UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 EAST LAMAR BLVD, SUITE 400
ARLINGTON, TEXAS 76011-4125

April 12, 2011

EA-10-258

Elizabeth Lewis, Administrator
Bozeman Deaconess Foundation
dba Bozeman Deaconess Hospital
915 Highland Boulevard
Bozeman, Montana 59715

SUBJECT: NRC INSPECTION REPORT 030-33305/2010-001 AND INVESTIGATION REPORT NO. 4-2010-033

Dear Ms. Lewis:

This letter refers to the onsite inspection conducted on January 27, 2010, and to the subsequent investigation conducted by the NRC's Office of Investigations at the Bozeman Deaconess Hospital facility in Bozeman, Montana. The inspection examined activities conducted under NRC Materials License 25-10994-04, in order to monitor radiation safety and security, as well as compliance with Commission rules and regulations and the conditions of the license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, and interviews with personnel. The inspection disclosed that certified nuclear medical technicians (CNMT) at BDH failed to secure radioactive materials from unauthorized access and/or removal from the hospital's nuclear medicine laboratory (hot lab).

The preliminary inspection findings were discussed with you; Robert Lunt, Cancer Center Administrator; Lawrence Slate, Radiation Safety Officer; and Don Majerus, Radiology Manager, at the conclusion of the onsite portion of the inspection on January 27, 2010. A final telephonic exit briefing was conducted with you and Mr. Slate on February 24, 2011.

Based on the results of this inspection and investigation, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations involved failing to comply with the requirements of: (1) 10 CFR 20.1801 that a licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas, and (2) 10 CFR 20.1802 that a licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

The first apparent violation is the result of failures by BDH personnel and management to: (1) ensure the BDH nuclear medicine laboratory (hot lab) was secure from unauthorized

removal of licensed materials and against unauthorized access, and (2) control and maintain constant surveillance of licensed material in a controlled or unrestricted area by allowing the hot lab door to remain propped open when personnel were absent. The second apparent violation occurred when BDH lost control of a vial containing samarium-153 and improperly disposed the radioactive byproduct material directly into regular trash. The loss was reported in the March 11, 2010, Licensee Event Report. The licensee's failure to secure the radioactive waste resulted in the medical byproduct and associated waste being sent to the municipal landfill. The landfill is an unrestricted area over which the licensee did not maintain control or surveillance. These two apparent violations are of concern because they could indicate weaknesses in the BDH materials management program and its programs to detect and deter security infractions; areas of concern include, staff training and awareness, problem detection, audit preparation and review, and the development and implementation of corrective actions.

Based on the information obtained during the NRC's investigation, the NRC is concerned that willfulness was associated with the first apparent violation identified above. The basis for the NRC's concern that willfulness was involved with the first apparent violation is discussed in the enclosed Factual Summary of the results of the investigation.

Before the NRC makes its enforcement decision, we are providing you an opportunity to request: (1) a Predecisional Enforcement Conference (PEC), or (2) Alternative Dispute Resolution (ADR). If a PEC is held, the NRC will issue a press release to announce the time and date of the conference, however it will be closed to public observation since information related to an Office of Investigation report will be discussed. If you decide to participate in a PEC or pursue ADR, please contact Ms. Vivian Campbell at 817-860-8287 within 10 days of the date of this letter. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

A predecisional enforcement conference will afford you the opportunity to provide your perspective on the apparent violations and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. In particular, we are interested in discussing improvements in your materials management program and your program to detect and deter security violations. In addition, we are interested in any corrective actions taken or planned to address the potential willfulness that is discussed in Enclosure 2, as well as actions you will take to ensure that your radiation safety officers (now and in the future) will have sufficient knowledge and authority to fulfill their responsibilities as defined in the applicable parts of 10 CFR 35.24.

In lieu of a PEC, you may also request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a third-party neutral. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral

mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Since the NRC has not made a final determination in this matter, no Notice of Violation is being issued for the two apparent violations at this time. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

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

Should you have any questions concerning this inspection or the enclosed report, please contact Ms. Vivian H. Campbell at (817) 860-8287.

Sincerely,

/RA/

Roy J. Caniano, Director
Division of Nuclear Materials Safety

Docket: 030-33305
License: 25-10994-04

Enclosures:
1. NRC Inspection Report 030-33305/2010-001
2. Factual Summary - Office of Investigations Report 4-2010-033
3. NRC Information Notice 96-28

cc w/Enclosures 1 and 2:
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Radiological Health Program
Dept of Public Health & Human Services
Licensure Bureau
P.O. Box 202953
Helena, MT 59620-2953

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ADAMS	☒Yes ☐ No	☒ SUNSI Review Complete	Reviewer Initials: RRM
Publicly Available	☒ Yes ☐ No	Sensitivity: Nonsensitive	

RIV:DNMS:NMSB-A	NMSB-A	C:NMSB-A	ACES:ES	D:DNMS
RRMuñoz;dlf	GMVasquez	VHCampbell	MCMaier	RJCaniano
/RA/	***/RA/***	***/RA/***	***/RA/***	***/RA/***
3/7/11	3/10/11	3/10/11	4/11/11	4/12/11

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U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket:	030-33305
License:	25-10994-04
Report:	030-33305/2010-001
EA:	EA-10-258
Licensee:	Bozeman Deaconess Hospital
Location:	Bozeman, Montana
Dates:	January 27, 2010, through February 24, 2011
Inspector:	Rick Muñoz, Health Physicist Nuclear Materials Safety Branch A
Approved By:	Vivian H. Campbell, Chief Nuclear Materials Safety Branch A
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

Bozeman Deaconess Hospital
NRC Inspection Report 030-33305/2010-001

This was an unannounced inspection conducted January 27, 2010, through February 24, 2011, of licensed activities involving the use and storage of byproduct material at Bozeman Deaconess Hospital (BDH) in Bozeman, Montana. The inspection was an examination of activities conducted under NRC Materials License 25-10994-04. The inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. An investigation was also conducted by the NRC's Office of Investigation during this time period. This report describes the findings of the inspection and investigation.

Program Overview

BDH is authorized under NRC License 25-10994-04 to possess and use byproduct material for performance of nuclear medicine and radiation therapy activities at its facilities located in Bozeman, Montana. In addition, the licensee is authorized to use mobile positron emission tomography. (Section 1)

Inspection Findings Considered for Escalated Enforcement

- The licensee's failure to secure licensed material in the nuclear medicine hot lab from unauthorized removal or access when not under direct and constant surveillance was identified as an apparent violation of 10 CFR 20.1801. (Section 2.2)

- The licensee's failure to secure from unauthorized removal licensed materials that were stored for decay-in-storage was identified as a second apparent violation of 10 CFR 20.1801. (Section 2.2)

Corrective Actions for Findings Considered for Escalated Enforcement

- The licensee immediately removed and destroyed a wooden wedge that was used to prop the hot lab door open and made sure that the door to the hot lab was locked. Unannounced site inspections would be conducted by the Radiation Safety Officer to ensure the door remains closed and locked when the lab is left unattended. (Section 3)

- The licensee submitted a Long-Term Comprehensive Corrective Action Plan via e-mail on September 3, 2010 (ML102500301), which included enhanced security measures for the hot lab and enhanced procedures. (Section 3)

- The licensee enhanced procedures to perform an inventory of waste being held for decay-in-storage as well as provisions for a second individual to observe and verify activities for material being processed for disposal. (Section 3)

Report Details

1 Program Overview

1.1 Inspection Scope

A routine inspection was conducted on January 27, 2010, at the licensee's facilities in Bozeman, Montana. The inspector reviewed the organization and scope of licensed activities, including the nuclear medicine, manual brachytherapy, high dose-rate remote (HDR) afterloader brachytherapy and positron emission tomography (PET) programs.

1.2 Observations and Findings

Bozeman Deaconess Hospital (BDH) was authorized under NRC License 25-10994-04 to possess and use material specified in 10 CFR 35.100-400 and 10 CFR 35.600. BDH was authorized medical use of radioactive material for diagnostic and therapeutic procedures. A written directive was required for therapeutic administrations. The facility has a nuclear medicine department, mobile van positron emission tomography, and a cancer center. One location of use was authorized on the license, which included the main hospital campus and the cancer center.

2 Inspection Findings

2.1 Inspection Scope

Information was collected through discussions with licensee personnel, tours of the facility, observations of licensed activities, demonstrations of procedures, and a review of records. Licensed activities were assessed as they related to the safety and security of the radioactive material and the licensee's policies and procedures for handling licensed materials. The areas evaluated included, but were not limited to, training, personnel dosimetry, instrumentation, security, postings, audits, and radiation surveys.

2.2 Observations and Findings

This is a medium size nuclear medicine department employing three full-time and one part-time certified nuclear medicine technologists. This licensee performs approximately six procedures per day, which included bone, lung, gall bladder, gastric emptying, GI bleeding, and cardiology studies. One 3-curie molybdenum/technetium-99 (Mo/Tc-99) generator is received weekly. Approximately 10 iodine-131 therapy procedures using greater than 30 millicuries (mCi) of iodine-131 are performed annually. The iodine-131 used for all therapy administrations was in capsule form. Since the last inspection, both samarium-153 (Sm-153) and strontium-89 were used once. All therapy administrations are accompanied by the appropriate written directive. The high dose rate remote afterloader was used for treatments twice since mid-2009. Manual brachytherapy using iodine-125 seeds was conducted 25 times in 2009. BDH has a radiation safety committee which met quarterly. Annual radiation protection audits were performed by the Radiation Safety Officer (RSO)/Medical Physicist and reviewed by the hospital administrator and radiology manager.

On the morning of January 27, 2010, at 6:45 a.m., upon arrival at the hospital, the inspector found the doors to the room (hot lab) unlocked allowing access to radiopharmaceuticals that were in the room, and no authorized personnel in the area to maintain control over the licensed material present in the nuclear medicine department. The imaging room doors were posted with "Caution Radioactive Materials" signs, and the doors were left slightly open. The inspector walked through the imaging room to the hot lab. Although the hot lab door had a mechanical cipher lock, the door was propped open with a wooden wedge and no licensee representative was present. Licensed material in the hot lab included four Mo/Tc-99 generators (three spent and one active); calibration sources; brachytherapy sources (iodine-125 and indium-111 (In-111)); and waste which was stored for decay-in-storage in the hot lab. Approximately eight minutes later, a nuclear medicine technologist arrived for the work day. After interviewing the technologist, the inspector determined that another nuclear medicine technologist had arrived earlier that morning and was outside the building performing acceptance testing on the imaging system inside the mobile PET trailer designed for that purpose. The total length of time that the hot lab was left unattended was not determined.

The RSO/Medical Physicist arrived at approximately 8 a.m. The RSO informed the inspector that, since his appointment as RSO on July 7, 2009, he had observed the hot lab door propped open on several occasions and that he had instructed the staff to keep the hot lab locked. He stated that, since his arrival in July 2009, he had been trying to make improvements to the radiation protection program in terms of safety procedures and security of material; however, he felt he did not have support from hospital management. Leaving the nuclear medicine hot lab door propped open (when no nuclear medicine personnel were in the area to maintain surveillance over the licensed material) had apparently been occurring for several years before the current RSO had arrived at the hospital.

The licensee failed to secure the licensed material that was stored in the nuclear medicine hot lab, a controlled area, from unauthorized removal or access, and the licensee did not control and maintain constant surveillance of licensed material in the hot lab that was not in storage. This was identified as an apparent violation of 10 CFR 20.1801 and 20.1802. (030-33305/10-001)

Based on the findings from the inspection, the licensee undertook a comprehensive assessment of its radioactive material. On March 10, 2010, an inventory of the decay-in-storage waste at BDH was completed as part of the assessment. The inventory in the hot lab revealed that a 30 mCi vial of Sm-153 (Lot S04811D) was determined to be lost. The vial was received in the nuclear medicine department on February 18, 2004. The receiving paperwork indicated that the vial originally contained 150 mCi of Sm-153 in liquid form. A 65 mCi dose of Sm-153 was injected into a patient on February 19, 2004. From the date of receipt, 52 mCi had decayed, thus 33 mCi remained in the vial after administration. The Sm-153 waste (vial, gloves, syringe, dressing, etc) was stored in the hot lab along with In-111 waste in separate bags. Based on its review, the licensee believes the most probable scenario is that the Sm-153 waste containing the vial (Lot S04811D) was inadvertently disposed of along with the In-111 waste. The licensee believes that the waste was not removed or stolen from the hot lab; rather, it was inadvertently disposed of along with other waste.

The licensee reported the loss of material to the NRC on March 11, 2010 (Event Number 45758). It could not be determined when the material went missing; however, the

inspector noted that the first disposal of In-111 occurred in July 2004, which means the Sm-153 would have completely decayed prior to disposal (according to the licensee's most probable scenario).

Based on the circumstances, the inspector determined that the licensee's scenario that the waste was inadvertently disposed of along with In-111 waste was reasonable. The licensee's failure to secure from unauthorized removal of licensed materials that was stored in controlled or unrestricted areas was identified as a second apparent violation of 10 CFR 20.1801. (030-33305/10-002)

2.3 Conclusions

The inspection identified two apparent violations. The first was an apparent violation of 10 CFR 20.1801 and 20.1802 involving the failure to secure licensed materials that were stored in the hot lab, a controlled area from unauthorized access and did not control and maintain constant surveillance over materials that were not in storage. The second was an apparent violation of 10 CFR 20.1801 involving the failure to secure licensed materials (Sm-153 waste) that were stored in the hot lab for decay-in-storage.

3 Corrective Actions

During the January 27, 2010, onsite portion of the inspection, the licensee acknowledged the failure to comply with NRC requirements and committed to prompt corrective actions. In response to the apparent violation, the licensee immediately removed and destroyed the wooden wedge and made sure that the door to the hot lab was locked. During the preliminary exit briefing, hospital administration representatives stated that they would conduct unannounced site inspections of the nuclear medicine department to ensure the door remains closed and locked when the lab is unattended. Enforcement will include staff counseling, training, and any corrective actions needed.

In addition, the licensee submitted a Long Term Comprehensive Corrective Action Plan via e-mail on September 3, 2010 (ML102500301). The hospital committed to securing the hot lab from unauthorized access by revising its safety and operating procedures. The revision added enhancing the access codes into the hot lab via their cipher locking mechanism and providing training to all affected individuals. The licensee also provided training on the new security policy, which was completed on August 30, 2010.

In response to the apparent violation involving the loss of the Sm-153 material, the hospital had implemented new policies and procedures to ensure stricter and safer radiation practices. A new policy, following Section 8.39 of NUREG 1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses: Program - Specific Guidance About Medical Use Licenses," was developed which stated that all long-term waste will be inventoried every 6 months. The new procedure also described material receipt and accountability. In addition, a policy and procedure had been developed that described that all waste to be disposed of will have an observer/witness before disposal. The observer/witness will verify screening and characterization, surveys, and inventory verification. Finally, the hospital in-service was modified to ensure that adequate training was being performed to address new policies and procedures. The licensee indicated that in the future, isotopes with relatively long half-lives will be not be purchased unless an agreement with the manufacturer is established so that any residual waste can be shipped back to the manufacturer.

4 Exit Meeting Summary

A preliminary exit briefing was conducted with the RSO/Medical Physicist, the hospital Administrator, the Radiology Manager, and the Cancer Center Administrator at the conclusion of the onsite portion of the inspection. Multiple follow-up telephone calls were conducted and electronic mail correspondence exchanged with the RSO through January 10, 2011. A final exit meeting was conducted telephonically with the RSO and the Vice President of Operations and Legal on February 24, 2011, to review the findings of the inspection and investigation. The licensee acknowledged the inspector's findings. No proprietary information was identified.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Lawrence Slate, RSO/Medical Physicist
Don Majerus, Radiology Manager
Robert Lunt, Cancer Center Administrator
Elizabeth Lewis, Vice President of Operations and Legal
Ronald Tharp, M.D, Authorized User/previous RSO
William Jordan, Practice Manager
John Bratke, NMTCB
Dawn Clemens, CNMT
Nicoline Ann Hauff, Nuclear Medicine Technologist
Joshua Penner, NMTCB
Jo Ann May, Radiation Oncology Supervisor
Mary Ellen Jafari, previous HP third-party consultant

INSPECTION PROCEDURES USED

IP 87131	Nuclear Medicine, Written Directive required
IP 87132	Brachytherapy
IP 86740	Inspection of Transportation Activities
IP 84101	Radioactive Waste Management

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-33305/10-001	APV	An apparent violation involving the failure to secure licensed material that was stored as well as licensed material that was not stored in the nuclear medicine hot lab from unauthorized removal or access and the licensee was not controlling and maintaining constant surveillance.
030-33305/10-002	APV	An apparent violation involving the failure to secure from unauthorized removal a samarium-153 vial that was stored for decay-in-storage in a controlled or unrestricted area.

Closed

None

Discussed

None

Attachment

LIST OF ACRONYMS AND ABBREVIATIONS USED

APV	apparent violation
BDH	Bozeman Deaconess Hospital
CFR	*Code of Federal Regulations*
CNMT	Certified Nuclear Medicine Technologist
EA	enforcement action
HDR	high dose-rate remote
NMTCB	Nuclear Medicine Technology Certification Board
NRC	Nuclear Regulatory Commission
PET	positron emission tomography
RSO	radiation safety officer
VIO	violation

FACTUAL SUMMARY
OFFICE OF INVESTIGATIONS REPORT 4-2010-033

On December 3, 2010, the U.S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), Field Office Region IV (RIV), completed an investigation at Bozeman Deaconess Hospital (BDH) to determine if willfulness was associated with apparent violations involving the failure of BDH personnel to secure radioactive materials from unauthorized access and/or removal from the Nuclear Medicine Department Laboratory ("hot lab").

When interviewed by OI, the Radiology Manager, the Radiation Safety Officer (RSO), the Chief Nuclear Medicine Technician (Chief NMT), two Technologists, a Staff Technician, and the previous RSO admitted that they were aware that the door to the "hot lab" was periodically propped open when no personnel were present. Several nuclear medicine staff members stated that the Chief NMT propped the door open and left the hot lab on numerous occasions. The Radiology Manager, RSO, Chief NMT, two technologists and a staff technician stated that although they did not know the specific NRC regulations (10 CFR 20.1801 and 20.1802) associated with the security requirements, they admitted that they were aware that the door to the "hot lab" was required to be closed and access by unauthorized persons was to be restricted. Nuclear Medicine personnel stated that the violations had occurred over a long period of time, beginning in 2001 or earlier. These individuals reported the security violations to the Chief NMT and the Radiology Manager, but their attempts to resolve the problems were ineffective.

When interviewed, the Chief NMT admitted having knowledge of the requirement to keep the "hot lab" secure and to understanding that not keeping the "hot lab" secure is a violation of NRC regulations. The Chief NMT admitted he had left the door open to work in a mobile PET unit outside the BDH building on the day of the inspection. The Chief NMT also acknowledged being informed by the current RSO of the need to close the "hot lab" door and that not closing the door was a violation. However, the Chief NMT continued to prop open the hot lab door and leave the area unsecured over a period of years.

When interviewed, the RSO stated that he had knowledge of the requirements of 10 CFR 20.1801 and 20.1802 to secure materials in the hot lab, prior to the NRC inspection on January 27, 2010. He admitted he knew that it was a violation to prop open the door to the "hot lab" when authorized personnel were absent. The RSO advised that he had communicated these requirements directly to the Chief NMT. When that did not result in the Chief NMT stopping the practice of leaving the hot lab unsecured, the RSO discussed it with the Radiology Manager. He also related that he told the Chief NMT that these actions were violations of NRC regulations. The RSO's oral reprimands did not bring to an end to the Chief NMT's practice of leaving the hot lab unsecured.

The RSO stated that he did not want to get the department in trouble and thought that he would try to bring them into compliance verbally. He stated that he did not document that the door to the "hot lab" was propped open without personnel being present, because he knew that a paper trail could get hospital personnel in trouble. The RSO told NRC investigators that he spoke with BDH's Senior Vice President of Operations and Legal, but in a general way without going into the specifics of the violations that were happening at BDH. The RSO indicated that he did not receive support but felt he was "brushed away" by the Senior Vice President's response, which asked how they could now be in violation when previous inspections did not find violations. The

RSO indicated that with the push back he received from nuclear medicine and BDH management, he “became complacent in trying to uphold his responsibility as RSO.”

When interviewed by OI, the Radiology Manager stated he did not have knowledge of 10 CFR 20.1801 and 20.1801, specifically, although he was aware that when a nuclear technicians left the “hot lab,” the door was required to be closed so that nuclear materials were secured, as well as, for fire safety. Although, the Radiology Manager told investigators that no other nuclear medicine staff employees had ever discussed with him the need to keep the “hot lab” door closed. An individual corroborated that the current RSO had informed the Radiology Manager of the need to secure the hot lab door.

The Radiology Manager, is a member of the radiation safety committee with direct authority over the technical operation of the Radiology Department, and he signed the September 2009 Bozeman Deaconess Hospital Annual Radiation Protection Medical Licensee Audit as the management reviewer. The audit prepared by the current RSO, stated that the nuclear medicine department needed to update all policies and procedures to reflect current regulations. He did not take effective action to ensure that deficiencies (including the failure to secure the hot lab door) were identified and corrected. The Radiology Manager did not take effective action to ensure that deficiencies, which were brought to his attention, were fully investigated and corrected.

When interviewed by OI, the former RSO, who served in that position from 2001 to 2009, stated he had no knowledge of NRC regulations that required the nuclear medicine laboratory to be kept secure from unauthorized access to prevent the removal of radioactive materials from the lab. Yet, as RSO, he did not try to learn or become familiar with NRC regulations in order to meet his responsibilities as defined in applicable parts of 10 CFR 35.24.