NIST on March 1, 2010, NIST is hereby providing the annual audit results for the SNM-362 license for calendar year 2014. The CO required NIST to provide such results for the years 2010-2014. Therefore, this letter transmits the last annual audit results that NIST will be submitting.

On August 21, 2013, NIST provided Mr. Vegel, previous Division Director, with a copy of the results of the Independent Assessment of NIST's Radiation-Safety Programs under licenses SNM-362 and 05-03166-06 and NIST's response to the findings and recommendations. It should be noted that license 05-03166-05 was terminated on December 27, 2010 and replaced with license 05-03166-06.

Thank you for your attention to this letter and attached annual audit results. Attachment D, referenced in the annual audit results, is not enclosed as it contains security related information. This attachment can be provided, if needed.

If you have any questions concerning the audit results, you may reach me at 301-975-4502 or at richard.kayser@nist.gov.

Sincerely,

Richard F. Kayser
Chief Safety Officer
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899-1730

Enclosure

cc: T. D. Naquin, Project Manager, NMSS/FCSE/FMB
D. Collins, Director, Division of Nuclear Materials Safety, USNRC Region I
A.K. Thompson, NIST IRSC Chairman

NIST

NUREG 1556 Audit of NRC Licenses SNM-362 and 19-23454-01E

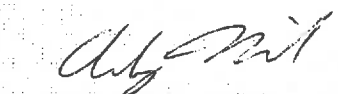
At the National Institute of Standards and Technology

Gaithersburg, MD

Conducted by:

Dakota Consulting Inc.
1110 Bonifant Street
Suite 310
Silver Spring, MD 20910
(240) 839-7812
(240) 328-5297 fax
Contact @dakota-consulting.com

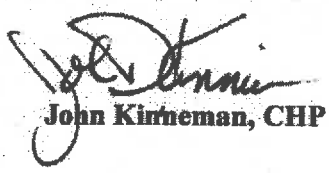
Prepared by:



Andy Miller, CHP

24 DEC 14

Date



John Kinneman, CHP

24 December 2014

Date

Table of Contents

Attachments

1. OVERVIEW

1.1 Introduction

An on-site audit of the radiation safety program was performed at the Gaithersburg, MD facility for the National Institute of Standards and Technology (NIST) from October 27 through 31, 2014. The audit was in support of activities covered by Nuclear Regulatory Commission (NRC) License SNM-362 issued to NIST Gaithersburg, MD with additional document reviews conducted off-site from November 1, 2014 through December 1, 2014.

The audit was performed by Andy Miller and John Kinneman. The audit followed the format recommended in NRC NUREG 1556, Volume 17, Appendix G (related to special nuclear material less than a critical mass), Volume 11, Appendix M (related to licenses of broad scope), Volume 8, Appendix M (related to exempt distribution), Volume 6, Appendix K (related to the Part 36 irradiators), and NRC Inspection Procedure 87137.

Mr. Miller and Mr. Kinneman conducted entry and exit briefings with the radiation safety staff and appropriate representatives of the Ionizing Radiation Safety Committee (IRSC) and NIST management. The entry briefing included representatives of the Gaithersburg Radiation Safety Division (GRSD): Mr. Tom O'Brien, Radiation Safety Officer (RSO), Mr. Tom McGiff, GSRD Health Physicist, and Mr. Manny Mejias, GSRD Health Physicist. The exit briefing included personnel from GSRD, the IRSC, and NIST management.

1.2 Audit Purpose and Scope

10 CFR 20.1101 requires, in part, that each NRC licensee conduct an annual audit of the radiation safety program to assess its content and implementation.

This audit included a review of the written radiation safety program at the NIST Gaithersburg site, including the broad scope license, the exempt distribution license, GSRD procedures, IRSC minutes, and applicable usage protocols and reviews. Auditors reviewed a variety of records, including the hazard review process for approving source acquisition and facility utilization, as well as records of laboratory surveillance, radioactive material inventory control and shipping,

personnel monitoring, and personnel training. Follow-up actions of the 2013 annual audit of the SNM-362 license were reviewed, as well as records of response and follow up actions to any inspections/incidents that may have occurred since the 2013 audit. The auditors toured several of the facilities under radiological control in Building 245 as well as other buildings on the NIST campus related to the security program and interviewed individuals who were determined to be in positions to materially contribute information for the audit.

1.3 Audit Details

The auditors conducted a performance based inspection based on interviews of GSRD personnel, NIST researchers, support personnel and tours of areas where license activities are conducted. During the audit, regulatory compliance was evaluated through observation, document reviews, and personnel interviews. Facilities and equipment were physically inspected. Issues identified were investigated as needed.

For the purposes of this audit, a finding is defined as any condition or action that apparently deviates from an applicable regulation, standard or procedure or adversely impacts the quality or reliability of any aspect of the radiation-safety program. A recommendation is defined as a suggestion that, when implemented, could improve the performance and effectiveness of a task, process or program. A noteworthy practice is defined as a practice that has resulted in the improvement in the effectiveness or efficiency of the radiation safety program.

There was one finding, eleven recommendations, and six noteworthy practices as a result of this audit.

1.4 Audit Report Format

The main body of the audit report follows the outline given in NUREG 1556 Volume 11, Appendix M. Attachment A is a completed Audit Checklist based on NUREG 1556, Volume 17, Appendix G. Attachment B is a completed Audit Checklist based on NUREG 1556, Volume 6, Appendix K. Attachment C is a completed Audit Checklist based in NUREG 1556, Volume 8, Appendix M. Attachment D is a completed Audit based on NRC Inspection Procedure 87137. Items on these checklists may overlap portions of the audit report as well as the other attachments.

The NUREG checklists were designed as standalone documents.

1.5 Past Audit Follow-up

The auditors reviewed the last audit performed in May 2013. Based on discussions with staff and a review of records, it was determined that all of the items on the previous item were being tracked for status and completion and the results were being communicated to the IRSC on a frequent basis. All of the items that were classified as findings have been addressed and closed.

1.6 Confirmatory Order compliance

The auditors discussed the status of compliance with the Confirmatory Order (CO) with the RSO. Based on discussions with the RSO, it was determined that CO compliance had been thoroughly reviewed by regional NRC inspectors at their last inspection.

It is our opinion that NIST is meeting the requirements of the CO and that the completion and submission of this audit would be the final step in meeting the CO.

1.7 Executive Summary

There was one finding, eleven recommendations, and six noteworthy practices as a result of this audit. Discussions on the audited program appear in Section 2. Specific findings, recommendations, and noteworthy practices are presented in Section 3.

The NIST program for radiation safety and regulatory compliance with regard to radiation and radioactive materials, within the scope of this audit, is effective, protective of worker safety and the health and safety of the public and the environment.

2. RADIATION SAFETY PROGRAM DISCUSSION

2.1 MANAGEMENT OVERSIGHT:

(Management support to radiation safety; IRSC; RSO; program audits, including annual reviews of program and ALARA reviews; control by authorized users; appropriate follow up on events and previous audit/inspection findings)

The NIST Director has the ultimate responsibility for establishing and maintaining the ionizing radiation safety program at NIST and provides executive leadership on issues involving compliance with regulatory requirements and the conditions of the license. The Director of NIST appoints the IRSC Chair and Vice Chair for indefinite terms at his/her discretion.

The NIST Chief Safety Officer is responsible for:

(1) Overseeing the establishment, implementation, and maintenance of ionizing radiation safety program at NIST supporting the SNM-362 NRC license; and

(2) Submitting applications for renewals of and amendments to NRC License Number SNM-362 pursuant to IRSC review and approval.

The IRSC provides oversight of the operations and activities of the NIST radiation safety programs. The IRSC provides the NIST RSO with independent advice and oversight for the ionizing radiation safety program at NIST Gaithersburg.

Records of IRSC meeting minutes were reviewed for the calendar years 2013 and 2014 meetings. Meetings were held regularly and a quorum was established for each meeting. Records indicated that the IRSC was continuing to maintain oversight over the ionizing radiation safety program and was exercising it responsibilities.

The RSO is well qualified and is a Certified Health Physicist. The RSO serves as the SNM-362 license manager and as the point of contact with the NRC. The RSO is responsible for managing the radiation safety program and all aspects of the utilization of ionizing radiation sources. The RSO, or designee, has the authority, as delegated by the NIST Director, necessary to meet his responsibilities and to immediately stop any operations that may (1) compromise the health or

safety of NIST employees and non-NIST personnel; (2) have an adverse impact on the environment or public; or (3) result in noncompliance with NRC, State, or local requirements. Overall, the management elements of the Radiation Safety Program at NIST (Director, Chief Safety Officer, IRSC, and RSO) are adequately structured and. staffed to exercise their organizational responsibilities.

2.2 AMENDMENTS AND PROGRAM CHANGES:

(Amendments to the license were properly implemented; if applicable, program and procedural changes were approved and implemented in accordance with license condition).

After an extensive review period involving numerous requests for additional information from the NRC, the licensee has successfully received a renewed license. Personnel were very familiar with the many commitments and conditions in the renewed license.

The NIST RSO receives generic NRC communications such as Regulatory Information Summaries, NMSS Newsletter, and other generic NRC communications. The RSO reviews these documents for information pertinent to NIST. All of these documents are filed after RSO review.

2.3 FACILITIES:

(Facilities as described in license; uses; control of access; engineering controls; calibration facilities; shielding; air flow)

The facilities are as described in the SNM-362 radioactive materials license. NIST is a broad scope licensee, which provides NIST with a great deal of flexibility in the management of its configuration of its facilities. During the tour of the facilities the auditors observed various engineering controls to protect workers from radioactive materials. These engineering controls include shielding, remote handling tools, and effective ventilation.

The entire NIST facility is enclosed with a fence. Access to the facility is through the front gate which has guards present who check each person's identification. All visitors must stop at the guard house to obtain a visitor badge and must be preapproved by a NIST employee.

Most sections of Building 245 where radioactive materials are used or stored require a key card to gain access to that area of the building. Once inside this area a key is required to gain access to the radioactive materials use areas. Other sections require key access.

Laboratories where radioactive materials are used or stored must be locked when not attended. During the facility tour, all doors to radioactive material laboratories where secured or were attended by NIST staff who were authorized for access.

Large radioactive material sources are in compliance with the previous NRC Order for Increased Controls on Quantities of Concern as well as the recently effective 10 CFR 37. Access to quantities of concern of radioactive materials is strictly controlled. Only personnel who have job functions requiring access to these sources are provided access to these areas. All other personnel must be escorted by an individual who has unescorted access.

Several of the radioactive materials laboratories contain fume hoods for working with radioactive materials. The air flow through the face of the hoods is checked quarterly by the GRSD staff and a sticker marking the proper height of sash is placed on the hood. GRSD staff run the EPA COMPLY code annually to verify NIST is in compliance with air emission constraints.

2.4 EQUIPMENT AND INSTRUMENTATION:

(Operable and calibrated survey equipment; procedures)

NIST maintains calibrated and operable survey instrumentation to support the radioactive materials work performed at the facility. During the tour of the facility radiation survey equipment was observed in all rooms posted for radioactive materials. All radiation survey equipment was calibrated and operable.

NIST is required to calibrate radiation survey equipment annually. Instrument calibrations are performed by GRSD staff using NIST primary standards. Instruments not meeting calibrations standards or not operating appropriately are removed from service until the instrument has been repaired and calibrated. Calibration records are maintained and are available for review by

external auditors such as the NRC. GRSD provides the laboratory with a loaner radiation survey instrument while the laboratory's radiation survey instrument is being calibrated by the GRSD staff.

Several liquid scintillation counters (LSCs) are available at the NIST facility. The LSCs used for compliance contamination surveys undergo quality control testing on each day of use by GRSD staff.

NIST has several whole body scanners, which are calibrated annually. GRSD staff perform periodic operational checks on the whole body scanners.

Pocket ionization chambers and electronic dosimeters are calibrated annually and records are maintained.

2.5 MATERIAL USE, CONTROL, AND TRANSFER:

(Materials and uses authorized; security and control of licensed materials; and procedures for receipt and transfer of licensed material)

Radioactive material packages are delivered to a central receiving warehouse, Building 301. NIST employees using a NIST vehicle transfer the radioactive material packages to Building 245. GRSD staff survey and inventory the radioactive materials packages. The packages are delivered to the laboratories by the GRSD staff.

NIST reported possession of sources having sufficient activity to require reporting to the National Source Tracking System as required by 10 CFR 20.2207 Reports of transactions involving nationally tracked sources.

All SRM shipments of radioactive material must be reviewed by GRSD staff. GRSD staff verifies that a current radioactive materials license is on file at NIST and the receiving facility is licensed to receive both the type and quantity of radioactive material in the Standard Reference Material (SRM) source. A record of this verification is maintained. GRSD staff was observed

processing SRM shipment requests. Some shipments of SRMs were delayed until GRSD staff could obtain the appropriate radioactive material license from the customer. Shipments of brachytherapy sources do not follow the same formal review procedure as SRMs. However, NIST staff contacts GRSD to verify the customer has a radioactive materials license on file and is authorized to receive the type and quantity of radioactive material being shipped. NIST staff were also aware of the restrictions on shipping certain licensed materials to certain foreign countries as per NRC requirements. This system works well to prevent the transfer of licensed material to an unauthorized recipient.

GRSD maintains an inventory of all sealed sources at NIST. Semi-annually all sealed sources are leak tested by GRSD staff. Annually GRSD sends to each Source Custodian a sealed source inventory. The Source Custodian updates the inventory and returns the updated inventory to GRSD. Selected leak test records for 2014 were reviewed and determined to be in compliance.

During the audit, one of the Source Custodians was asked to provide the inventory of radioactive materials present in a laboratory: The Source Custodian was able to provide a radioactive materials inventory. Records were kept in electronic and paper formats but the Custodian. All Source Custodians were able to locate the requested sources.

GSRD maintains records of SNM inventory, receipt and transfers. GSRD files semi-annual report in the Nuclear Materials Management and Safeguard System (NMMSS).

Based on discussions with staff, it was determined that laboratories where radioactive materials are used or stored must be locked when not attended. During the facility tour, all doors to radioactive material laboratories where secured or were attended by NIST staff who were authorized for access. In the opinion of the auditors NIST is compliant with the requirements of 10 CFR 20.1801 and 1802.

2.6 AREA RADIATION SURVEYS AND CONTAMINATION CONTROL:

(Radiological surveys; air sampling; leak tests; inventories; handling of radioactive materials; contamination controls; records; and public doses)

GRSD technicians perform weekly radiation contamination surveys in laboratories where unsealed radioactive materials are used. Direct radiation dose measurements and wipe surveys are performed in each weekly survey. Weekly surveys are documented and a copy of the latest survey is posted at the entrance of the room. A health physicist reviews the weekly surveys.

Laboratories that use unsealed radioactive materials are audited by a health physicist quarterly. The audit consists of an independent radiation survey and a review of compliance items. Items of noncompliance are documented on the audit report and entered into a database system. Completed corrective actions are documented in the database system. During the next audit all items that have not been corrective are followed up by the health physicist.

Area monitors are place throughout Building 245. The data from these area monitors shows compliance with 10 CFR 20 public dose limits. GRSD also runs the COMPLY code annually to demonstrate compliance with air emission constraints.

Source Custodians were asked to describe their work with radioactive materials and what type of radiation surveys they performed. At the conclusion of their work, the Source Custodians indicated they performed a wipe survey.

2.7 TRAINING AND INSTRUCTIONS TO WORKERS

(Training and retraining requirements and documentation; interviews and observations of routine work; staff knowledge of all routine activities; 10 CFR Parts 19 and 20 requirements; emergency situations; and supervision by authorized users)

The main entrances to Building 245 and the Physics Building were posted with a NRC Form 3, a Section 206 notice, employee rights as specified in the energy Reorganization Act of 1974, and a notice where the license, regulations and radiation safety program documents can be located.

Safety training is required per NRC and DOT regulations as well as a license condition for SNM-

362 radioactive materials license. GRSD develops and maintains appropriate training materials. Radiation Safety training is provided both online and in a lecture format. New employees are required to complete the radiation safety training prior to working with radioactive materials. The training consists of an online portion followed by classroom lecture and hands on training. Records of radiation safety training are maintained by GRSD.

During the audit, Source Custodians were questioned about emergency procedures. All Source Custodians gave appropriate emergency response answers and they knew how to contact GRSD and the police department if the incident occurred after hours.

2.8 RADIATION PROTECTION

(Radiation protection program with ALARA provisions; external and internal dosimetry; exposure evaluations; dose and survey records and reports; annual notifications to workers; bulletins and other generic communications)

Dosimetry services are provided by the NVLAP accredited US Navy Dosimetry Center in Bethesda, Maryland. Whole body and extremity dosimeters are provided to workers based on a hazard assessment. Dosimeters are exchanged on a quarterly frequency. Radiation workers who received 100 mrem or more in a year are provided a copy of their radiation doses or upon request. Typical doses to employees working under the SNM-362 license are very low.

Occupational radiation dose records are maintain by GRSD. Selected dosimetry records were reviewed for 2013 and occupational radiation doses were in compliance with 10 CFR 20.1201. Most radiation doses were less than 10 percent of the occupational dose limits.

2.9 RADIOACTIVE WASTE MANAGEMENT

(Disposal; effluent pathways and control; storage areas; transfer; packaging, control, and tracking procedures; equipment; incinerators, hoods, vents, and compactors; license conditions for special disposal method)

Radioactive waste is stored in Room A010. Room A010 is a former accelerator vault. A010 has a fire detection and alarm system but no fire suppression system (no fire sprinkler or fire extinguishers).

Liquid radioactive waste is stored in A010. The liquid waste was appropriately labeled and were stored in a secondary containment container.

Radioactive waste which will be shipped for disposal at a commercial disposal facility is transferred to Building H100 for storage and preparation. Radioactive waste generated under the SNM-362 license is kept separate from waste generated under other radioactive material licenses.

Most solid radioactive waste is compacted into 55 gallon drums prior to shipment to a commercial disposal facility. Waste brokers mark and label the drums for shipment. The waste brokers also prepare the shipping papers based on information provided by NIST. NIST staff regularly performs wipe surveys and exposure rate surveys on the drums.

NIST does not perform incineration of radioactive waste.

2.10 DECOMMISSIONING

(Records relevant to decommissioning; decommissioning plan/schedule; notification requirements; cost estimates; funding methods; financial assurance; and Timeliness Rule requirements; changes in radiological conditions since decommissioning plan was submitted)

NIST had a contractor prepare an update to the decommissioning cost estimate report in 2010.

GRSD maintains radioactive materials inventory records, survey records, and disposal records. All of these records are part of the required decommissioning records.

2.11 TRANSPORTATION

(Quantities and types of licensed material shipped; packaging design requirements; shipping papers; hazardous materials (HAZMAT) communication procedures; return of sources; procedures for monitoring radiation and contamination levels of packages; HAZMAT training; and records and reports)

DOT and IATA trained staff prepare radioactive materials for shipment. Staff was observed

preparing SRMs for shipment. Staff members had all necessary radiation survey equipment, shipping papers, and supplies required to package radioactive material for shipment. Radioactive materials were only packaged after GRSD has approved the shipment (license verification). Staff members were very knowledgeable regarding DOT and IATA regulations and were competent in preparing the radioactive materials for shipment.

New employees must complete DOT and IATA training prior to shipping radioactive materials. DOT and IATA refresher training is provided by the GRSD staff every two years.

Records were reviewed for selected radioactive materials shipments made in 2014. All shipping records were in compliance with DOT and IATA regulations.

2.12 NOTIFICATIONS AND REPORTS

(Reporting and followup of theft, loss, incidents and overexposures. Notification of change in RSO and/or authorized user. Radiation exposure reports provided to individuals.)

Based on discussions and observations, it was determined that the RSO was very familiar with the NRC reporting requirements and the NRC Emergency Operations Center phone number.

2.13 POSTING AND LABELING

(Notices; license documents; regulations; bulletins and generic information; posting of radiation areas; and labeling of containers of licensed material)

Based on observations, doors to facilities were posted with "Caution- Radioactive Materials" signs and "Caution – Radiation Area" signs as appropriate. Equipment and containers were frequently found labeled with a variety of type of "Caution – Radioactive Materials" postings. Waste containers were also appropriately labeled.

Areas marked "Caution – Radiation Area" were in compliance with the applicable dose rates. The entrances to Buildings were posted with a current copy of NRC Form 3.

2.14 INDEPENDENT AND CONFIRMATORY MEASUREMENTS

(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with staff's results and regulations)

During this audit, no independent and confirmatory measurements were made.

No food, drinks, or tobacco use were observed in any of the radiological laboratories.

3. AUDIT RESULTS

There was one finding, eleven recommendations, and six noteworthy practices as a result of this audit.

3.1 Findings

Findings

10 CFR 20.1904 states, in part that, the licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures. [emphasis added]

The Labeling and Posting guidance promulgated by GSRD and issued on April 25, 2014 is not being followed. Specifically, apparent violations of labeling are present in B156, B134 and the low scatter neutron room.

Figure 1- B 156 Lab - container labeling

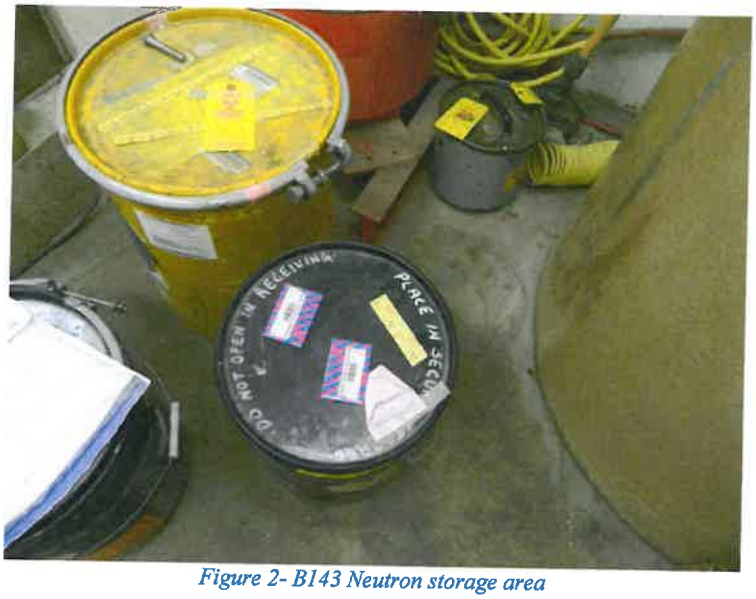


Figure 2- B143 Neutron storage area

Figure 3- B23 Neutron Low Scatter room

If the quantity of unlabeled materials in each of these containers meets the labeling thresholds as listed in 10 CFR 20.1905, then an apparent violation exists.

3.2 Recommendations

Recommendation 1:

The Labeling and Posting guidance promulgated by GSRD and issued on April 25, 2014 is not being followed. Specifically, in the horizontal range in Room [redacted], the irradiation room is posted with a "Danger – High Radiation Area" sign. The guidance requires that GSRD post the area with a "Caution – High Radiation Area" sign.

Figure 4 - Dual signage [redacted]

Recommendation 1 Discussion:

The regulations allow either type of wording on the posting, and the facility complies with 10 CFR 20.1902. It is recommended the GSRD change the signage to meet the current guidance or change the guidance.

Recommendation 2

In the vertical ranges in Rooms [redacted] and [redacted], the emergency stop buttons are green and are not labeled as to their function. In the horizontal range in Rooms [redacted], the emergency stop buttons are red and a labeled as to their function (Emergency Stop).

Figure 5 - Emergency stop button in vertical ranges in Rooms [redacted] and [redacted]

Recommendation 2 Discussion:

It is recommended that all emergency stop buttons be labeled as to their purpose.

Figure 6 - Emergency stop in horizontal range Room [redacted]

Personnel who operate the facility are very familiar with the location and function of the emergency stop button. A clearly labeled button may prevent an incident with ancillary personnel or other users whose experience is not as robust.

Recommendation 3:

In the vertical ranges in Rooms [redacted] and [redacted] there are several radiation detection systems that indicate the presence of an unshielded source (e.g. Room [redacted] has 4 independent systems). It is recommended that the licensee review the regulatory requirements and license commitments and use no more than two radiation detection systems that are used for safety.

Figure 7 - First detection system – right side

Figure 8 - Second detection system - left side

Figure 9- Third detection system - center

Figure 10- Fourth detection system

Recommendation 3 Discussion:

The use of a system to detect radiation fields and warn users is required by the regulations. A backup system is an additional best practice. Two additional systems add to the complexity of

the system. Additionally, the user takes a hand held radiation detector with them on entry to the room.

Should a detector fail and give a signal that is contrary to the others installed, the users may be presented with conflicting information as to the actual situation inside the vault. Fewer systems to maintain and calibrate will minimize sources of failure and will also lower the need to test and calibrate the detectors.

Recommendation 4:

In the vertical range in Room [redacted], there are plastic sheathed cables stored on a wooden chair. These items were considered by the auditors as adding to the combustible load of the room.

Figure 11 - Cable storage in Room [redacted]

Recommendation 4 Discussion:

It is recommended that these items be relocated outside of the irradiation area unless required for an experiment. It is further recommended that these areas not be used as a general storage area for equipment that is not part of current experiments. A best practice example is the condition of the horizontal range in Room [redacted]

Recommendation 5:

In the pool room, there are security seals installed at select spots in the facility. It is recommended that the seals be replaced with more durable seals (e.g. zip ties, wired lead seals).

Figure 12 - Pool Room seals

Recommendation 5 Discussion:

The seals are used as an indicator that personnel have accessed the interior of the pool. Over time, the adhesive could degrade to the point where the seal could become dislodged and give the impression that access had occurred when it had not. There are several types of seals (e.g. zip ties, wired lead seals) that are more durable and better suited for this location.

Recommendation 6:

In the pool room, there is an automatic pool makeup water system that will add water to the pool should the water level drop below a set point. It is recommended that an alarm be added to the system that notifies security if the automatic pool makeup water system is activated.

Recommendation 6 Discussion:

Water is used as the personnel shielding for this pool. The pool has been installed in the ground for a number of years. Should the pool liner fail, water will discharge into the ground and the automatic pool makeup water system will add water to the pool as designed.

It is recommended that an alarm be added to the system that notifies security if the automatic pool makeup water system is activated. This would notify personnel that water was being added and could be an early warning of pool in a room that is rarely occupied.

Recommendation 7:

NIST maintains copies of Sealed Source and Device (SS&D) registrations for certain sources and devices. Given the sensitive nature contained in the registrations, it is recommended that these registrations be kept in a secure location (e.g. with T&R items).

Recommendation 7 Discussion:

SS&D forms show dimensions and contain engineering information that would be useful for individuals whose intended actions are less than beneficial to the public.

Recommendation 8:

A complete list of tie down documents for the E distribution licenses was not available during the audit. It is recommended that these documents be obtained from files or the NRC to ensure all requirements are identified.

Recommendation 8 Discussion:

Tie down documents are an important part of any license as they explain the methods or rationale for exemptions to regulatory requirements or specify additional commitments made by the licensee.

Given the large volume of communications between the licensee and the regulatory during the exhaustive license renewal process, a large number of documents will be collected. The RSO is aware of this issue and has assigned personnel to complete this project. After organizing them, it

might be worthwhile to request a visit with the license reviewer to ensure that both the licensee and the regulator agree to the same set of tie downs.

Recommendation 9:

Ensure that the inventory of Generally Licensed devices includes H-3 exist signs (e.g. Library in Building 101).

Figure 13- Generally licensed exit sign in Library

Recommendation 9 Discussion:

Generally licensed devices need to be tracked in a manner similar to specifically licensed materials. The NRC has recently issued notices of violation to regarding the improper oversight of these devices. This is challenging as they can arrive on campus via procurement without the prior knowledge of GSRD staff.

Recommendation 10:

It is recommend that NIST assure that the individuals who design system changes and upgrades have input in the testing and maintenance procedures at the time of design. Those procedures should include routine maintenance of alarms, communications systems, security systems, and detection systems, and records maintained of performance and maintenance tests.

Recommendation 11:

Recognizing that NIST plans significant changes to many of the aspects of their physical security program including hardware, software and procedures, it is recommend that special care be taken to develop and implement clear acceptance criteria and procedures to assure that all systems function as intended and designed. In addition, care should be taken in the planning and execution of these changes to assure that all persons responsible for operating or using the systems are properly trained in the changes, that written procedures are updated including both operating procedures and the testing and maintenance procedures.

3.3 Noteworthy Practices

The following Noteworthy Practices identified during the audit are presented:

- NIST has worked diligently to implement best practices for security. The use of on-site assessments by outside experts and vendors for upgrading security systems was a very good investment of time and resources.

- NIST has a robust and thorough program for T&R for personnel who have access to information and system details regarding security but not unescorted access to these same facilities.

- The GSRD and the IRSC have an aggressive self-identification of potential violations or areas of the regulations that are interpretive in nature. This is a major strength of the program. Experience with the regulators has shown that identifying and correcting your own issues gathers corrective action credit that can often offset potential civil penalties.

- Recently, efforts were undertaken to characterize and removing unused sources for transfer or disposal. This will lower the overall risk to personnel, the facilities, and the licensee.

- The waste room in the basement of A010 has been cleared out of extraneous items. We applaud this effort and encourage more of the same with respect to surplus shipping containers and un-needed items.

- The GSRD Safety Evaluation process is off and running well. The investment here will pay dividends in the future by better documenting the safety basis for activities.

Suggested Audit Checklist

Based on NUREG-1556, Vol 17, Appendix G
***Note:* All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.** For example, licensees do not need to address areas which do not apply to their activities and activities which have not occurred since the last audit need not be reviewed at the next audit.

1. **AUDIT HISTORY** ☐ N/A (N/A means "Not applicable" – Initial Audit)

   A. Last audit of this location conducted **May 2013**

   B. Problems/deficiencies identified during last two audits or two years, whichever is longer

      ☒ Yes ☐ No

   C. Open problems/deficiencies from previous audits:
      No. Findings noted in the previous audit have been closed. Observations (suggestions) were addressed as needed.

   D. Any previous problem/deficiency not corrected or repeated
      ☐ Yes ☒ No ☐ N/A

   Explain:

   Based on discussions with licensee personnel and a review of records the finding from the previous audit was recommended to be closed.

2. ORGANIZATION AND SCOPE OF PROGRAM

A. Briefly describe organizational structure and note any personnel changes.

1. Structure is as described in license documents? ☒ Yes ☐ No

2. Multiple authorized locations of use? ☒ Yes ☐ No

3. Briefly describe scope of activities involving licensed material, frequency of use, staff size, etc.

See discussion in Section 2.1 of the main audit report.

B. Radiation Safety Officer ☒ Yes ☐ No
1. Authorized on license ☒ Yes ☐ No
2. Fulfills duties as RSO ☒ Yes ☐ No

C. Use only by authorized individuals ☒ Yes ☐ No

Remarks:

3. TRAINING, RETRAINING, AND INSTRUCTIONS TO WORKERS

A. Instructions to workers per [10 CFR 19.10] ☒ Yes ☐ No

B. Training program required ☒ Yes ☐ No

C. Training records maintained ☒ Yes ☐ No

D. Evaluation of individuals' understanding of procedures and regulation based on interviews, observation of selected workers
☒ Yes ☐ No

1. Each has an up-to-date copy of the licensee's safe use and emergency procedures

2. Adequate understanding of:

   a. Current safe use procedures ☒ Yes ☐ No

   b. Emergency procedures ☒ Yes ☐ No

E. Revised Part 20, Workers cognizant of requirements for:

1. Radiation Safety Program [20.1101] ☒ Yes ☐ No

2. Annual dose limits [20.1301, 20.1302] ☒ Yes ☐ No

3. New NRC Forms 4 and 5 ☒ Yes ☐ No

4. 10% monitoring threshold [20.1502] ☒ Yes ☐ No

5. Dose limits to embryo/fetus and declared pregnant women [20.1208] ☒ Yes ☐ No

6. Procedures for opening packages [20.1906] ☒ Yes ☐ No

Remarks:

4. INTERNAL AUDITS, REVIEWS OR INSPECTIONS

A. Audits are conducted ☒ Yes ☐ No

1. Audits conducted by External vendors

2. Frequency: Annualy

B. Content and implementation of the radiation protection program reviewed annually
[20.1101(c)] ☒ Yes ☐ No

C. Records maintained [20.2102] ☒ Yes ☐ No

5. FACILITIES

Facilities as described in license application ☒ Yes ☐ No

Remarks:

6. MATERIALS

Isotopes, quantities, and use as authorized on license ☒ Yes ☐ No

Remarks:

7. LEAK TESTS

A. Leak test performed as described in correspondence with NRC (consultant;leak test kit; licensee performed) ☒ Yes ☐ No

B. Frequency: every 6 months or other interval, as approved by NRC or Agreement State ☒ Yes ☐ No

C. Records with appropriate information maintained ☒ Yes ☐ No

Remarks:

8. INVENTORIES

A. Conducted at 6-month intervals ☒ Yes ☐ No

B. Records with appropriate information maintained ☒ Yes ☐ No

Remarks:

9. RADIATION SURVEYS

A. Instruments and Equipment: ☒ Yes ☐ No

1. Appropriate operable survey instrumentation possessed or readily available ☒ Yes ☐ No

2. Calibrated as required [20.1501] ☒ Yes ☐ No

3. Calibration records maintained [20.2103(a)] ☒ Yes ☐ No

B. Briefly describe survey requirements [20.1501(a)]:

The licensee performs surveys after experiments (researchers), weekly (GSRD techs) and Quarterly (GSRP HP).

C. Performed as required [20.1501(a)] ☒ Yes ☐ No

1. Radiation levels within regulatory limits ☒ Yes ☐ No

2. Corrective action taken and documented ☒ Yes ☐ No

D. Records maintained [20.2103] ☒ Yes ☐ No

E. Protection of members of the public

1. Adequate surveys made to demonstrate either (a) that the TEDE to the individual likely to receive the highest dose does not exceed 100 mrem in a year, or (b) that if an individual were continuously present in an unrestricted area, the external dose would not exceed 2 mrem in any hour and 50 mrem in a year [20.1301(a)(1), 1302(b)] ☒ Yes ☐ No

2. Unrestricted area radiation levels do not exceed 2 mrem in any one hour [20.1301(a)(2)] ☒ Yes ☐ No

3. Records maintained [20.2103, 2107] ☒ Yes ☐ No

Remarks:

10. RECEIPT AND TRANSFER OF RADIOACTIVE MATERIAL (INCLUDES WASTE DISPOSAL)

A. Describe how packages are received and by whom:

Packages come to a central facility for FedEx. Freight deliveries often come direct to Building 245.

B. Written package opening procedures established and followed [20.1906(e)]
☒ Yes ☐ No

C. If package shows evidence of degradation, monitor for contamination and radiation levels
☒ Yes ☐ No ☐ N/A

D. Monitoring of degraded packages performed within time specified[20.1906(c)]
☒ Yes ☐ No ☐ N/A

E. Transfer(s) between licensees (including "disposal") performed per 70.36 and 70.42
☒ Yes ☐ No ☐ N/A

F. Records of receipt/transfer maintained [20.2103(a), 70.51(b)(1)] ☒ Yes ☐ No

G. Transfers within licensee's authorized users or locations performed as required [L/C]
☒ Yes ☐ No ☐ N/A

H. Package receipt/distribution activities evaluated for compliance with 20.1301 [20.1302]
☒ Yes ☐ No ☐ N/A

Remarks:

11. TRANSPORTATION (10 CFR 71.5(a) and 49 CFR 170-189)

A. Licensee shipments are:

1. Delivered to common carriers ☒ Yes ☐ No ☐ N/A
2. Transported in licensee's own private vehicle ☐ Yes ☒ No ☐ N/A
3. No shipments since last audit ☐ Yes ☒ No ☐ N/A

B. Packages

1. Authorized packages used [173.415, 416(b)] ☒ Yes ☐ No ☐ N/A
2. Closed and sealed during transport [173.475(f)] ☒ Yes ☐ No

C. Shipping Papers

1. Prepared and used [172.200(a)] ☒ Yes ☐ No
2. Proper {Shipping name, Hazard Class, UN Number, Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, Category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, "Cargo Aircraft Only" (if applicable)} [172.200-204] ☒ Yes ☐ No
3. Readily accessible during transport [177.718(e)] ☒ Yes ☐ No

D. Vehicles ☒ Yes ☐ No

1. Cargo blocked and braced [177.842(d)] ☒ Yes ☐ No
2. Placarded, if needed [172.504] ☒ Yes ☐ No
3. Proper overpacks, if used (shipping name, UN Number, labeled statement indicating that inner package complies with specification package) [173.25] ☒ Yes ☐ No

E. Any incidents reported to DOT [171.15, 16] ☐ Yes ☒ No

Remarks: **Based on observation of SRM personnel performing shipping.**

12. PERSONNEL RADIATION PROTECTION

A. ALARA considerations are incorporated into the Radiation Protection Program [20.1101(b)] ☒ Yes ☐ No

B. Adequate documentation of determination that unmonitored occupationally individuals are not likely to receive >10% of allowable limit [20.1502(a)] ☒ Yes ☐ No ☐ N/A

OR

C. External dosimetry provided and required ☒ Yes ☐ No ☐ N/A

1. Supplier Naval Dosimetry Center Frequency Monthly and quarterly

2. Supplier is NVLAP-approved [20.1501(c)] ☒ Yes ☐ No

3. Dosimeters exchanged at required frequency [L/C]] ☒ Yes ☐ No

D. Occupational intake monitored and assessed [20.1502(b)] ☒ Yes ☐ No ☐ N/A

E. Reports

1. Reviewed by GSRD staff Frequency as received

2. Auditor reviewed personnel monitoring records for 2012.

3. Prior dose determined for individuals likely to receive doses [20.2104] ☒ Yes ☐ No

4. Maximum exposures TEDE Other

5. NRC Forms or equivalent [20.2104(d), 2106(c)]

a. NRC Form 4 "Cumulative Occupational Exposure History"
☒ Yes ☐ No
Complete:
☒ Yes ☐ No

b. NRC Form 5 "Occupational Exposure Record for a Monitoring Period"
☒ Yes ☐ No
Complete:
☒ Yes ☐ No

6. Worker declared her pregnancy in writing during inspection period (review records) ☒Yes ☐ No ☐ N/A

If yes, determine compliance with [20.1208] ☒ Yes ☐ No

Check for records per [20.2106(e)] ☒ Yes ☐ No

F. Records of exposures, surveys, monitoring, and evaluations maintained [20.2102, 2103, 2106, L/C] ☒ Yes ☐ No

Remarks:**Doses are well below limits. ALARA is evident.**

13. AUDITOR'S INDEPENDENT MEASUREMENTS (IF MADE)

A. Survey instrument Serial No. Last calibration
None made on this audit.

B. Auditor's measurements compared to licensee's ☐ Yes ☐ No
N/A

C. Describe the type, location, and results of measurements: N/A

14. NOTIFICATION AND REPORTS

A. Licensee in compliance with [19.13, 70.50] (reports to individuals, public and occupational, monitored to show compliance with Part 20
☒ Yes ☐ No ☐ None

B. Licensee in compliance with [20.2201, 70.50] (theft or loss)
☐ Yes ☐ No ☒ None

C. Licensee in compliance with [20.2202, 70.50] (incidents)
☐ Yes ☐ No ☒ None

D. Licensee in compliance with [20.2203, 70.50] (overexposures and high radiation levels)
☒ Yes ☐ No " None

E. Licensee aware of telephone number for NRC Emergency Operations Center [(301) 816-5100]
☒ Yes ☐ No

15. POSTING AND LABELING

A. NRC Form 3 "Notice to Workers" is posted [19.11] ☒ Yes ☐ No

B. Parts 19, 20, 21, Section 206 of Energy Reorganization Act, procedures adopted pursuant to Part 21, and license documents are posted, or a notice indicating where documents can be examined is posted [19.11, 21.6] ☒ Yes ☐ No

C. Other posting and labeling per [20.1902, 1904] and the license is not exempted by [20.1903, 1905] ☐ Yes ☒ No

Remarks:

See Section 3.1 of the audit report for discussions of a finding on posting.

16. RECORDKEEPING FOR DECOMMISSIONING

A. Records of information important to the safe and effective decommissioning of the facility maintained in an independent and identifiable location until license termination ☒ Yes ☐ No

B. Records include all information outlined in [70.25(g)] ☒ Yes ☐ No

Remarks:

17. BULLETINS AND INFORMATION NOTICES

A. Receipt of NRC Bulletins, NRC Information Notices, NMSS newsletters,etc. ☒ Yes ☐ No

B. Appropriate action taken in response to Bulletins, Information notices, etc. ☒ Yes ☐ No

Remarks:

18. SPECIAL LICENSE CONDITIONS OR ISSUES

A. Review special issue conditions or other issues, and describe findings:
None for SNM

B. Problems/deficiencies identified at licensee facilities other than at audit location:

C. Evaluation of compliance:

19. CONTINUATION OF REPORT ITEMS

(If more space is needed, use separate sheets and attach to report.)

20. PROBLEMS OR DEFICIENCIES NOTED; RECOMMENDATIONS☐ N/A

Note: Briefly state (1) the requirement and (2) how and when violated. Provide recommendations for improvement.

See Findings 1- 4 in the attached report for requirements and potential violations.

21. EVALUATION OF OTHER FACTORS

A. Senior licensee management is appropriately involved with the radiation safety program and/or RSO oversight
☒ Yes ☐ No

B. RSO has sufficient time to perform his/her radiation safety duties and is not too busy with other assignments
☒ Yes ☐ No

C. Licensee has sufficient staff
☒ Yes ☐ No

Remarks/recommendations:

Suggested Audit Checklist for 10 CFR Part 36 Irradiators

Based on NUREG-1556, Vol 6, Appendix K

Note: **All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit.** For example, licensees do not need to address areas which do not apply to their activities and activities which have not occurred since the last audit need not be reviewed at the next audit.

Audit History

A. Last audit of this location conducted on (date) **May 2013**

B. Were previous audits conducted at intervals not to exceed least every 12 months? [10 CFR 20.1101] **Yes**

C. Were records of previous audits maintained? [10 CFR 20.2102] **Yes**

D. Were any deficiencies identified during last two audits or two years, whichever is longer? **Yes**

E. Were corrective actions taken? (Look for repeated deficiencies).
Yes. Findings and observations were noted in the previous audit. None of these findings or observations dealt with Part 36 issues.

Organization And Scope of Program

A. If the mailing address or places of use changed, was the license amended? **N/A**

B. If ownership changed or bankruptcy filed, was NRC prior consent obtained or was NRC notified? **N/A**

C. Radiation Safety Officer

1. If the RSO was changed, was license amended?
N/A No change of RSO since last audit.

2. Does new RSO meet the licensee's training requirements?
N/A No change of RSO since last audit.

3. Is RSO fulfilling his/her duties?
Yes.

4. To whom does RSO report?
NIST management and chair of the RSC

D. If the designated contact person for NRC changed, was NRC notified?
N/A no change of RSO since last audit.

E. Sealed Sources and Devices

1. Does the license authorize all of the NRC regulated radionuclides contained in irradiators?
Yes. Licensee is a Type A Broad Scope. License conditions list applicable nuclides and amounts.

2. Have copies of (or access to) SSD Certificates?
The license does not follow the current NRC region based licensing template which references and requires SSD data. Licensee is aware that NRC may be of assistance in locating SSD's when necessary. Licensee has reported contacting vendors for SSD's.

3. Are the sealed sources, and if applicable, devices in accordance with the description in the Sealed Source and Device (SSD) Registration Certificates? [10 CFR 32.210]
N/A The license does not follow the current NRC region based licensing template which references and requires SSD data.

4. Have manufacturers' manuals for operation and maintenance?
Yes. Observed manufacturer's manuals in the Vertical Range area.

5. Are the actual uses of the irradiator consistent with the authorized uses listed on the license?
Yes. Licensee uses irradiators for calibrations and materials studies.

6. Are the sealed sources used under conditions specified in the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" on the SSD Registration Certificates?
Not examined. As SSD's are obtained, the licensee is encouraged to ensure that these areas are reviewed as part of the internal licensing and hazard review process.

Training and Instructions to Workers

A. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed per [10 CFR 19.12]?
Yes. Observed HP staff and researchers wearing dosimetry when in irradiator areas as instructed. Electronic dosimeters were issued to visitors and their use was enforced.

Refresher training provided, as needed?
Annual refresher training records included those individuals likely to exceed 1 mSv in a year.
Records maintained?
Yes. Records were maintained by GSRD.

B. Did each individual permitted to operate the irradiator without a supervisor present, receive instruction according to the license commitments and 10 CFR 36.51 before operating the irradiator?
Yes, based on discussions with GSRD staff and irradiator operator

C. Are records of training, tests, safety reviews, and annual evaluations maintained for each authorized irradiator operator? [10 CFR 36.81(b), (c)]
Yes, based on discussions with GSRD staff.

D. Did individuals who perform non-routine operations receive training before performing these operations?
N/A. The licensee does not perform non-routine operations. Manufacturers or vendors are used to accomplish these tasks.

E. Did interviews reveal that individuals know the emergency procedures?
Yes. Based on discussions with the irradiator operator, the individual knew the appropriate emergency procedures.

F. Did this audit include observations of irradiator operations?
No. Site visit only. At the time of the audit, no irradiations were being performed.

G. Do workers know requirements for the following:
1. the radiation safety program
2. annual dose limits
3. new Form NRC 4 and 5
4. 10% monitoring threshold
5. dose limits to embryo/fetus and declared pregnant worker
6. grave danger posting?

Yes. Based on discussions with the irradiator operator, the individual was familiar with the requirements listed above. In addition, the GSRD staff member with irradiator program safety oversight was familiar with these requirements as well.

Radiation Survey Instruments And Radiation Monitors

A. Are all portable survey meters calibrated at least annually to an accuracy of ± 20% for the gamma energy of the sources in use? [10 CFR 36.57(c)]
Yes. Based on a review of records and discussions with GSRD staff.

B. Are portable survey meters of a type that does not saturate and read zero at high dose rates? [10 CFR 36.57(c)]
Yes.

C. Are calibration records maintained?
Yes.

D. Are all operable survey instruments able to detect 0.5 microsievert (0.05 mrem) per hour?
Yes.

E. Has the licensee evaluated the location and sensitivity of the radiation monitor to detect sources carried by the product conveyor system for automatic conveyor systems? [10 CFR 36.29(a)]
N/A. The licensee does not irradiate materials using a conveyor system.

F. Has the licensee tested the operability and sensitivity of monitor used to detect the presence of high radiation levels in the radiation room before personnel entry at frequency specified in license application?
Yes.

G. Has the licensee tested the operability and sensitivity of monitor used to detect contamination of pool water due to leaking sources? (frequency of checks as specified in license application?)
N/A as the pool irradiator source strength is lower than the levels specified in 10 CFR 36.1(b).

H. For underwater irradiators not in a shielded radiation room, has the licensee tested the operability and sensitivity of monitor used to detect abnormal radiation levels? (frequency of checks as specified in license application?)
N/A as the pool irradiator source strength is lower than the levels specified in 10 CFR 36.1(b).

Conductivity Meters

A. Are appropriate operable conductivity meters possessed and used?
N/A as the pool irradiator source strength is lower than the levels specified in 10 CFR 36.1(b). Therefore the requirements of 10 CFR 36.63 do not apply.

B. Are conductivity meters calibrated at least annually? [10 CFR 36.63(b)]
N/A as the pool irradiator source strength is lower than the levels specified in 10 CFR 36.1(b). Therefore the requirements of 10 CFR 36.63 do not apply.

Sealed Source Accountability Program

A. Are records maintained showing the receipt, location, transfer, and disposal of each sealed source? [10 CFR 30.51(a)(1)]
Yes. GSRD maintains a database of all sealed sources in use or in storage.

B. Is material accountability program as described in application being implemented?
Yes.

Personnel Radiation Protection

A. Are ALARA considerations incorporated into the radiation protection program? [10 CFR 20.1101(b)]
Yes.

B. Is documentation kept showing that unmonitored individuals receive <=10% of limit? [10 CFR 20.1502(a)]
Yes.

C. Did unmonitored individuals' activities change during the year which could put them over 10% of limit?
No. Not in the irradiator use areas covered under Part 36.

D. If yes to C above, was a new evaluation performed?

E. Is external dosimetry provided to individuals as required by 10 CFR 36.55 and to individuals likely to receive >10% of limit?
Yes.

1. Irradiator Operators: Is the dosimetry supplier NVLAP approved? [10 CFR 20.1501(c)]
Yes. The Naval Dosimetry Center is NVLAP approved.

2. Are the dosimeters exchanged monthly for film badges and quarterly for TLDs?
Yes.

3. Are dosimetry reports reviewed by the RSO upon receipt?
Yes.

4. Are dosimeters provided to persons who enter the radiation room of a panoramic irradiator? [10 CFR 36.55(b)]
Yes. Observed all personnel in radiation room with dosimetry.

5. Annual checks of accuracy of pocket dosimeters performed? [10 CFR 36.55(b)]
Yes. Based on discussions with GSRD personnel. The licensee also uses electronic dosimeters.

6. Are the records NRC Forms or equivalent? [10 CFR 20.2104(d), 10 CFR 20.2106(c)]
Yes.
   a. NRC-Form 4 "Cumulative Occupational Exposure History" completed?
   Yes.
   b. NRC-Form 5 "Occupational Exposure Record for a Monitoring Period" completed?
   Yes.

7. Declared pregnant worker/embryo/fetus
   a. If a worker declared her pregnancy, did licensee comply with [10 CFR 20.1208]?
   N/A in the irradiator area based on discussions with the licensee.
   b. Were records kept of embryo/fetus dose per [10 CFR 20.2106(e)]?
   N/A in the irradiator area based on discussions with the licensee.

F. Are records of exposures, surveys, monitoring, and evaluations maintained [10 CFR 20.2102, 10 CFR 20. 2103, 10 CFR 20. 2106, 10 CFR 36.57(a)]
Yes

Public Dose

A. Is public access controlled in a manner to keep doses below 1 mSv (100 mrem) in a year? 10 CFR 20.1301(a)(1)]
Yes. The licensee uses environmental TLD system to assess public doses in areas adjacent to irradiator facilities.

B. Has a survey or evaluation been performed per 10 CFR 20.1501(a)? Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?
Yes. The licensee assesses public doses in areas adjacent to irradiator facilities. No additions of changes to storage, security or use of surrounding areas have occurred to trigger a new evaluation.

C. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour? [10 CFR 20.1301(a)(2)]

No. Based on measurements with a calibrated ion chamber.

D. Is access to sealed sources controlled in a manner that would prevent unauthorized use or removal? [10 CFR 20.1801]
Yes. The licensee has a robust security program that meets the current NRC regulations.

In the pool room, there are security seals installed at select spots in the facility. It is recommended that the seals be replaced with more durable seals (e.g. zip ties, wired lead seals).

E. Records maintained? [10 CFR 20.2103, 10 CFR 20.2107]
Yes.

Operating And Emergency Procedures

A. Have operating and emergency procedures been developed? [10 CFR 36.53]
Yes. Operating and emergency procedures were examined at the irradiator console and in the GSRD offices.

See the recommendations section of this report for a recommendation regarding labeling of Emergency Stop buttons.

B. Do they contain the required elements?
Yes.

C. Does each individual working with the sealed sources have a current copy of the operating and emergency procedures (including emergency telephone numbers)?
Yes.

D. Did any emergencies occur?
No emergencies had occurred since the last audit.

1. If so, were they handled properly?
N/A
2. Were appropriate corrective actions taken?
N/A
3. Was NRC notification or reporting required? [10 CFR 20.2201, 2202, 2203, 10 CFR 30.50 and 10 CFR 36.83]
N/A. The RSO is familiar with the NRC emergency response number and the reporting requirements.

Leak Tests

A. Were sealed sources leak tested at prescribed intervals? 10 CFR 36.59
Yes.

B. Was the leak test performed according to regulatory requirements? 10 CFR 36.59
Yes.

C. Are records of results retained with the appropriate information included?
Yes.

D. Were any sealed sources found leaking and if yes, were appropriate actions taken and was NRC notified? [10 CFR 20.2201,10 CFR 20.2203, 10 CFR 21.21, 10 CFR 30.50, 10 CFR 36.59,10 CFR 36.83]
No. No irradiator sources were found to be leaking during the audit period.

Inspection and Maintenance Checks

A. Are all procedures for maintenance of the irradiator being followed where applicable?
Yes. Based on discussions with licensee personnel, the manufacturer's recommendations for maintenance are followed.

B. Are all checks to determine proper functioning and wear of the source movement systems performed at frequencies as specified in the license application?
Yes.

C. Are labels, signs, and postings clean and legible?
Yes. The signs in the calibration ranges were observed as being posted, clean and legible.

D. Are checks for operability as required by 10 CFR 36.61(a) (not included in item 4.) performed at frequencies and according to procedures described in license application:

1. Each aspect of the access control system
   Yes.
2. Emergency source return control
   Yes.
3. Heat/smoke detectors, extinguisher system
   Detection yes. Extinguishers are handheld and under surveillance.
4. Pool water replacement system high and low water indicators
   N/A
5. For underwater irradiators, was the intrusion alarm tested for operability? (frequency of checks as specified in license application)?
   N/A

E. Are checks for functioning and condition of equipment performed at required frequencies and according to procedures described in license application:

1. Assessment of the condition and operability of the source rack protector are performed at the required frequencies [10 CFR 36.61(a)].
   N/A as the pool irradiator source strength is lower than the levels specified in

10 CFR 36.1(b)

2. Assessment of water added to the pool to determine if there is pool leakage are performed at required frequencies as required by [10 CFR 36.61(a)(14)].
N/A as the pool irradiator source strength is lower than the levels specified in 10 CFR 36.1(b)

   In the pool room, there is an automatic pool makeup water system that will add water to the pool should the water level drop below a set point. It is recommended that an alarm be added to the system that notifies security if the automatic pool makeup water system is activated. This would notify personnel that water was being added and could be an early warning of pool failure as the water is the primary personnel shielding for this source in a room that is rarely occupied.

3. Assessment of radiation damage to electrical wiring are performed at required frequencies as required by [10 CFR 36.61(a)(15)].
Yes. Part of the maintenance check.

4. Water conductivity and analysis are performed at required frequencies [10 CFR 36.63]

   Although not required, the licensee does filter the water in the pool irradiator in a water purification system. The licensee also samples the water to look for contamination on a monthly basis.

5. Confirmation that water circulation system is leak tight. [10 CFR 36.61(a)(7)]
N/A
See item 2. Above.

6. Functioning of the source position indicator [10 CFR 36.61(a)(2)]
Yes. Part of the maintenance check.

7. Leak tightness of water circulation system, visual inspection [10 CFR 36.61(a)(7)]
N/A
See item 2. Above.

Repair and Preventive Maintenance

A. Are repair and maintenance of components related to the radiological safety of the irradiator performed by the manufacturer or person specifically authorized by the NRC or an Agreement State and according to license requirements (e.g., extent of work, procedures, dosimetry, survey instrument, compliance with 10 CFR 20.1301 limits)?
Yes. Based on discussions with GSRD staff, manufacturers or vendors are used to accomplish these tasks.

B. Malfunctions and defects found during inspection and maintenance checks are repaired without undue delay.
Yes.

Transportation

Note: This section will not apply if you have not transported sealed sources during the period covered by this audit.

A. Were sources shipped since the last audit?
No.

B. If so, were 10 CFR Part 71 requirements followed?
N/A

C. DOT-Type A or Type B packages used? [10 CFR Part 71, 49 CFR 173.415, 49 CFR 173.416(b)] If Type B, NRC Certificate of Compliance granted before shipment or shipper is registered as a user of the Type B package? NRC-approved QA program?
N/A

D. Package performance test records on file? [49 CFR 173.415(a)]
N/A

E. Special form sources documentation? [49 CFR 173.476(a)]
N/A

F. Package has 2 labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? [49 CFR 172.403, 49 CFR 173.441]
N/A

G. Package properly marked? [49 CFR 172.301, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324]
N/A

H. Package closed and sealed during transport? [49 CFR 173.475(f)]
N/A

I. Shipping papers prepared, used, and maintained? [49 CFR 172.200(a)]
N/A

J. Shipping papers contain proper entries? {Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity, category of label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (if applicable)} [49 CFR 172.200, 49 CFR 172.201, 49 CFR 172.202, 49 CFR 172.203, 49 CFR 172.204, 49 CFR 172.604]
N/A

K. Secured against movement? [49 CFR 177. 834]
N/A

L. Placarded on vehicle, if needed? [49 CFR 172.504]
N/A

M. Proper overpacks, if used? [49 CFR 173.25]
N/A

N. Any incidents reported to DOT? [49 CFR 171.15, 49 CFR 171.16]
N/A

Auditor's Independent Survey Measurements

A. Describe the type, location, and results of measurements. Does any radiation level exceed regulatory limits [10 CFR 20.1501(a) & 1502(a)]?
Not measured during this visit.

Notification and Reports

A. Was a telephone report made within 24 hours as described in 10 CFR 36.83(b), 10 CFR 30.50(c)(1), and a written report within 30 days as described in 10 CFR 30.50(c)(2) of any of the following:

1. Source stuck in an unshielded position
   N/A
2. Any fire or explosion in a radiation room
   N/A
3. Damage to the source rack
   N/A
4. Failure of the cable or drive mechanism used to move the source racks
   N/A
5. Inoperability of the access control system
   N/A
6. Detection of radioactive contamination attributable to licensed radioactive material
   N/A
7. Detection of radioactive contamination attributable to licensed radioactive material
   N/A
8. Structural damage to the pool liner or walls
   N/A
9. Abnormal water loss or leakage from the source storage pool
   N/A
10. Pool water conductivity exceeding 100 microsiemens per centimeter.
    N/A

No events related to the use of Part 36 materials were reported by the licensee.

B. Was any radioactive material lost or stolen? Were reports made? [10 CFR 20.2201, 10 CFR 30.50]
No. Based on reports from GSRD staff, no irradiator sources were reported as lost or stolen.

C. Did any reportable incidents occur? Were reports made? [10 CFR 20.2202, 10 CFR 30.50]
No. Based on reports from GSRD staff, no reportable incidents occurred with irradiators.

D. Did any overexposures and high radiation levels occur? Reported? [10 CFR 20.2203, 10 CFR 30.50]
No. Based on reports from GSRD staff, no over exposures or high radiation levels occurred with irradiators.

E. If any events (as described in items a through c above) did occur, what was root cause? Were corrective actions appropriate?
N/A

F. Is the management/RSO/shift foreman licensee aware of telephone number for NRC Emergency Operations Center? [(301) 816-5100]
Yes. Based on discussions, the RSO is keenly aware of the telephone number for the NRC EOC.

Posting and Labeling

A. NRC-Form 3 "Notice to Workers" posted? [10 CFR 19.11]
Yes. Observed at the entrances to Building 245.

B. NRC regulations, license documents posted or a notice posted? [10 CFR 19.11, 10 CFR 21.6]
Yes. Observed posting with this information at the entrances to Building 245.

C. Other posting and labeling? [10 CFR 20.1902, 10 CFR 20.1904]
Yes. Caution Radioactive Materials (posted on pool deck vice door), Radiation Area, High Radiation Area posted appropriately.
While not a violation, the postings in the horizontal range in Room B104 are not consistent with the Labeling and Posting guidance promulgated by GSRD and issued on April 25, 2014. Specifically, inside the horizontal range in Room [redacted], the irradiation room is posted with a "Danger – High Radiation Area" sign. The guidance requires that GSRD post the area with a "Caution – High Radiation Area" sign. The regulations allow either posting, and the facility complies with 10 CFR 20.1902. Recommend changing the sign or changing the guidance.

Record Keeping for Decommissioning

A. Records kept of information important to decommissioning? [10 CFR 30.35(g)]
Yes. GSRD maintains a database of all locations of use, records of spills, and amounts of materials authorized.

B. Records include all information outlined in [10 CFR 30.35(g)]?
Yes.

Bulletins And Information Notices

A. NRC Bulletins, NRC Information Notices, NMSS Newsletters, received?
Not reviewed. Licensee staff were very familiar with the NRC website which contains this information.

B. Appropriate training and action taken in response?

No. There were no specific IN's issued applicable to Part 36 during the audit period.

Special License Conditions or Issues

A. Did auditor review special license conditions or other issues (e.g., non-routine operations)?
Yes.

License condition 12
Notwithstanding the requirements of 10 CFR 36.23(b), the licensee is exempt from the requirements that: (1) detection of entry, by an independent backup access control, while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard, and (2) the alarm must alert at least one other individual who is onsite of the entry. When an operator is not present the licensee shall arm the independent backup access control system identified in the licensee's letter dated March 5, 2013.

License condition 13
Notwithstanding the requirements of 10 CFR 36.23(c), the licensee is exempt from the requirements that attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in 10 CFR 36.23(b). The licensee shall comply with 10 CFR 35.615(b).

License condition 15
Notwithstanding the requirements of 10 CFR 36.27(a), the licensee is exempt from the requirement that the sources must automatically become fully shielded if a fire is detected.

License condition 16
Notwithstanding the requirements of 10 CFR 36.27(b) the licensee is exempt from the requirement that the radiation room must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room.

License condition 17
Notwithstanding the requirements of 10 CFR 36.31(a), the licensee is exempt from the requirements that (1) the console key must be attached to a portable radiation survey meter by a chain or cable, and (2) the door to the radiation room must require the same key used for source movement (i.e., control console key).

Letters dated October 31, 2013 and December 27, 2013

Discussion

License condition 12 and 13
Based on observations and discussions with licensee personnel (GSRD and the operator), the licensee is complying with the exemptions as stated in the license condition and as described in the license application letter of March 5, 2013.

License condition 15, 16 and 17
Based on observations and discussions with licensee personnel (GSRD and the operator), the licensee is complying with the exemptions as stated in the license condition and as described in the license application letter of June 5, 2013.

Letters dated October 31, 2013 and December 27, 2013
Based on a review of records, observations and discussions with licensee personnel (GSRD and the operator), the licensee is following the commitments in these letters.

Deficiencies Identified in Audit; Corrective Actions

A. Summarize problems/deficiencies identified during audit.

No apparent violations of 10 CFR 36 were identified.

B. If problems/deficiencies identified in this audit, describe corrective actions planned or taken. Are corrective actions planned or taken at ALL licensed locations (not just location audited)? Include date(s) when corrective actions are implemented.

N/A

C. Provide any other recommendations for improvement.

- The Labeling and Posting guidance promulgated by GSRD and issued on April 25, 2014 is not being followed. Specifically, in the horizontal range in Room [redacted], the irradiation room is posted with a "Danger – High Radiation Area" sign. The guidance requires that GSRD post the area with a "Caution – High Radiation Area" sign. The regulations allow either posting, and the facility complies with 10 CFR 20.1902. Recommend changing the sign or changing the guidance.

- In the vertical ranges in Rooms [redacted] and [redacted] the emergency stop buttons are green and are not labeled as to their function. In the horizontal range in Rooms [redacted], the emergency stop buttons are red and a labeled as to their function (Emergency Stop). It is recommended that all emergency stop buttons be labeled as to their purpose.

- In the vertical ranges in Rooms [redacted] and [redacted] there are several radiation detection systems that indicate the presence of an unshielded source (e.g. Room [redacted] has 4 independent systems). It is recommended that the licensee review the regulatory requirements and license commitments and use no more than two radiation detection systems that are used for safety.

- In the vertical range in Room [redacted], there are plastic sheathed cables stored on a wooden chair. These items add to the combustible load of the room. It is recommended that these items be relocated outside of the irradiation area unless required for an experiment. It is further recommended that these areas not be used as

general storage areas. A best practice example is the condition of the horizontal range in Room [redacted].

- In the pool room, there are security seals installed at select spots in the facility. It is recommended that the seals be replaced with more durable seals (e.g. zip ties, wired lead seals).

- In the pool room, there is an automatic pool makeup water system that will add water to the pool should the water level drop below a set point. It is recommended that an alarm be added to the system that notifies security if the automatic pool makeup water system is activated.

- The licensee is required to have copies of Sealed Source and Device registrations for certain sources and devices. Given the sensitive nature contained in the registrations, it is recommended that these registrations be kept in a secure location (e.g. with T&R items).

Evaluation of Other Factors

A. Senior licensee management is appropriately involved with the radiation protection program and/or Radiation Safety Officer (RSO) oversight?
Yes. Based on discussion, observations and records review, it appears that senior licensee management is highly engaged and appropriately involved.

B. RSO has sufficient time to perform his/her radiation safety duties?
Yes.

C. Licensee has sufficient staff to support the radiation protection program?
Yes. The RSO is supported by an experienced staff of technicians and health physicists who use the appropriate equipment to make radiation safety assessments, responses and decisions.

§32.18 Certification of Application/License Review and Reviewer Check List

GENERAL COMMENTS:

10 CFR 32.18: EXEMPT QUANTITIES OF BYPRODUCT MATERIAL (10 CFR 30.18)

A. Applicant satisfies §30.33 for the manufacture, distribution, and transfer of exempt quantities of BPM except for a license to transfer BPM manufactured, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State.

COMMENTS:
Yes. The licensee has a very good system for ensuring copies of customer licenses and reviewing them before shipment of BPM as required.

B. The BPM is not contained in any food, beverage, cosmetic, drug, or commodity designed for ingestion, inhalation by, or application to humans.

COMMENTS:
Licensee adds this statement to the SRM when distributed. Complies.

C. The BPM is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.

COMMENTS:
The items distributed are standard reference materials in very small but well characterized and measured quantities. As such they are not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution

D. Applicant has submitted copies of prototype labels and brochures for approval.

COMMENTS:
Labels in use match the prototype labels provided during the licensing process.

10 CFR 32.19: CONDITIONS FOR LICENSE UNDER 10 CFR 32.18

A. No more than 10 exempt quantities set forth in §30.71, Schedule B shall be sold or transferred in any single transaction (an individual exempt quantity maybe composed of fractional parts so that the sum does not exceed unity)

COMMENTS:
Licensee has a system that will ensure no more than 10 exempt quantities will be sold or transferred in any single transaction

B. Each quantity shall be separately and individually packaged with no more than 10 individual packages contained in any outer package for transfer. The external surface dose rate of the outer package must not exceed 0.5 mrem per hour

COMMENTS:
Complies. Noted during shipment preparation.

C. The immediate container shall bear a durable, legible label which:

1. Identifies the radioisotope and quantity of activity
   COMMENTS:
   Observed on containers in storage and being prepared for shipment. Also on the SRM certificate.

2. Bears the words, "RADIOACTIVE MATERIAL"
   COMMENTS:
   Observed.

D. Label or accompanying brochure shall state:

1. Contents are exempt from NRC or Agreement State licensing requirements
   COMMENTS:
   Observed.

2. Bear the words, "RADIOACTIVE MATERIAL - NOT FOR HUMAN USE INTRODUCTION INTO FOODS, BEVERAGES, COSMETICS, DRUGS, OR MEDICINALS, OR INTO PRODUCTS MANUFACTURED FOR COMMERCIAL DISTRIBUTION IS PROHIBITED - EXEMPT QUANTITIES SHOULD NOT BE COMBINED"
   COMMENTS:
   Observed

3. Set forth additional radiation safety precautions and instructions for handling, use, storage, and disposal of radioactive material
   COMMENTS:
   Observed on paperwork that accompanies package.