UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

June 29, 2017

Mr. Bryan Lowry
Interim Site Director
Mallinckrodt Nuclear Medicine, LLC
2703 Wagner Place
Maryland, MO 63043

SUBJECT: NRC ROUTINE INSPECTION REPORTS NO. 03000001/2017001(DNMS), 03038173/2017001(DNMS), AND 03010801/2017001(DNMS) – MALLINCKRODT NUCLEAR MEDICINE, LLC; AND NOTICE OF VIOLATION

Dear Mr. Lowry:

On January 23, 2017, through January 27, 2017, three inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Maryland Heights, Missouri facility with continued in-office review through May 22, 2017. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of three incidents entered into your corrective action program and a review of your assessment of dose to members of the public for calendar years 2014 and 2015 from Mallinckrodt's operations. Ms. Deborah A. Piskura of my staff conducted a final exit meeting by telephone with you, Mr. Manuel Diaz, and other members of your staff on May 22, 2017, to discuss the inspection findings. The enclosed inspection report presents the results of the inspection (Enclosure 2).

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations, as well as 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, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated 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 violation involved the failure to conduct an adequate radiation survey to evaluate the potential radiological conditions (personal contamination) before exiting a restricted area as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1501. The violation is cited in the enclosed Notice of Violation (Notice) (Enclosure 1), and the circumstances surrounding it are described in detail in Enclosure 2. The violation is being cited in the Notice because it was identified by the inspectors. The violation is of particular concern because the contamination resulted in a significant personnel exposure. The inspectors attribute the cause of the spread of the contamination to the employee's failure to conduct adequate personal surveys, including surveys of items carried out of the laboratory where radioactive material was handled.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

Based on the results of this inspection, the NRC has also determined that two additional Severity Level IV violations of NRC requirements occurred. Because Mallinckrodt Nuclear Medicine, LLC identified these violations and entered them into its corrective action program, these violations are being treated as Noncited Violations (NCVs), consistent with Section 2.3.2 of the Enforcement Policy. The NCVs concerned: (1) unauthorized transfers of two depleted uranium shields, as required by 10 CFR 40.51(a) and 40.51(b)(5); and (2) the failure to timely submit an annual report of the results of individual monitoring for each individual for whom monitoring was required by 10 CFR 20.1502 during that year, as required by 10 CFR 20.2206. These NCVs are described in Enclosure 2. If you contest the violations or significance of these NCVs, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region III; and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response 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. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Ms. Piskura if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

/RA/

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

Docket Nos. 030-00001; 030-38173;
030-10801
License Nos. 24-04206-01; 24-04206-02;
24-04206-05MD

Enclosures:
1. Notice of Violation
2. IR Nos. 03000001/2017001(DNMS);
03038173/2017001(DNMS);
03010801/2017001(DNMS)

cc w/encls: Mr. Manuel Diaz, Radiation
Safety Officer
State of Missouri

Letter to Mr. Bryan Lowry from Aaron McCraw, dated June 29, 2017

SUBJECT: NRC ROUTINE INSPECTION REPORTS NO. 03000001/2017001(DNMS), 03038173/2017001(DNMS), AND 03010801/2017001(DNMS) – MALLINCKRODT NUCLEAR MEDICINE, LLC; AND NOTICE OF VIOLATION

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NOTICE OF VIOLATION

Mallinckrodt Nuclear Medicine LLC
Maryland Heights, Missouri

Docket No. 030-00001
License No. 24-04206-01

During an NRC inspection conducted on January 23 through 27, 2017, with continued in office review through May 22, 2017, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations of quantities of radioactive materials, and the potential radiological hazards that could be present.
>
> Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.
>
> Contrary to the above, the licensee did not make surveys to ensure compliance with 10 CFR 20.1201, which limits occupational doses to workers, and 10 CFR 20.1802, which requires that licensed material in unrestricted area and not in storage be controlled. Specifically, a Mallinckrodt employee did not perform an adequate survey upon leaving the cyclotron chemistry laboratory of Building 700 on October 10, 2016. As a result, the individual exited the licensee's restricted area with contamination on a notebook and on his person and spread the contamination to items in an unrestricted area.

This is a Severity Level IV violation (Section 6.7).

Pursuant to the provisions of 10 CFR 2.201, Mallinckrodt Nuclear Medicine LLC 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 for the violation: (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 previous 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 requiring information 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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC's Public Document Room or in 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. 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.

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

Dated this 29th day of June 2017.

U.S. Nuclear Regulatory Commission
Region III

Docket Nos.	030-00001 030-38173 030-10801
License Nos.	24-04206-01 24-04206-02 24-04206-05MD
Report Nos.	03000001/2017001(DNMS) 03038173/2017001(DNMS) 03010801/2017001(DNMS)
Licensee:	Mallinckrodt Nuclear Medicine, LLC
Facility:	2703 Wagner Place Maryland Heights, Missouri
Inspection Dates:	January 23-27, 2017, with continued in-office review to May 22, 2017
Exit Meeting Date:	May 22, 2017
Inspectors:	Deborah A. Piskura, Senior Health Physicist Materials Inspection Branch Bryan A. Parker, Senior Health Physicist Materials Licensing Branch Peter J. Lee, Ph.D., CHP, Health Physicist Materials Control, ISFSI, and Decommissioning Branch
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Mallinckrodt Nuclear Medicine, LLC
NRC Inspection Report 03000001/2017001(DNMS)

On January 23-27, 2017, with continued in-office review to May 22, 2017, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine team inspection of Mallinckrodt Nuclear Medicine, LLC's (licensee) Maryland Heights, Missouri manufacturing facility. The inspection reviewed the licensee's activities conducted under its manufacturing (-01), cyclotron production (-02), and medical distribution (-05MD) licenses. The inspectors reviewed several program areas including management oversight, the corrective action program and incident investigation, external dose assessment, and area surveys. The inspectors reviewed seven incidents that occurred prior to the previous inspection: these incidents were entered into the licensee's corrective action program (CAP). This inspection included a review of the licensee's investigation of an incident that occurred on October 10, 2016, involving personnel contamination; the incident was considered the most significant incident entered into the CAP since the previous routine inspection.

One violation of NRC requirements was identified during this inspection involving the licensee's failure to conduct an adequate survey to assess personal contamination before exiting from a restricted area, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1501. The individual removed contaminated items from the restricted area and subsequently spread contamination to items in an unrestricted area. The inspectors determined that the October 10, 2016, contamination incident resulted from ineffective contamination control techniques by the individual who worked in the cyclotron chemistry laboratory. Although the individual initially identified contamination on his hands, the individual exited the restricted area and removed a contaminated laboratory notebook from the restricted area. The individual proceeded to spread contamination to items in his office, an unrestricted area. The violation is of particular concern because the contamination resulted in a significant personnel exposure. The inspectors attributed the cause of the spread of the contamination to the employee's failure to conduct adequate personal surveys, including surveys of items carried out of the laboratory where radioactive material was handled.

Two other violations of NRC requirements were identified during this inspection. These violations involved: (1) unauthorized transfers of two depleted uranium shields, as required by 10 CFR Section 40.51(a) and 40.51(b)(5); and (2) the failure to timely submit an annual report of the results of individual monitoring for each individual for whom monitoring was required by 10 CFR 20.1502 during that year, as required by 10 CFR 20.2206. These non-repetitive, licensee-identified, and corrected violations are being treated as Noncited Violations (NCV), consistent with Section 2.3.2.b of the NRC Enforcement Policy.

REPORT DETAILS

1.0 Program Overview and Inspection History

Mallinckrodt Nuclear Medicine LLC (licensee) was authorized for licensed activities under three NRC licenses, 24-04206-01 (the broad scope manufacturing), 24-04206-02 (cyclotron production), and 24-04206-05MD (medical distribution). The licensee operated a Type A broad scope manufacturing and distribution program, with authorization to conduct animal studies. The majority of the licensee's operations involved the manufacture and distribution of dry top elution molybdenum-99/ technetium-99m generators (approximately 500 units per week). The licensee's dry top elution generators contained lead or depleted uranium shielding. The licensee received its raw molybdenum-99 from its sister plant in the Netherlands. The licensee also produced and/or processed: xenon-133, sodium iodide-131 and iodide-123, thallium-201, indium-111, germanium-68, gallium-67, and other cyclotron-produced products, as well as cold products/kits for compounding radiopharmaceuticals. No animal research was conducted at the time of this inspection. Between April and October 2016, the licensee reactivated its manufacture and distribution activities for xenon-133. At the time of this inspection, the licensee had ceased these activities.

All licensed activities were performed at the Maryland Heights complex. The licensee employed approximately 300 individuals at its site. Buildings 100 and 200 housed administrative offices and research laboratories. The licensee stored waste in Building 250. Product storage, dispensing, and packaging operations, as well as customer support and verification operations were conducted in Building 300. The licensee used Building 400 to prepare its products for shipment. All manufacturing of radiopharmaceuticals was performed within Building 600. The licensee utilized an underground conveyor system between Buildings 400 and 600 for the movement of completed generator units for packaging. The licensee used Building 500 for the storage, processing, and separation of low-level radioactive waste and the handling and processing of all liquid radioactive wastes. In Buildings 700 and 800, the licensee housed six cyclotron units used for the production of various materials under its NRC License No. 24-04206-02; at the time of this inspection, five units were in operation for the production of isotopes. Building 150 served as the licensee's main warehouse where returned generators were dismantled for the recovery and reuse of the shielding material (lead or depleted uranium) or the safes.

During the last routine inspection on September 21 to 25, 2015, with continued in office review to December 21, 2015, the inspector identified unresolved items concerning two elevated personnel extremity exposures and one high radiation area event entered into the licensee's CAP. The NRC conducted a special follow-up inspection on January 12-15, 2016, with continued in office review to February 19, 2016, to review these unresolved items. Four violations of NRC requirements were identified during the special follow-up inspection. The violations concerned two failures to implement a procedure and one failure to maintain a procedure, as required by License Condition 20. The fourth violation concerned the failure conduct adequate radiation surveys to evaluate the potential radiological conditions before performing work on a contaminated component as required by 10 CFR 20.1501. These non-repetitive, licensee-identified,

and corrected violations were dispositioned as NCVs, consistent with Section 2.3.2.b of the Enforcement Policy. The NRC also conducted a special inspection on October 22, 2015, to observe the licensee's biennial emergency response exercise; no violations were identified during that inspection.

2.0 Program Oversight and Radiation Safety Committee

2.1 Inspection Scope

The inspectors reviewed the licensee's oversight and implementation of its radiation protection program. The review included health physics staffing, the radiation safety committee (RSC), and annual reviews. The inspectors interviewed selected licensee staff, reviewed selected records, and toured facilities. The inspectors reviewed RSC meeting minutes from September 2015 to 2016.

2.2 Observations and Findings

The radiation safety program was managed by a dedicated, full-time radiation safety officer (RSO), supported by three health physicists and five health physics technicians. The RSO reported to the director of environmental health and safety who in turn, reported to the site director. Since the on-site inspection, the individual who served as the director of environmental health and safety retired, and the position has been eliminated. The health physics staff audited all areas of use and storage at frequencies based on the amount of material processed/used. The health physics staff also performed confirmatory surveys (daily, weekly, and quarterly based on amount of material and use) of these areas to ensure compliance with its NRC license and regulations. The health physics staff promptly responded to contamination events and spills.

The licensee established a RSC to review its uses, users and facilities. The membership of the committee included staff from various manufacturing groups. The licensee conducted RSC meetings on a quarterly basis. The licensee established a quorum for each RSC meeting and documented its business in meeting minutes. The meeting topics included approval of new uses and users; dose reduction initiatives, items entered into the CAP, and radiation protection issues.

The licensee reviewed the content of its radiation protection program annually. The last annual review for calendar year 2015 was conducted in March and September 2016. The licensee documented the results of its annual reviews and presented the audit findings and recommendations to the RSC. For 2015, the audit team made a recommendation for improvements to shielding and work stations in order to reduce dose to workers; the licensee implemented these recommendations.

2.3 Conclusions

The RSC provided adequate oversight of the radiation protection program. The RSC's review of the radiation protection program ensured that procedures would be performed in a manner that would maintain doses "as low as is reasonably achievable" (ALARA). The inspectors identified no violations of NRC requirements.

3.0 Corrective Action Program

3.1 Inspection Scope

The inspectors reviewed select incidents identified by the licensee and entered into its corrective action program. The inspectors interviewed select licensee staff and reviewed select incident reports, corrective actions follow up and closure reports, and select incidents entered into the licensee's tracking database. The inspection included a review of the licensee's implementation of its corrective action program. The review included selected events in the licensee's incident reporting log for detailed evaluation, and interviews of selected licensee staff.

3.2 Observations and Findings

Condition 19 of License No. 24-04206-01 requires, in part, that the licensee maintain a CAP to identify and correct deficiencies associated with radiation safety. The licensee established a standard operating procedure (SOP) 33-201, "Corrective Action Program," effective date September 5, 2014. The licensee used its CAP to prioritize the significance of issues that require corrective action and track completion of corrective actions. The licensee established a procedure, SOP 33-138, "Incident Investigation," effective date September 5, 2014, describing its four investigation levels for incidents or items entered into its CAP. The RSO managed the implementation of the licensee's CAP. The investigation categories were based on the radiological significance of the incident. For example, the licensee would characterize a dose to personnel in excess of Part 20 limits as a Category 1 incident; Category 1 incidents would be investigated by a team with members outside of the licensee's Maryland Heights facility. An example of a Category 2 incident would include an unplanned acute extremity dose in excess of 5,000 millirem. Category 3 incidents included significantly elevated radiation levels in a posted or non-posted area and skin contamination. Category 4 incidents involved events with minor safety significance (typically, contamination of clothing or surfaces within the restricted areas) and these incidents were not tracked by the licensee. Based on the significance of an incident, the licensee could elevate its review to a higher category. The licensee used a commercially available software system for tracking the items entered into its CAP.

The RSO indicated that no significant events (Category 1) had occurred since the last inspection. Since the previous routine inspection in September 2015, the licensee entered seven incidents into its CAP at the Category 2 investigation level. These events involved elevated extremity and skin doses from germanium-68 uses, failure to provide a timely annual report for 2015 individual monitoring data to the NRC's Radiation Exposure Information and Reporting System (REIRS), missing labels on a package, unauthorized transfer of licensed material, failure to perform surveys of an incoming package, and the unexpected release of iodine-131 from a pressurized vessel (although contained within the glove box). Four of these events that represent radiological and regulatory significance are described in Sections 4 and 5 of this report.

A review of selected licensee incident reports indicated, in general, that the licensee determined the root cause(s) of the incident and implemented corrective actions to help prevent recurrence. In one incident, however, the licensee's root cause determination and corrective action proposal did not address the potential issues. Specifically, the report for incident number 16-0076, in which an individual became contaminated while

preforming work with germanium-68, provided no root cause for the contamination event. The licensee's incident report stated that no corrective actions would be implemented for this incident based on the individual's education and professional certification. A fundamental goal of a CAP is to establish confidence that the licensee is effectively detecting, correcting, and preventing problems that could impact radiation safety. The inspectors noted that certain details pertinent to this incident involving an elevated skin dose from a germanium-68 contamination was omitted from the licensee's incident report and summary table and had the potential to minimize the institutional learnings from this event, which was similar to a finding from the previous special follow-up inspection, as discussed in NRC Inspection Report No. 03000001/2016001(DNMS). The details of this incident were revealed during interviews with the individual involved in the contamination incident. This event is further described in Section 5 of this report.

3.3 Conclusions

While no regulatory compliance issues were identified with the implementation of the CAP, the inspectors noted an indicator of the lack of specific event details that benefit the licensee's institutional learnings from events. This observation was also noted during the previous special follow-up inspection and described in NRC Inspection Report No. 03000001/2016001(DNMS).

4.0 Elevated Skin Doses from Germanium-68 Contamination (Incident Nos. 15-0128 and 16-0076)

4.1 Inspection Scope

The inspectors reviewed the circumstances of two incidents involving the handling of germanium-68 that resulted in elevated skin doses to two individuals. The inspectors reviewed selected records including the incident reports, the SOPs related to the tasks performed by the individuals, dosimetry badge records, and dose assessment records. The inspectors interviewed selected licensee staff including the RSO, health physicists and technicians, the individuals, and production laboratory personnel.

4.2 Observations and Findings

a. Incident No. 15-0128 Elevated Skin Dose from Germanium-68 use in glove box

On December 29, 2015, an individual, received an elevated skin dose while performing work with germanium-68 within a glove box where the exhaust fan was not turned on. The lack of the fan and ventilation created a higher than expected exposure to germanium-68 contamination to the individual performing the work. The licensee initiated an investigation of this incident and entered it as a Category 2 incident into its CAP.

On December 29, 2015, a cyclotron chemistry technician dispensed a quantity of germanium-68 in a bulk quantity vial for a customer. The individual performed the dispensing operation within a glove box in the cyclotron chemistry laboratory. A health physics technician observed this process. At the completion of the dispensing process,

the health physics technician surveyed the cyclotron chemistry technician and identified contamination on the individual's beard. The technician's electronic dosimeter read 85 millirem; however, the staff did not hear an audible alarm from the electronic dosimeter at any time during this dispensing operations. The licensee subsequently determined that the technician's electronic dosimeter malfunctioned due to a corroded wire.

The health physics office responded to the incident. Health physics staff decontaminated the individual's beard and collected a urine sample and nasal swabs. A small amount of germanium-68 was detected in the nasal swabs and the urine sample analysis revealed approximately 124 net counts in the urine. Health physics staff instructed the individual to collect a 24-hour urine sample for internal dose assessment; the licensee assigned a dose of less than one millirem. The licensee sent his dosimetry to the vendor for emergency processing. The licensee restricted the individual from work with licensed material until it received the results of dosimetry analysis.

Although instructions in the SOP informed the user to turn on the blower, the individual stated that he was unaware that he needed to manually turn on the ventilation blower for the glove box. On January 6, 2016, the dosimetry vendor provided the individual's dose report to the licensee: 331 millirem whole body and 777 millirem extremity for the monitoring period of December 2015. The licensee determined that the individual exceeded his annual ALARA goal and quarterly threshold. The 2015 annual occupational dose for the individual was reported as 2,036 millirem whole body and 3,409 millirem extremity; these doses were below the annual occupational dose limits listed in 10 CFR 20.1201.

The licensee determined that the root causes of this incident included lack of training and a failure to follow the SOP for performing work within the glove box. None of the procedures for working with germanium-68 were referenced in the licensee's NRC license; therefore, failure to follow them did not constitute a violation of NRC regulatory requirements. The malfunctioning dosimeter unit contributed to the incident because no audible alarm could be heard that may have alerted the staff of elevated radiation levels within the glove box. The licensee's corrective actions included providing training to its personnel and relocating these germanium-68 dispensing operations to the hot cell. Operations within the licensee's hot cell are not dependent on the user to manually turn on the ventilation/filtration system.

b. Incident No. 16-0076 Elevated Skin Dose from Germanium-68 contamination

On October 10, 2016, an individual identified that he was contaminated with germanium-68 at the completion of performing a reaction in a chemical fume hood. The licensee initiated an investigation of this incident and entered it as a Category 2 incident into its CAP.

On October 10, 2016, an individual performed two routine chemical scrubber reactions using germanium-68 within a fume hood in the cyclotron chemistry laboratory of Building 700; one reaction study performed in the morning and the second study performed in the early afternoon. The individual donned personal protective equipment consisting of disposable coveralls over his street clothes and two layers of latex gloves. The individual identified no contamination at the completion of the first reaction study and

exited the laboratory. The individual re-entered the laboratory at approximately 1:00 pm to resume another study. After completion of the work, the individual de-gowned and exited the laboratory, a restricted area. He identified through personal surveys that his hands, face, and beard were contaminated. The individual notified the health physics staff of his personal contamination. The individual left the laboratory/gowning area, carrying a contaminated notebook and pen, and waited for health physics staff to respond in his office. The individual spread contamination to a computer keyboard in his office, an unrestricted area.

A health physics technician responded to the incident, searched for the individual, and found him in his office. Initial surveys of the individual identified contamination of approximately 5,000 counts per minute (cpm) on the face and 4,000 cpm on the right hand. These surveys also identified contamination that the individual had spread to a pen, laboratory notebook, and a computer keyboard; these items were located in the individual's office, an unrestricted area. The health physics technician collected the contaminated articles and brought the individual to the health physics office. Initial decontamination efforts with soap and water reduced the contamination of the individual's right hand and face to levels indistinguishable from background. Surveys measured contamination on individual's shirt and abdomen at approximately 50,000 cpm. A senior health physicist reevaluated this contamination on the abdomen at approximately 200,000 cpm.

The health physics staff licensee attempted to decontaminate the individual's abdomen through multiple washes with soap and water, progressing to a mild chloride solution. These efforts were unsuccessful at reducing the contamination; the licensee assumed the contamination was fixed. The licensee released the individual with instructions to collect a 24-hour urine sample. The licensee provided the individual with a survey instrument and instructions to shower and conduct personal contamination surveys. During that evening the individual bathed at his residence, performed additional personal surveys and noted no contamination.

The individual returned to the health physics staff on the following morning, October 11, 2016, for additional surveys, which identified no contamination on his person. The health physics staff analyzed the urine sample and detected no germanium-68 activity and no uptake.

Based on the licensee's dose assessment, the licensee assigned a skin dose of 8.5 rem to the individual's abdomen. The licensee forwarded the results of its dose calculations for the individual to the dosimetry badge vendor for entry into the permanent dose record. The NRC performed an independent dose assessment for the individual using Varskin® 4 code; the NRC's results were higher than the licensee's dose assessment with a skin dose of 10 rem. The discrepancy was attributed to the dose contribution of the decay products and the time that the material remained on the individual's skin. The licensee agreed to modify the reported dose to the individual.

Although the licensee identified and entered this incident into its CAP, the licensee's investigation did not determine a root cause for the contamination incident. The licensee's rationale for a lack of corrective actions for this incident were based on the individual's education, experience, and professional certification. The inspectors' interview with the individual revealed that the most likely cause of the spread the

contamination was by transfer from his hands to the laboratory notebook to his abdomen. The individual demonstrated how he carried his notebook, placed on the abdomen which most likely contaminated his personal clothing and seeped through the shirt to his skin. These details of the incident were not described in the licensee's incident report. The individual stated that he is knowledgeable and conscientious of the importance of performing adequate surveys. The individual indicated that he was rushing to make an appointment.

Title 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations of quantities of radioactive materials, and the potential radiological hazards that could be present. Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. Title 10 CFR 20.1201(a)(2)(ii) requires, with exceptions not applicable here, that the licensee control occupational dose to the skin or to any extremity of individual adults to an annual dose limit of 50 rem shallow-dose equivalent.

The licensee's failure to make surveys to ensure compliance with 10 CFR 20.1201, which limits occupational doses to workers, and 10 CFR 20.1802, which requires that licensed material in unrestricted area and not in storage be controlled is a violation of 10 CFR 20.1501. Specifically, a Mallinckrodt employee did not perform an adequate survey upon leaving the cyclotron chemistry laboratory of Building 700 on October 10, 2016. As a result, the individual exited the licensee's restricted area with contamination on a notebook and on his person, and spread the contamination to items in an unrestricted area.

The violation is of particular concern because the contamination resulted in a significant personnel exposure. The inspectors attribute the cause of the spread of the contamination to the employee's failure to conduct adequate personal surveys, including surveys of items carried out of the laboratory where he had just handled radioactive materials. The individual left the laboratory with contamination, and removed contaminated items from the area. The licensee's investigation did not address the cause of the contamination. The licensee's report did not disclose that once the individual exited the laboratory with contamination on his person that he carried contaminated items out of the laboratory and proceeded to spread contamination to his computer key board in his office, an unrestricted area. The licensee surveyed the fume hood and cart within the laboratory and found no contamination. The licensee's investigation of this incident was misdirected because the health physics staff did not perform a reenactment of this incident or observe future chemical reaction experiments with this individual in an effort to determine the root cause(s) and develop corrective actions. Because a root cause was not thoroughly evaluated, the licensee did not pursue corrective actions to address the basic issue, specifically the individual's failure to remain in a controlled area while contaminated with radioactive material. Additionally, the licensee did not evaluate any potential offsite contamination (e.g., the individual's residence or vehicle), as a result of this incident.

The inspectors reviewed the licensee's radiation protection program and procedures for performing a personal contamination survey. The review determined that while the

licensee's procedure informed the individual to contact health physics staff if contamination is identified, the procedure did not require/instruct a contaminated individual to remain in the area until assistance arrives, thereby minimizing the potential for spreading contamination. The licensee's radiation protection program, Section 11, item 11.9, "Radioactive Spills," bullet 4 states, "Avoid spreading the spilled material by remaining just outside the spill area until surveyed for contamination. Do not leave the area…" Although this procedure was intended for spills, the inspectors determined that a lack of specific instructions in the licensee's procedure for performing a personal contamination survey contributed to this incident.

4.3 Conclusions

The inspectors identified a violation of 10 CFR 20.1501 specific to the October 10, 2016, germanium-68 contamination incident. The inspectors determined that the October 10, 2016, contamination event resulted from ineffective contamination control techniques. The contamination was spread to items in an unrestricted area through transfers of contamination from items removed from the restricted area within Building 700. The contamination was spread to items in an unrestricted area due to the employee's failure to conduct a reasonable and necessary survey. The licensee's root cause determination was narrowly focused on the cause of the contamination at the individual's work station within the cyclotron chemistry laboratory rather than the cause of the spread of contamination to an unrestricted area. The licensee's rationale for not pursuing corrective actions for this event was based on the on the individual's education, experience, and professional certification. The contamination event resulted in a significant skin dose to the individual. The licensee's procedures did not provide specific instruction a contaminated individual to remain in the area until assistance arrives, thereby minimizing the potential for spreading contamination.

5.0 Unauthorized Transfers of Depleted Uranium Generator Shields (Incident Nos. 15-0103 and 16-0027)

5.1 Inspection Scope

The inspectors reviewed the circumstances of two incidents involving unauthorized transfers of depleted uranium shielding. The inspectors reviewed selected records including the incident reports, interviewed selected licensee staff including the RSO, health physicists, and health physics technicians.

5.2 Observations and Findings

On October 1, 2015, a lead recycling plant notified the licensee of an item found in a batch of scrap lead was marked as "Caution Radioactive Shield Uranium." The lead recycling plant identified that a load of metal from the licensee contained a depleted uranium generator shield. The depleted uranium shield weighted approximately 21.3 kilograms (47 pounds). This source material is not considered a small quantity pursuant to 10 CFR 40.22 (a)(2), which grants a general license to possess source material no more than 7 kilograms (15.4 pounds) at any one time. The licensee initiated an investigation of this incident and entered it as a Category 2 incident into its CAP.

The health physics staff coordinated with its transportation group to arrange for its courier to retrieve, package, and transport the depleted uranium shield back to the Maryland Heights facility; the licensee received the depleted uranium shield on October 2nd. The licensee's investigation determined that personnel in the generator reclaim area mistook the depleted uranium shield as identified to be destroyed based on the markings, "JUNK" handwritten in marker across the top of the shield. According to the licensee's investigation, the staff noted that "dummy" stainless steel safes have similar physical appearance to depleted uranium generator shields, with markings "Training Purposes Only". The licensee attributed the root cause of the unauthorized transfer to a lack of training and confusing markings on the depleted uranium shield. The licensee's corrective actions included changes to the types of markings placed on depleted uranium shields and providing training to the staff.

On June 9, 2016, the licensee transferred a depleted-uranium-shielded generator to an Agreement State licensee that was not authorized by its license to possess depleted uranium. This source material is also not considered a small quantity pursuant to 10 CFR 40.22(a)(2). The licensee initiated an investigation of this incident and entered it as a Category 2 incident into its CAP.

The licensee used a software-based system for its distribution of radiopharmaceuticals to customers. The licensee also maintained an electronic copy of each of customer's license. For each order, the distribution system verified the customer's request against the customer's license authorizations. If the customer was not authorized to receive a radionuclide or quantity, the licensee's ordering system should display an alert, prompting additional review of the order by the staff. However, for this unauthorized transfer, the ordering and license verification system did display an alert, and the staff placed the order for a depleted-uranium-shielded generator instead of a lead-shielded generator. As part of its investigation, the licensee tested its ordering and license verification system by entering mock orders for customers known not to be authorized for depleted-uranium-shielded generators. These tests did not identify the known mock orders in the computer system. The transportation staff also simulated orders for customers known not to be authorized for the previous, obsolete V3 model depleted-uranium-shielded generators. These mock orders for depleted-uranium-shielded model V3 generators were identified by the licensee's database as "unauthorized." The licensee's staff identified a programming error in its ordering and license verification system concerning an incompatible product code for its new V4 generator line. The programming error allowed the customer to receive a depleted-uranium-shielded generator, on June 9, 2016, that was not authorized by its Agreement State license.

Title 10 CFR 40.51(a), states that no licensee shall transfer source material except as authorized pursuant to this section. Title 10 CFR 40.51(b)(5), requires, in part, that the licensee may transfer source material to any person authorized to receive such source material under terms of a specific license or a general license or their equivalent issued by the Commission or an Agreement State. The licensee's transfer of depleted uranium generator shields to two entities on October 1, 2015, and June 9, 2016, that were not authorized to received such source material is a violation of 10 CFR 40.51(a) and 40.51(b)(5).

The licensee attributed the root cause of the unauthorized transfer to an outdated computer programming code for its obsolete generator model that carried through to code for its new generator model. The licensee's corrective actions included revising its customer license verification system to correct the outdate computer programming code.

The licensee identified these incidents and entered them into the CAP. This non-repetitive, licensee-identified and corrected violation is being treated as a NCV, consistent with Section 2.3.2.b of the NRC Enforcement Policy.

5.3 Conclusions

One violation of 10 CFR 40.51(a) and (b)(5), with two examples, of NRC requirements was identified for two instances involving unauthorized transfer of depleted uranium to an entity who was not authorized to receive such source material. The licensee identified these incidents and entered them into the CAP. This non-repetitive, licensee-identified, and corrected violation is being treated as an NCV, consistent with Section 2.3.2.b of the NRC Enforcement Policy.

6.0 Production, Manufacturing, and Laboratory Uses

6.1 Inspection Scope

The inspection included observations of several production and manufacturing processes, as well as laboratory use of licensed material. The observations included radiation worker practices to ensure doses were ALARA, equipment performance, and adherence to procedures. The inspectors observed production processes in the generator line, the thallium line, and the germanium line. The inspectors toured the laboratory and production areas including the cyclotrons, interviewed select licensee staff, and reviewed select records. In addition, the inspectors observed a germanium-68 dispensing operation in the hot cell.

6.2 Observations and Findings

At the time of this inspection, the licensee operated five of its six cyclotrons to produce various isotopes. Each cyclotron was housed within a dedicated room behind a large shielded door. Access to the area was controlled. Material was discharged to hot cells to prepare the material for use. The facility also included numerous hot cells, mini-cells, laboratories, a machine shop, an analytical counting lab, and an exhaust unit. Several SOPs govern the cyclotron/hot cell/target handling activities. The inspectors observed cyclotron maintenance operations involving the replacement of a carbon multi-layer beam extraction foil. The inspectors observed cyclotron personnel perform surveys, use personal protective equipment and dosimetry, and use remote handling tools and portable shielding.

The inspectors observed hot cell operations for the preparation of a bulk quantity of germanium-68 in the cyclotron chemistry lab. The technician used time, distance, and shielding in accordance with ALARA principles to handle the material and measure the vial in the dose calibrator. The process involved capping the vial by hand, using a "crimper." This practice did not result in significant exposures to the personnel involved.

The inspectors observed generator manufacturing within the hot cell operations in the sterile core. The licensee demonstrated its quality assurance procedures. The licensee used process, design, and engineering controls implemented prior to the last inspection to maintain exposures to generator manufacturing workers ALARA and prevent significant contamination outside of the manufacturing enclosure.

At the time of this inspection, no radioiodine was received or dispensed; therefore, radioiodine handling was not observed by the inspectors. The inspectors toured the iodine production lab and evaluated the continuous air monitoring system (CAM). Based on sampling flow rates, detector efficiency, alarm set-points of counting rate, and background counting rate, the inspectors verified the alarm set-points and determined that the licensee maintained its workers' internal exposures to a minimum.

The licensee maintained its laboratories within Building 600 under negative pressure. Hot cells and glove boxes were monitored continuously to ensure they were maintained at negative pressure with respect to the adjacent rooms. The air exhaust ducts were connected to a main filter bank in the "penthouse." The filter bank included high-efficiency particulate air (HEPA) filters and activated charcoal filters arranged in a series to filter the air prior to release to the atmosphere. The licensee installed a radiation detector to continuously monitor the filtered air. The licensee established alarm set points to ensure that it would not exceed air concentration limits specified in 10 CFR Part 20 for isotopes currently in production. However, the inspectors noted that the alarm set point for xenon-133 had the potential to exceed the effluent release limit in 10 CFR Part 20, though no xenon-133 was being produced at the time of the inspection. The licensee agreed to reassess its xenon-133 alarm set point if production were to resume. The licensee staff calibrated the detector monthly, as well as monitored the efficiency of the filters. Any loss of minimum air flow through the filter bank triggered a local audible alarm within the affected laboratory and a remote alarm to health physics staff.

6.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspectors identified no violations of NRC requirements. Observations of production activities indicated that the licensee had been effective at ensuring that radiation workers conducted activities such that their exposures were ALARA. Radiation workers were knowledgeable of the operating procedures applicable to their activities.

7.0 Occupational Dose

7.1 Inspection Scope

The inspection included a review of the licensee's individual and collective occupational doses for calendar year 2015 to November 2016. The review included the results of individual personnel monitoring, interviews of licensee personnel, review of plant ALARA planning and goals, and observations of monitoring practices in production and laboratory areas.

7.2 Observations and Findings

The licensee provided whole body and extremity personnel monitoring devices supplied by a vendor that held current, applicable accreditation from the National Voluntary Laboratory Accreditation Program of the National Institute of Standards and Technology. The licensee exchanged monitoring devices monthly for approximately 240 staff. The licensee established a bioassay program to monitor its workers internal uptakes, as needed.

Manufacturing and laboratory personnel wore whole body and extremity (right and left) monitoring devices, including electronic dosimeters when signed in on radiation work permits (RWPs). The licensee used the electronic dosimeters to track radiation doses. The licensee established alarm set points to alert the worker of doses or dose rates that exceeded established thresholds. Based on interviews with licensee personnel, the inspectors concluded that licensee staff understood the limitations and authorizations of their individual RWPs and knew their RWP dose and dose rate alarm set points. The inspectors observed licensee personnel using time, distance, and shielding whenever possible to maintain their doses ALARA. The inspectors observed licensee staff frequently surveying work areas to maintain awareness of current radiological conditions. The inspectors noted that the doses were trending up for cyclotron operations.

The maximum personnel exposures for 2015 and year-to-date 2016 were reported as follows:

Year	Whole Body	Extremity
2015	2,036	19,638
January-November 2016	2,661	11,803

The licensee implemented a program for informing its staff of declared pregnant worker policies and procedures and for monitoring and recording fetal dose in accordance with 10 CFR 20.1208 and 20.2106. The licensee provided declared pregnant workers with separate fetal dose monitors; doses were individually tracked and monitored.

Title 10 CFR 20.2206 requires that the licensees identified in paragraph (a), including licensees who manufacture and distribute specified quantities of technetium-99m, submit an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by 10 CFR 20.1502 during that year, on or before April 30 of each year.

The licensee staff reviewed the 2015 annual exposure reports from the dosimetry vendor, which revealed numerous errors. The licensee identified that the dosimetry data for approximately 50 individuals were reported high (the exposures were doubled). Members of the licensee staff contacted the dosimetry vendor on several occasions requesting corrections to the exposure reports. According to the licensee, the vendor did not respond to its requests until the week of May 31, 2016. The vendor provided corrected exposure data on June 2, 2016; the licensee submitted its report to REIRS on June 3, 2016. The licensee's failure to submit its annual report or the results of individual monitoring for each individual for whom monitoring was required by 10 CFR 20.1502 during 2015, on or before April 30, 2016, is a violation of 10 CFR 20.2206.

The licensee determined that the root causes of the late filing of its 2015 exposure data was attributed to lack of institutional knowledge among the health physics staff (the responsible employee retired) and delays obtaining correct information from the dosimetry vendor. The licensee's corrective actions included adding a reminder to the office calendar and assigning an individual as a contact/liaison to the dosimetry vendor.

The licensee identified this incident and entered it into its CAP. This non-repetitive, licensee-identified, and corrected violation is being treated as a NCV, consistent with Section 2.3.2.b of the NRC Enforcement Policy.

7.3 Conclusions

One violation of NRC requirements was identified for the licensee's failure submit an annual report of the results of individual monitoring for 2015 as required by 10 CFR 20.1502 during that year on or before April 30, 2016. The licensee identified this violation and entered it into its CAP. This non-repetitive, licensee-identified, and corrected violation is being treated as a NCV, consistent with Section 2.3.2.b of the NRC Enforcement Policy.

8.0 Public Dose and Effluent Monitoring

8.1 Inspection Scope

The inspection included a review of the licensee's monitoring of public doses from licensed activities. The review included the results of public dose monitoring for the previous five years, with emphasis on public dose for calendar years 2014, 2015, and 2016, interviews with health physics staff and a review of selected records.

8.2 Observations and Findings

The licensee placed environmental thermoluminescent dosimeters (TLDs) at ten stations along the fence line of the site; these TLDs were exchanged monthly. The TLDs read doses between 8 and 398 millirem (mrem) for 2016 and between 15 and 352 mrem for 2015, with the highest doses at the fence line near Building 800. The doses from Building 800 were trending higher for the years 2015 and 2016 at the fence line due to a higher contribution from material stored in the spent target bunker. The licensee continues to assess its public dose contribution from the activities in Building 800. The licensee determined occupancy factors for these ten stations based on the fraction of the workweek during which the space beyond the fence line was potentially occupied. The licensee determined occupancy factors of either 0.03 (3 percent) and 0.30 (30 percent) for its fence line area. The licensee determined by calculation, applying the occupancy factors of each respective fence line TLD, that the dose to an individual member of the public did not exceed NRC's annual dose limit of 100 mrem per year. In the calendar years 2014 and 2015, licensee staff determined that the maximally exposed member of the public received approximately 35.7 and 33.9 mrem respectively, which is lower than NRC's annual limit of 100 mrem. If production increases further, the licensee will need to reassess potential doses to members of the public outside the fence line and take appropriate measures to ensure compliance with regulatory limits.

The licensee used a commercial software package to estimate public dose from its radionuclide emissions in air. The inspectors reviewed the licensee's evaluation to

demonstrate compliance with air effluent limits of 10 CFR 20.1301 and 20.1302 for the calendar years 2014 and 2015 for all nuclides produced or used at the plant. The licensee evaluated the public dose from its air effluents by determining the actual quantities produced or used at the plant, as well as air sampling data and applying appropriate release fractions. The results of the licensee's evaluation showed that the dose from air effluents was less than applicable NRC limits or constraints. While the licensee maintained doses from air effluents below annual constraints, the inspectors noted that, due to building wake effect, the potential exists for recirculation of air effluents into the building ventilation system. Although no overexposures have been reported for workers working in the building, the licensee continues to assess its doses from air effluents for additional actions that can keep occupational exposures ALARA.

8.3 Conclusions

The licensee continued to maintain public doses from all licensed activities ALARA.

9.0 Instrumentation Calibration and Quality Control

9.1 Inspection Scope

The inspectors reviewed the licensee's calibration of survey instrumentation and dose calibrator quality control. The inspectors interviewed selected licensee staff; observed facilities, calibrations, and tests in progress; and reviewed selected procedures and records.

9.2 Observations and Findings

The licensee used portal monitors for final personal surveys in several areas of its plant. The health physics staff calibrated these monitors at six-month intervals, according to the manufacturer's instructions. The health physics staff performed weekly operational checks with a reference source to ensure the monitors were operational.

The licensee performed in-house calibrations of over 200 survey instruments on a staggered basis, at approximately 6-month intervals. The licensee maintained a software database as a reminder of calibration due dates. The inspectors observed survey instruments in use that had been calibrated within six months, were operational, and responded appropriately to radiation. Certain high-range survey instruments were sent offsite to a service firm for calibration.

The licensee possessed two calibration devices containing cesium-137 sources. The licensee stored each calibrator in a dedicated, shielded room within the health physics staff's office area. The licensee properly posted the rooms and kept the room locked when unattended. The licensee also locked the shutters on the calibrator units when not in use. Each room was equipped with warning lights to alert persons when the sources were exposed.

The licensee possessed several dose calibrators used for the production of radiopharmaceuticals and in its quality control laboratories. Licensee staff performed constancy checks on each dose calibrator on each day of use. The licensee established a three percent tolerance for constancy measurements versus expected readings. Licensee staff performed monthly accuracy checks and linearity tests every 12 to 18

months, depending on the instrument. The licensee established a five percent tolerance for accuracy and linearity checks. Licensee staff understood the expected response to a failed check. The licensee performed geometrical variance checks on dose calibrators prior to their first use. The licensee also established a five percent tolerance for geometrical variance checks, and licensee staff knew how to properly respond to deviations outside of that tolerance. The licensee performed quarterly linearity, annual accuracy, and daily constancy checks on its dose calibrator units in accordance with 10 CFR 32.72(c).

9.3. Conclusions

The licensee ensured that it maintained an adequate supply of survey instruments for routine required and ad hoc surveys in production and laboratory areas. The licensee's calibration of survey instruments ensured that the instruments were operational and responded appropriately to radiation. The licensee completed instrument calibrations at the required frequency. The licensee also established adequate quality control checks and tests for dose calibrators used in the manufacture of radiopharmaceuticals. Licensee staff who used and maintained the instruments understood the proper response to out-of-tolerance instruments. Based on record reviews, interviews with personnel, and the observations described above, the inspectors identified no violations of NRC requirements.

10.0 Radioactive Waste Management

10.1 Inspection Scope

The inspectors reviewed the licensee's waste management program with focus on disposal of radioactive material through the sanitary sewer system. The review included observation of the licensee's facilities, interviews of selected licensee personnel, and review of selected records of disposal to the sanitary sewer system. The inspectors also reviewed the records for an offsite waste shipment.

10.2 Observations and Findings

The licensee disposed of all liquid radioactive waste through drains and dedicated lines that accumulated in storage tanks in Building 500. The tanks were filled and emptied on a rotational frequency to extend the decay time. The licensee held the wastes in the tanks for decay prior to sampling for radioactivity and release to the sewer system. All liquid wastes passed through a series of filters to ensure water solubility prior to discharge into the sanitary sewer system. The licensee agitated the contents of the tanks to ensure uniform mixing. The inspectors observed the health physics staff collect a sample of the liquid for isotopic and quantitative analysis. The health physics staff recorded the contents and concentration of each release in a software database that featured warnings if the concentration exceeded applicable 10 CFR Part 20 sewer disposal limits. If the licensee received such a warning, it held the waste for further decay and sampling prior to release.

On July 27, 2016, the licensee shipped one truckload of radioactive waste to an authorized waste handler. The type and quantity of radioactive material within the 55-gallon drums was identified using gamma spectroscopy on the surface of the drums. After loading radioactive waste into the trucks, health physics staff performed ambient

exposure rate surveys of the truck and cab to verify compliance with regulatory limits. The inspectors reviewed the shipping manifest for this waste shipment to a licensed waste broker on July 27, 2016. The waste broker certified in writing, that all radioactive waste had been received and disposed of, as of July 28, 2016.

10.3 Conclusions

The licensee managed its liquid radioactive wastes to ensure that disposals to the sanitary sewer system were within regulatory release limits. Based on record reviews, interviews with personnel, and the observations described above, the inspectors identified no violations of NRC requirements.

11.0 Distribution Activities under License No. 24-04206-05MD

11.1 Inspection Scope

The inspectors reviewed the licensee's activities authorized under its medical distribution license. The inspectors reviewed the licensee's system for verifying customer authorization for requested materials and interviewed selected staff.

11.2 Observations and Findings

As described in Section 5, Mallinckrodt maintained a computer system to verify that each customer was authorized to receive the radioactive material in each shipment. Licensee staff demonstrated how the computer system notified the staff and did not process orders unless the customer was authorized for the type and quantity of radioactive material requested. Licensee staff understood the necessary actions in the event that the system identified an order that involved radioactive material that the customer was not authorized to receive. The licensee periodically audited the accuracy of the computer system's database.

The inspectors selected several customers to verify that the information in the licensee's database corresponded with the customers' authorization on the respective NRC or Agreement State license.

11.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspectors identified no violations of NRC requirements.

12.0 Other Areas Inspected

12.1 Inspection Scope

The inspectors reviewed other aspects of the licensee's program including: (1) security of byproduct materials; (2) area contamination surveys; (3) area posting and labeling of material; and (4) training. The inspectors toured selected areas where licensed material was used and stored, reviewed selected records, and interviewed selected licensee staff. The inspectors also attended a training session on January 25, 2017, for augmentee staff who perform maintenance services in the cyclotron facilities.

12.2 Observations and Findings

The inspectors examined select sealed sources and noted them to bear a clearly visible label identifying the source radionuclide and total source activity. The inspectors observed that the licensee posted copies of NRC-Form 3. The inspectors also observed that the areas where licensed material was used and stored were appropriately locked and posted with “CAUTION-RADIOACTIVE MATERIALS” and “CAUTION RADIATION AREA” signs. All laboratory and storage areas were secured or maintained under constant visual surveillance. There was no evidence of eating or drinking in the restricted areas. The licensee provided radiation safety training to approximately 40 individuals on January 25, 2017; the course material presented was commensurate with the duties to be performed by the augmentee staff.

12.3 Conclusions

Based on record reviews, interviews with personnel, and the observations described above, the inspectors identified no violations of NRC requirements.

13.0 Exit Meeting Summary

The NRC inspectors presented the preliminary inspection findings following the onsite inspection on January 27, 2017, and during the telephonic exit meeting on May 22, 2017. The inspectors confirmed that none of the potential report input discussed was considered proprietary. Proprietary material received during the inspection was returned to the licensee or destroyed. The licensee acknowledged the findings presented.

LIST OF PERSONNEL CONTACTED

#Todd Barnes, Production Manager
#Eric Berry, Vice President, Environmental Law
#David Boozer, Engineering Manager
Steve Brodnaik, Cyclotron Manager
#+Manuel Diaz, Radiation Safety Officer/Health Physics Manager
#Gerald Fuller, Human Resources Manager
Eric Hill, Senior Health Physicist
+Gary Hosna, Compliance Director
#Jennifer Janowitz, EHS Manager
#+Shaun Kelly, Principal Health Physicist
#+Tony Kinney, Associate General Counsel
#Corey Lamb, EHS Specialist
#+Bryan Lowery, Interium Site Director
#Tom McCormack, Distribution Manager
#Brad Nelson, Senior Production Health Physicist/Emergency Manager
#Jim Schuh, Director EHS-Nuclear Operations (retired)
+Mike Witte, Chairman, Radiation Safety Committee

Numerous production staff members were also contacted as part of this inspection

The identities of individuals for whom radiation exposure information has been discussed have not been included in this report in order to protect their personal privacy.

#Attended exit meeting on January 27, 2017
+Individuals contacted on May 22, 2017 for final telephonic exit meeting

INSPECTION PROCEDURES (IP) USED

IP 87102, “Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)
IP 87125, “Materials Processor/Manufacturer Programs”
IP 88045, “Effluent Control and Environmental Protection”
IP 84900, “Low-Level Radioactive Waste Storage
IP 88035, “Radioactive Waste Processing, Handing, Storage, and Transportation”

LIST OF ACRONYMS USED

ALARA	as low as reasonably achievable
CAM	continuous air monitor system
CAP	Corrective Action Program
CFR	*Code of Federal Regulations*
cpm	counts per minute
HEPA	high efficiency particulate air
IP	inspection procedure
mrem	millirem
NCV	Noncited violation
NRC	U.S. Nuclear Regulatory Commission
REIRS	Radiation Exposure Information and Reporting System
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
RWP	Radiation Work Permit
SOP	Standard Operating Procedure
TLD	thermoluminescent dosimeter