

October 4, 2013

EA-13-155

Mr. Terry Alexander  
Executive Director of Occupational Safety  
and Environmental Health  
The Regents of the University of Michigan  
Radiation Safety Service  
1239 Kipke Drive  
Ann Arbor, Michigan 48109-1010

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03001988/2013001(DNMS) AND  
NOTICES OF VIOLATION — THE REGENTS OF THE UNIVERSITY OF  
MICHIGAN RADIATION SAFETY SERVICE

Dear Mr. Alexander:

On June 24-28, 2013, with continued in-office review through September 20, 2013, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection of your facilities located in Ann Arbor and Flint, Michigan. The in-office review included receipt and review of information that was unavailable during the onsite inspection including, in part, corrective actions to prevent similar violations of NRC regulatory requirements. The purpose of the inspection was to determine whether activities authorized under your license were conducted safely and in accordance with NRC requirements. The enclosures present the results of this inspection.

During this inspection, the NRC staff examined activities conducted under your license as they relate to public health and safety, compliance with the Commission's rules and regulations, and compliance with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, 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 website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violations involve security failures. Details about the apparent violations are available in the Security Addendum to Inspection Report, enclosed with this letter.

Enclosures 2 and 4 contain Sensitive  
Unclassified Non-Safeguards Information.  
When separated from Enclosures 2 and 4,  
this transmittal letter and Enclosures 1  
and 3 are decontrolled.

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The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with Mark Driscoll of your staff during the inspection exit meetings on August 13, 2013 and September 24, 2013, and with Dennis Palmieri of your staff on September 9, 2013.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in the Security Addendum to Inspection Report No. 03001988/2013001(DNMS) within 30 days of the date of this letter, (2) request a Pre-decisional Enforcement Conference (PEC), or (3) request 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, the conference will be closed to public observation because security-related information will be discussed. The NRC normally tries to schedule either a PEC or an ADR session within 30 days of the date of the letter. Please notify Aaron T. McCraw at 630-829-9650 of your intentions within 10 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as "Response to Apparent Violations in the Security Addendum to Inspection Report No. 03001988/2013001(DNMS); EA-13-155," and should include, for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. 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. In addition, if you choose to provide a written response, please mark your entire response, "Security-Related Information-Withhold from Public Disclosure under Title 10 of the *Code of Federal Regulations* (CFR) 2.390." In accordance with 10 CFR 2.390(b)(ii), the NRC is waiving the affidavit requirements for your response to this letter. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information.

If you choose to request a PEC, the 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: 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 lieu of a PEC, you may also request ADR with the NRC in an attempt to resolve these issues. 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.

T. Alexander

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Please be advised that the number and characterization of the apparent violations 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.

The NRC has also determined that two Severity Level IV (SL IV) safety violations and an SL IV security violation of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The violations are described in detail in the attached inspection report and security addendum. The violations are cited in the enclosed Notices of Violation (Notices); one describing the safety violations and one non-public Notice describing the security violation. The NRC is citing two of the violations in the Notices because they were identified by the inspectors. The NRC is citing the other violation because, although the violation was identified by your staff and your staff took immediate corrective action, your staff did not implement comprehensive action to address the cause of the violation to prevent recurrence.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notices when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC's website at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and Enclosures 1 and 3 will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. Enclosures 2 and 4 contain security-related information and their disclosure to unauthorized individuals could present a security vulnerability; therefore, Enclosures 2 and 4 will not be made available electronically for public inspection.

T. Alexander

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Please feel free to contact Robert Gattone of my staff if you have any questions concerning this matter. You can reach Mr. Gattone at 630-829-9823.

Sincerely,

*/RA/*

Patrick L. Loudon, Acting Director  
Division of Nuclear Materials Safety

Docket No. 030-01988  
License No. 21-00215-04

Enclosures:

1. Notice of Violation (Publicly Available)
2. Notice of Violation (Non-Publicly Available)
3. NRC Inspection Report No. 03001988/2013001(DNMS) (Publicly Available)
4. Security Addendum to Inspection Report (Non-Publicly Available)

cc w/encls: Mark Driscoll, Radiation Safety Officer  
State of Michigan

T. Alexander

- 4 -

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cc w/encls: Mark Driscoll, Radiation Safety Officer  
State of Michigan

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NOTICE OF VIOLATION

The Regents of the University of Michigan  
Radiation Safety Service  
Ann Arbor, Michigan

Docket No. 030-01988  
License No. 21-00215-04

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on June 24-28, 2013, with continued in-office review through September 20, 2013, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Condition 28 of License No. 21-00215-04 states, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in specified documents, including the licensee's application dated February 24, 2011. Item 7.4.2 of the application states that human use research is approved by either the Subcommittee on the Human Use of Radioisotopes (SHUR) or the Radioactive Drug Research Committee (RDRC) and by the Internal Review Board (IRB).

Contrary to the above, on April 24, 2012, a cadmium-109 sealed source was used on two human research subjects under a physician's supervision, and the use was not approved by the SHUR or the RDRC.

This is a Severity Level IV violation (Section 6.3.).

- B. Title 10 of the *Code of Federal Regulations* (CFR) 30.36(d) requires, in part, that licensees provide notification to the NRC in writing within 60 days of any of the following occurrences:
- (1) The license has expired,
  - (2) The licensee has decided to permanently cease principal activities at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements,
  - (3) No principal activities under the license have been conducted for a period of 24 months, or
  - (4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.

Contrary to the above, as of July 16, 2013, no principal activities had been conducted at the Murchie Science Building (MSB), a separate building at the licensee's campus in Flint, Michigan, since approximately October 2004; the building contained residual radioactivity such that the building was unsuitable for release in accordance with NRC requirements; and the licensee failed to notify the NRC in writing within 60 days of this occurrence.

This is a Severity Level IV violation (Section 6.9.).

Enclosure 1

Notice of Violation

2

Pursuant to the provisions of CFR 2.201, The Regents of the University of Michigan Radiation Safety Service is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 4th day of October, 2013.

**U.S. NUCLEAR REGULATORY COMMISSION  
REGION III**

Docket No. 030-01988

License No. 21-00215-04

Report No. 03001988/2013001(DNMS)

EA No. EA-13-155

Licensee: The Regents of the University of Michigan  
Radiation Safety Service

Main Facility: 1239 Kipke Drive  
Ann Arbor, Michigan 48109-1010

Dates: June 24-28, 2013, with continued in-office  
review through September 20, 2013

Exit Meeting Dates: August 13, 2013  
September 24, 2013

Inspectors: Robert G. Gattone, Jr., Senior Health Physicist  
Geoffrey M. Warren, Health Physicist

Approved By: Aaron T. McCraw, Chief  
Materials Inspection Branch  
Division of Nuclear Materials Safety

Enclosure 3



## **EXECUTIVE SUMMARY**

### **The Regents of the University of Michigan Radiation Safety Service NRC Inspection Report No. 03001988/2013001(DNMS)**

During a routine inspection, the inspectors identified apparent violations involving security issues. In addition, the inspectors identified an additional violation involving a security issue. The apparent violations and the additional violation involving security issues are documented in the Security Addendum to Inspection Report. The inspectors also identified violations involving use of cadmium-109 for human research without the required approval, and failure to provide notification to the U.S. Nuclear Regulatory Commission (NRC) in writing within 60 days of no principal activities being conducted at a separate building for a period of 24 consecutive months, and the building contained residual radioactivity such that it was unsuitable for release in accordance with NRC requirements.

The licensee's corrective actions to prevent a similar safety violation include issuance of a "Cease and Desist Order" to stop all use of the cadmium-109 source while the licensee investigated if the user was authorized for human use research. In addition, the licensee committed to revise its authorized user application process to correctly capture all human use research requests to ensure that they are approved as required.

The licensee disagreed with the violation for failure to provide notification to the NRC in writing within 60 days of no principal activities being conducted at a separate building for a period of 24 consecutive months, and the building contained residual radioactivity such that it was unsuitable for release in accordance with NRC requirements; therefore, the licensee did not provide corrective actions for that violation.

Report Details

**1 Program Overview**

Licensed Activities and Inspection History

The Regents of the University of Michigan Radiation Service (licensee) is authorized under the U.S. Nuclear Regulatory Commission (NRC) Materials License No. 21-00215-04 (specific license) to conduct medical broad scope activities that includes use of licensed material by individuals designated by the licensee's Radiation Policy Committee (RPC). The licensee maintained a student population of approximately 42,000 at the main campus in Ann Arbor, Michigan. The license also authorizes licensed activities to be conducted at facilities in Dearborn, Flint, Belleville, and Pellston, Michigan. The licensee's RPC had designated approximately 350 individuals as Authorized Users, and about 1,500 people worked as Supervised Users. The licensee utilized licensed materials for medical applications and research and development.

The licensee's Radiation Safety Service (RSS), led by the Radiation Safety Officer (RSO) was located within its Occupational Safety & Environmental Health (OSEH) department. The OSEH department was overseen by an Executive Director, who reported to the Associate Vice President for Facilities and Operations. Approximately 13 staff members worked in the RSS. The RSS staff conducted instrument calibrations, conducted leak tests, and reviewed authorized user applications. The RSS technicians were involved with package delivery and receipt, laboratory reviews, confirmatory surveys, laboratory close-out, and assistance to research and development staff regarding radiation safety matters.

Medical use was conducted at the University of Michigan Hospital, Cardiovascular Center, C.S. Mott Children's Hospital, and Von Volgflander Women's Hospital. At the University of Michigan Hospital, the licensee used licensed materials under the authorities of Title 10 of the *Code of Federal Regulations* (CFR) 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000. Radiopharmaceutical therapies included iodine-131 metaiodobenzylguanidine (MIBG) human research cancer treatments at the University of Michigan Hospital. Manual brachytherapy activities included iridium-192 ribbons for cervical and lip cancer treatments at the University of Michigan Hospital, iodine-125 seeds for eye treatments, and yttrium-90 TheraSpheres® for neuroblastoma treatments at the Cardiovascular Center. The University of Michigan Hospital also contained a blood bank that utilized a self-shielded irradiator for irradiating biological materials.

Radioactive materials for research and development were located at approximately 1200 laboratories within a few dozen buildings. Research and development activities were trending down and primarily involved biological research with millicurie quantities of carbon-14, hydrogen-3, iodine-125, phosphorus-32, and sulfur-35. Occasional iodine-125 iodinations were done with 5 to 10 millicuries. The licensee used phosphorus-32 and phosphorus-33 for tooth development studies at the Eisenhower Place facility. The licensee also maintained and operated three self-shielded cesium-137 irradiators for research and development.

On May 24, 2012, with continued NRC in-office review through June 26, 2012, the NRC conducted a reactive inspection to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event that the licensee reported to the NRC on May 22, 2012. As a result, on July 12, 2012, the NRC cited a Severity Level IV violation of 10 CFR 35.63(d) involving use of a dosage that differed from the prescribed dosage by more than 20 percent without approval from an authorized user.

As a result of a routine NRC inspection conducted on February 6 through 10, 2012, with continued NRC in-office review through February 24, 2012, the NRC cited two Severity Level IV violations of NRC requirements. One of the violations involved failure to include the number of fractions in a high dose rate remote afterloader treatment written directive as required by 10 CFR 35.40(b). The other Severity Level IV violation involved a security issue.

The NRC conducted a reactive inspection on March 15 and 16, 2011, with continued in-office review through October 6, 2011, in response to a medical event. As a result, on January 6, 2012, the NRC cited a Severity Level III violation of 10 CFR 35.41(a) and (b) with no civil penalty involving failure to develop written procedures to provide high confidence that each brachytherapy treatment was in accordance with the written directive.

## **2 Human Research**

### **2.1 Inspection Scope**

The inspectors reviewed the licensee's human research involving a cadmium-109 sealed source. The inspectors reviewed selected records; interviewed selected licensee staff members, including the RSO; observed applicable licensee staff members demonstrate how they used the source for human research; and observed staff members demonstrate or describe their responses to abnormal, realistic scenarios posed by the inspectors.

### **2.2 Observations and Findings**

On January 30, 2009, the licensee's RSS received an application from a Medical Doctor requesting use of two cadmium-109 sources for conducting x-ray fluorescence (XRF) analyses of human research subjects' bones to identify lead content. The request included a source containing 300 millicuries and another containing 30 millicuries. The application was the licensee's first application for human research involving sealed sources used external to the human body. The Doctor stopped working at the licensee's facilities prior to this inspection.

On June 4, 2009, a member of the RSS staff sent an email message to the Doctor stating, in part, that the Doctor's application was granted temporary approval by the licensee's RSO limited to ordering the cadmium-109 sources, loading the sources into XRF instruments, and using the sources to calibrate the XRF instruments. The email message also stated that the temporary authorization did not authorize human nor animal use and that the Doctor must submit an application that must be approved by the licensee's Radioactive Drug Research Committee (RDRC)/Sub-Committee on the Human Use of Radioisotopes (SHUR) and the licensee's Internal Review Board (IRB)

prior to using the sources on humans. The SHUR also functioned as the RDRC. On December 8, 2009, the Radiation Protection Committee (RPC) approved the Doctor for non-human use of the cadmium-109.

On December 14, 2010, the licensee received a cadmium-109 source containing approximately 32.7 millicuries. The licensee did not order nor receive a 300 millicuries cadmium-109 source.

The licensee used an “eResearch Regulatory Management” web-based system to centralize its review and approval process for human research applications. The Doctor submitted the eResearch Application for approval. Item 21.1 of the eResearch Application asked, “Will research subjects be exposed to ionizing radiation from external radiation sources for the purpose of research in this study?” The Doctor properly responded, “Yes.” Item 21.2 of the eResearch Application asked, “Will research subjects be exposed to ionizing radiation from internal radioactive sources for the purposes of research in this study?” The Doctor properly responded, “No.”

On April 5, 2012, the IRB approved the Doctor’s application for human research. Since the Doctor responded, “No.” to Item 21.2 of the eResearch Application, the application was not forwarded to the RDRC/SHUR for approval.

On April 24, 2012, the cadmium-109 was used on two human research subjects under the Doctor’s supervision. Based on a discussion between the Doctor and an RSS staff member, the Doctor thought he was approved for human use of the cadmium-109 because he was a Medical Doctor and he was approved by the licensee’s IRB for such use.

On June 15, 2012, a licensee staff member conducted a “compliance review” of the cadmium-109 human use and identified that the SHUR had not approved the use. The staff member emailed a member of the SHUR to express his concern that the cadmium-109 use had not been approved by the SHUR.

On June 15, 2012, the SHUR member emailed that, since the cadmium-109 use did not involve ingestion of a radiopharmaceutical, the SHUR did not review the request. The SHUR member also responded that the cadmium-109 use was comparable to a bone density scan and it results in very minimal dose to human research subjects. The SHUR member carbon copied the email to the licensee’s RSO asking if he agreed with the SHUR member’s response to the licensee staff member. On June 18, 2012, the RSO emailed the SHUR member that he agreed because the cadmium-109 source is used similar to an x-ray machine with very minimal radiation dose to a human research subject.

Prior to July 11, 2012, an individual working under the supervision of the Doctor (supervised individual) informed the RSS that, on April 24, 2012, the cadmium-109 source was used on two human research subjects.

Condition 28 of License No. 21-00215-04 states, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in specified documents, including the licensee’s application dated February 24, 2011. Item 7.4.2 of the application states that human use research is approved by either the SHUR or the RDRC and by the IRB. The licensee’s use of the

cadmium-109 source for human research on April 24, 2012, without approval from the SHUR or the RDRC is a violation of Condition 28 of the license.

In response to the discovery that the cadmium-109 source was used for human research on April 24, 2012, the RSS issued a "Cease and Desist Order" to stop all use of the cadmium-109 source while RSS investigated if the Doctor was authorized for human use research. The licensee concluded that the Doctor was not approved by the SHUR or the RDRC; therefore, the licensee effectively identified the aforementioned violation of Condition 28 of the license. In addition, the RSS corresponded with Harvard University to confirm that the Doctor was approved as a permit holder for the same cadmium-109 human research that was conducted at the licensee's facility, and the inspectors reviewed records of that correspondence.

The inspectors noted that the licensee had implemented immediate corrective action in response to its self-identified violation prior to this inspection; however, the licensee did not implement comprehensive action to address the cause of the violation to prevent recurrence. As a result of the inspection, the cause of the violation was identified as the aforementioned Doctor's response of "No." to Item 21.2 of the eResearch Application, which resulted in the application not being forwarded to the RDRC/SHUR for approval. As comprehensive corrective action, the licensee committed to revise the verbiage in its eResearch Application to ensure that it specifically captures requests for external use of radioactive sealed sources on human research subjects such that those requests are forwarded to the RDRC/SHUR for approval. The Doctor's request for human use research involving sealed sources of licensed material used external to human research subjects' bodies was the licensee's only request of its kind as of this inspection.

During review of the aforementioned email message dated June 15, 2012, from a SHUR member to a licensee staff member that was carbon copied to the licensee's RSO, the inspectors noted that one of the SHUR members appeared to believe that requests for human research that do not involve ingestion of a radiopharmaceutical need not be reviewed by the SHUR. In response to this finding, the licensee planned to take action to ensure that the eResearch Application process correctly captures all human use research requests to ensure that they are approved in accordance with Condition 28 of its NRC license.

The inspectors noted that the cadmium-109 source measured 0.3 millirem per hour at about four inches from the unshielded source based on a licensee staff member's survey that was conducted with an Ion Chamber instrument. The inspectors did not conduct a confirmatory survey of the source because the inspectors' NRC-owned survey instrument began to malfunction earlier during the inspection.

The inspectors observed an individual who was involved with the cadmium-109 human use under the Doctor's supervision demonstrate how the research was done. The inspectors noted, in part, that the individual donned dosimetry badges in accordance with the licensee's permit authorization and used time, distance and shielding to reduce occupational radiation dose. Based on discussions with individuals currently involved with use of the cadmium-109 source, the individuals were aware that they were not authorized to use the source for human use research.

The inspectors observed an individual who was involved with the cadmium-109 human use under the Doctor's supervision demonstrate how she would respond to abnormal,

realistic scenarios posed by the inspectors. The individual provided adequate responses to scenarios involving loss of the source and damage to the source, both of which included contacting the RSS. The inspectors observed a member of the RSS staff demonstrate how he would respond to calls involving loss of the cadmium-109 source and damage to the source, and the staff member's responses were adequate.

### 2.3 Conclusions

The inspectors identified a violation of Condition 28 of the NRC license involving use of cadmium-109 for human research without the required approval by the SHUR or the RDRC.

## **3 Notification of Cessation of Principal Activities**

### 3.1 Inspection Scope

The inspectors reviewed the licensee's actions associated with cessation of principal activities in the Murchie Science Building (MSB), a separate building at the licensee's campus in Flint, Michigan, by interviewing selected licensee staff members; reviewing selected licensee records, including survey records and leak test records; touring selected facilities; and observing the licensee conduct removable and ambient count rate surveys of selected areas of the building.

### 3.2 Observations and Findings

Since 1989, the licensee possessed a Shimadzu Gas Chromatograph (GC) Model GC-14A, Serial No. 82060DN, containing approximately 10 millicuries of nickel-63 (Source Serial No. SS-599) at the MSB. The licensee thought that the GC was possessed and used pursuant to a General License (GL); however, the inspectors observed that the GC had no labels or tags indicating that it was authorized under a GL. In addition, the licensee was unable to provide documentation to determine if the GC was authorized under a GL.

A Shimadzu representative determined that there was no record of a GL associated with the nickel-63 source with Source Serial No. SS-599. In addition, the Shimadzu representative was told by someone who had worked at Shimadzu when the source was sold in 1989 that the majority of GCs that were distributed from Shimadzu during that era were distributed to clients authorized to receive and use the GCs by a specific license issued by the NRC or an Agreement State. In addition, the inspectors corresponded with a member of the NRC Headquarters staff who searched applicable NRC databases, including, in part, the General License Tracking System database and the search results indicated that the GC was not distributed under a general license. Based on the information provided by the Shimadzu representative and a member of the NRC Headquarters staff, and the absence of labels or tags on the GC indicating that it was authorized under a GL, the inspectors concluded that the GC was not possessed by the licensee under a General License.

The inspectors identified that the GC was authorized on the specific license in 1989 and at the time of this inspection. For example, Items 6.J., 7.J., 8.J., and 9.J. of Amendment No. 100 of the specific license authorized, in part, nickel-63 plated sources totaling no more than 50 curies for research and development as defined in 10 CFR 30.4, including

educational instruction or demonstration. As such, the inspectors determined that a principal activity associated with the GC was research and development as defined in 10 CFR 30.4, including educational instruction or demonstration. The GC was used for research and development and demonstration purposes; however, the GC had not been used since 2003.

In addition to the GC, the licensee had conducted research and development, including DNA sequencing, with carbon-14, hydrogen-3, phosphorus-32, sulfur-35, and radioiodine involving low microcurie quantities per experiment at the MSB. The inspectors identified that Amendment No. 100 of the specific license authorized, in part, use of carbon-14, hydrogen-3, phosphorus-32, sulfur-35, and radioiodine for research and development as defined in 10 CFR 30.4. As such, the inspectors determined that a principal activity associated with carbon-14, hydrogen-3, phosphorus-32, sulfur-35, and radioiodine was research and development as defined in 10 CFR 30.4. The licensee's last use of licensed material at the MSB involved research and development with phosphorus-32, a principal activity, which ceased in approximately October 2004.

The inspectors reviewed selected licensee survey records of MSB rooms where licensed material had been used, including ambient count rate and removable contamination survey records dated March 30, 1999, for Room 285A; September 20, 2001, for Rooms 280A and 283; September 27, 2002, for Room 481; December 5, 2003, for Rooms 577, 577A, and 577B; April 28, 2005, for Room 560; and April 27, 2010, for Rooms 268, 279. The surveys were conducted after the last use of licensed material in the rooms. The survey records indicated that no residual radioactivity was present in accessible areas of the rooms.

The inspectors toured several MSB rooms and observed an RSS staff member conduct ambient count rate and removable contamination surveys of accessible areas selected by the inspectors; including areas in Rooms 560 and 577A. The staff member used a pancake probe affixed to a survey instrument that was last calibrated in July 2012 for conducting the count rate surveys. The staff member used a liquid scintillation counter to obtain removable contamination survey results. The survey results indicated that no residual radioactivity was present.

The inspectors observed that the GC was stored in the MSB and it appeared to be in good condition. The inspectors observed leak test records of the GC nickel-63 source dated April 30, 2012, October 17, 2012, and April 26, 2013, and the results were negative. The GC nickel-63 source represented residual radioactivity present at the MSB.

As of July 16, 2013, the licensee had not notified the NRC in writing that no principal activities had been conducted for a period of 24 months in any separate building or outdoor area that contained residual radioactivity such that the building is unsuitable for release in accordance with NRC requirements.

Title 10 CFR 30.36(d) requires, in part, that within 60 days of the occurrence of no principal activities being conducted for a period of 24 months in any separate building that contains residual radioactivity such that the building is unsuitable for release in accordance with NRC requirements, the licensee shall provide notification to the NRC in writing of such occurrence. The licensee's failure to provide notification to the NRC in

writing within 60 days of no principal activities being conducted at the MSB, a separate building that contained residual radioactivity (e.g., the nickel-63 GC source) such that the building is unsuitable for release in accordance with NRC requirements, is a violation of 10 CFR 30.36(d)(4).

The inspectors determined that the cause of the violation was the licensee's misinterpretation of 10 CFR 30.36(d). Specifically, the licensee misinterpreted that the definition of "principal activities" as defined in 10 CFR 30.4 included the licensee's continued research and development in the MSB without using licensed material. The licensee also misinterpreted "residual radioactivity" as defined in 10 CFR 20.1003 to exclude, in part, the nickel-63 GC source because the GC had no measurable radiation and the nickel-63 source had no history of leakage.

The licensee disagreed with the violation for failure to provide notification to the NRC in writing within 60 days of no principal activities being conducted at a separate building for a period of 24 consecutive months, and the building contained residual radioactivity such that it was unsuitable for release in accordance with NRC requirements; therefore, the licensee did not provide corrective actions for this violation.

### 3.3 Conclusions

The inspectors identified a violation of 10 CFR 30.36(d)(4) involving failure to provide notification to the NRC in writing within 60 days of no principal activities being conducted at the MSB, a separate building that contained residual radioactivity such that the building is unsuitable for release in accordance with NRC requirements.

## 4 Other Areas Inspected

### 4.1 Inspection Scope

The inspectors reviewed other areas of the licensee's radiation protection program by interviewing selected staff, observing licensed activities, observing demonstrations of how licensed activities had been or would be conducted based on scenarios posed by the inspectors, and reviewing selected records. Areas reviewed included, in part, licensed material access control, occupational dose monitoring, medical use of licensed material, research, survey instrument calibration, management oversight, radiation surveys, compliance with the Decommissioning Planning Rule (10 CFR 20.1402), corrective actions taken to prevent previously cited violations, safety checks on an irradiator pertinent to the air compressor and loss of electrical power, and radioactive waste handling.

### 4.2 Observations and Findings

The inspectors noted that: (1) licensee personnel controlled access to licensed materials, in use and in storage; (2) the licensee monitored appropriate personnel for radiation exposure when they used licensed materials, and no individuals received occupational doses above regulatory limits; (3) licensee personnel involved with diagnostic and therapeutic medical use of licensed material demonstrated adequate knowledge of radiation safety concepts and procedures; (4) survey instruments were properly calibrated and used; (5) RPC meetings included appropriate attendance and



topics; (6) audits of the licensee's radiation safety program and reviews of individual laboratories were comprehensive; (7) confirmatory surveys yielded results that were consistent with the licensee's survey records and postings; and (8) the licensee retained the results of surveys important to decommissioning, such as identified contamination that will require remediation to meet the unrestricted use criteria of 10 CFR 20.1402.

While reviewing the licensee's corrective actions for a Severity Level IV violation of 10 CFR 35.40(b)(5) that was cited on March 20, 2012, concerning the failure to document the number of fractions on a written directive for an HDR treatment, the inspectors observed that the licensee: (1) revised the written directive form to require documentation of the number of fractions in two areas of the form; and (2) revised the checklist for high dose rate remote afterloader brachytherapy (HDR) treatments to require verification that the number of fractions was documented on the written directive. Personnel preparing written directives for HDR treatments described these actions and demonstrated that the revisions ensured that the number of fractions is documented on the written directive. The licensee's corrective actions were adequate to prevent a similar violation; therefore, the violation is closed.

While reviewing the licensee's corrective actions for a Severity Level IV violation of 10 CFR 35.63(d) that was cited on July 17, 2012, concerning the use of a nuclear medicine dosage that differed from the prescribed dosage by more than 20 percent, the inspectors observed that the licensee provided refresher training to all nuclear medicine technologists (NMTs) on the requirement to verify that the labels on the syringe indicated that the dosage matched the prescribed dosage for the patient. In addition, the licensee reviewed that requirement more often with the staff. The inspectors noted that licensee personnel performed periodic spot checks to monitor the NMTs' performance. NMTs stated that they were instructed to circle the patient's name and initial the chemical form of the dosage to demonstrate that they reviewed that information prior to administering the dosage to the patient. The licensee's corrective actions were adequate to prevent a similar violation; therefore, the violation is closed.

The inspectors observed that the licensee's safety checks on an irradiator pertinent to the air compressor and loss of electrical power included all of the required checks. The inspectors noted that the safety checks were conducted monthly.

During the inspectors' observations of a Senior OSEH Representative's (Representative) demonstrations of how radioactive waste was handled at the licensee's North Campus Transfer Facility (NCTF), the inspectors noted that: (1) the authorized trash compactor had not been used to compact radioactive waste for approximately 13 years; (2) fire extinguishers were charged and checked at the appropriate frequency; (3) compaction of radioactive waste would include, in part, recording the content of licensed material, use of personal protection equipment, personnel radiation surveys to identify radioactive contamination, and use of calibrated and appropriate survey instruments; (4) compactor air effluent ducts were equipped with filter banks and pressure differential gauges; (5) decay-in-storage was implemented as required; (6) liquid waste containers were on spill trays; (7) the facility liquid waste area had a bermed entrance and epoxy floors; and (8) an area air sampler was installed in the room for ambient airborne activity assessment and it employed charcoal and particulate filter sampling media. In addition, the inspectors observed a member of the licensee's staff collect removable

contamination samples from trash compactor surfaces that were selected by the inspectors. All of the survey results were negative for removable radioactive contamination.

During the inspectors' observations of the Representative's demonstrations of how radioactive waste was handled at the licensee's Medical Science Research Bldg. - III Waste Facility (MSRB-III), the inspectors noted that: (1) the facility had a water sprinkler fire suppression system; (2) radioactive waste was not compacted at the facility; (3) both entry doors were secured from unauthorized access; (4) fire extinguishers were charged and checked at the appropriate frequency; (5) a calibrated ion chamber survey instrument was available for use; and (6) the Representative conducted proper operability and battery checks prior to use of a calibrated survey instrument.

#### 4.3 Conclusions

The licensee effectively implemented other areas of its radiation safety program.

### **5 Exit Meeting Summary**

On June 28, 2013, the inspectors presented preliminary inspection findings following the onsite inspection. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. Telephonic exit meetings were conducted on August 13, 2013 and September 24, 2013. The licensee acknowledged the findings presented.

ATTACHMENT: SUPPLEMENTAL INFORMATION

**SUPPLEMENTAL INFORMATION**

**PARTIAL LIST OF PERSONNEL CONTACTED**

Robert Ackerman, Chief Nuclear Medicine Technologist  
^\*Terry Alexander, Executive Director of Occupational Safety and Environmental Health (OSEH)  
Kathy Andrews, Director of Operations, Life Sciences Institute  
\*James Ashton-Miller, Associate Vice President  
Larry Atherton, Laboratory Supervisor  
\*Stuart Berry, Senior OSEH Representative  
\*Lois Brak, Assistant Vice President for Research-Regulatory Compliance and Oversight  
Bonnie Brown, Associate Director of the Medical School Facility  
Brent Carriveau, Officer, University of Michigan Police Department  
Michelle Coeman, Laboratory Supervisor  
Mary Davis, Authorized User  
#\*Mark Driscoll, Radiation Safety Officer  
David Dupuis, Police Command Specialist  
\*Karl Fischer, Health Physicist  
\*Russell Garcia, Health Physicist  
David Hubers, R.Ph., Nuclear Medicine Pharmacist  
Siyang Huang, Supervised User  
John Hufziger, Director of Infrastructure Services  
\*Ray Hutchinson, Associate Director, Medical School  
Eric Kolb, Information Network Administrator  
Susan Lawson, Nuclear Medicine Technologist  
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^\*Joe Miklos, Senior Health Physicist  
Jenniffer Neault, Secretary, Radiation Safety Service  
\*Ruthan Nichols, Chair, Radiation Protection Committee  
^\*Dennis Palmieri, Senior Health Physicist  
Sung Park, Authorized User  
Joann Prisciandaro, Ph.D., Medical Physicist  
Justin Quinn, Health Physicist  
Anthony Ricco, Officer, University of Michigan Police Department  
Shawn Rice, Technician, RSS  
Bruce Richardson, Authorized User  
Victor Tkachev, Supervised User  
\*Stan Uitti, Health Physicist  
\*Pat Ward, Director, Medical School Regulatory Affairs  
Monique Wilhelm, Laboratory Supervisor  
\*Diane Wilson, Regulatory Specialist, Medical School

\* Attended preliminary exit meeting on June 28, 2013

^ Participated in the telephonic exit meeting on September 20, 2013

# Participated in the telephonic exit meeting on September 24 2013

**INSPECTION PROCEDURES USED**

TI2600/017  
87134

Attachment