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

March 11, 2016

Mr. Sumit Verma
Site Director
Mallinckrodt, LLC
2703 Wagner Place
Maryland Heights, MO 63043

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03000001/2016001(DNMS)
MALLINCKRODT, LLC

Dear Mr. Verma:

On January 12, 2016, through January 15, 2016, two inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a special inspection at your Maryland Heights, Missouri facility with continued in-office review through February 19, 2016. The purpose of the inspection was to review the facts and circumstances of three incidents entered into your corrective action program prior to the last routine inspection. The in-office review included a review of the documentation for the three incidents. Ms. Deborah A. Piskura of my staff conducted a final exit meeting by telephone with Mr. Manuel Diaz and Mr. James Schuh, of your staff on February 19, 2016, to discuss the inspection findings. The enclosed inspection report presents the results of the inspection.

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 four Severity Level IV violations of NRC requirements occurred. The violations were 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 enclosed inspection report documents detailed information concerning the violations.

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 to conduct adequate radiation surveys to evaluate the potential radiological conditions before performing work on a contaminated component, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1501. These non-repetitive, licensee-identified, non-willful, and corrected violations are being treated as noncited violations, consistent with Section 2.3.2 of the Enforcement Policy.

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the enclosed inspection report. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, please submit the information in accordance with the methods described in Title 10 of the *Code of Federal Regulations* (CFR) Section 30.6(a)(1) and (b)(2).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response if you choose to provide one, will be made available electronically for public inspection in the NRC'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 of my staff 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 No. 030-00001
License No. 24-04206-01

Enclosure:
IR 03000001/2016001(DNMS)

cc w/encl: Mr. Manuel Diaz, Radiation
Safety Officer
James R. Schuh, Chairman,
Radiation Safety Committee
State of Missouri

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Sincerely,

/RA/

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

Docket No. 030-00001
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Enclosure:
IR 03000001/2016001(DNMS)

cc w/encl: Mr. Manuel Diaz, Radiation
Safety Officer
James R. Schuh, Chairman,
Radiation Safety Committee
State of Missouri

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Letter to Sumit Verma from Aaron McCraw dated March 11, 2016

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03000001/2016001(DNMS)
MALLINCKRODT, LLC

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Region III

Docket No.	030-00001
License No.	24-04206-01
Report No.	03000001/2016001(DNMS)
Licensee:	Mallinckrodt, LLC
Facility:	2703 Wagner Place Maryland Heights, Missouri
Inspection Dates:	January 12, 2016 - January 15, 2016 with continued in-office review through February 19, 2016
Exit Meeting Date:	February 19, 2016
Inspectors:	Deborah A. Piskura, Senior Health Physicist Materials Inspection Branch Division of Nuclear Materials Safety John G. Cassidy, Senior Health Physicist Health Physics and Incident Response Branch Division of Reactor Safety
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Mallinckrodt, LLC
NRC Inspection Report 03000001/2016001(DNMS)

On January 12, 2016 through January 15, 2016, two inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the Mallinckrodt, LLC (licensee), Maryland Heights, Missouri manufacturing facility, with continued in-office review through February 19, 2016. This was a special inspection conducted to review three incidents that occurred prior to the last routine inspection. The inspectors reviewed several program areas including management oversight, the corrective action program and incident investigation, external dose assessment, and area surveys. This inspection focused on a review of the licensee's investigation of the three incidents and the licensee's corrective action program (CAP).

The licensee's CAP included licensee review of events, prioritization based on risk significance, root cause analysis, and corrective action implementation and follow up. The review of selected events determined that the licensee's prioritization scheme was risk-based and applied consistently.

These incidents described above and reported in the licensee's CAP were initially characterized as unresolved issues. During this inspection, the NRC completed its review of these incidents reported in the licensee's CAP, and the unresolved issues are now considered closed.

Four violations of NRC requirements were identified during this inspection. The violations involved the licensee's failures to: (1) implement its standard operating procedure (SOP) 5-190, "Reprocess of Ultra-Technekow® DTE Generator; (2) implement its SOP 15-40, "Preparation of Petten, Nordian and Beatrice Mo-99 Shipping Casks for Return," for performing tasks related to transferring a cask from the hot cell to waste management; (3) maintain its SOP 15-40, "Preparation of Petten, Nordian and Beatrice Mo-99 Shipping Casks for Return," for performing tasks related to cleaning the cask in waste management; and (4) conduct adequate radiation surveys to evaluate the potential radiological conditions before performing rebuild work on the contaminated cyclotron scatter plate as required by 10 CFR 20.1501.

These non-repetitive, licensee-identified, non-willful, and corrected violations are being treated as noncited violations, consistent with Section 2.3.2 of the Enforcement Policy.

REPORT DETAILS

1 Program Overview and Inspection History

The licensee operated a Type A broad scope manufacturing and distribution program. The licensee's operations included the manufacture of molybdenum99/technetium-99m generators; sodium iodide-131 and iodide-123; indium-111; and other cyclotron-produced products, and cold products/kits for compounding radiopharmaceuticals. The licensee was in the process of reactivating its manufacture and distribution activities for xenon-133, pending FDA approval. The licensee established a radiation safety committee to review its uses, users, and facilities. All licensed activities were performed at the Maryland Heights complex. The licensee employed approximately 250 individuals at its site.

The licensee introduced a new generator model Ultra-TechneKow® Version 4 (V4) in 2015 and developed a dedicated manufacturing/production line for this model. In November 2015, the licensee ceased production of its previous generator model, Version 3 (V 3); the licensee intended to repurpose the former production line at a future date.

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 radiation safety office staff audited all areas of use and storage at frequencies based on the amount of material processed/used. The radiation safety office 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 previous routine inspection on May 20, 2014 through May 24, 2014, identified two violations for the licensee's failure to: (1) post two high radiation areas in accordance with 10 CFR 20.1902(b); and (2) label two Molybdenum/Technetium generators for commercial distribution with the correct quantity of radioactivity in accordance with 10 CFR 32.72(a)(4)(i). These Severity Level IV violations were treated as noncited violations, consistent with Section 2.3.2 of the Enforcement Policy. These violations were entered in the licensee's corrective action program. During the last routine inspection on September 21 to 25, 2015, with continued in office review through December 21, 2015, the inspector identified one unresolved item concerning two elevated personnel extremity exposures and one high radiation area event entered into the licensee's CAP; this report details the NRC's follow up review of the unresolved item. 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 the inspection.

2 Incidents Reported into the Corrective Action Program

2.1 Inspection Scope

The inspectors reviewed select incidents identified by the licensee and entered into its CAP. The inspectors interviewed select licensee staff and reviewed select incident reports, corrective actions followup 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 CAP. The review included selected events in the licensee's incident reporting log for detailed evaluation, and interviews of selected licensee staff.

2.2 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 required corrective action and track completion of corrective actions. The licensee established 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 millrem. 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. In October 2015, the licensee obtained a commercially available software system for tracking of items entered into the CAP.

The RSO indicated that no significant events (Category 1) had occurred since the last routine inspection in September 2015. Since the previous inspection in May 2014, the licensee entered three events into its CAP at the Category 2 investigation level. These events involved two elevated extremity exposures to personnel and one elevated exposure rate in the waste management area. These events are described in Sections 3, 4, and 5 of this report.

A fundamental goal of a CAP is to establish confidence that the licensee is effectively detecting, correcting, and preventing problems which could impact radiation safety. The inspectors noted during their review of these event reports that certain details of the incidents were omitted and had the potential to minimize the institutional learnings from the event(s).

2.3 Conclusions

The inspectors identified no violations of NRC requirements. The licensee continued to effectively use and improve its CAP. The licensee's investigations of events were adequate and contributed to the implementation of corrective actions.

3 Elevated Shallow Dose Equivalent (Extremity Exposure) from Direct Handling of a Molybdenum-99 Generator Column (Incident No. 14-0122)

3.1 Inspection Scope

The inspectors reviewed the circumstances of an incident involving the direct handling of a generator column that resulted in an elevated shallow dose equivalent to an individual. The inspectors reviewed selected records including the incident report, the SOP related to the task performed by the individual, dosimetry badge records, and dose assessment records. The inspectors interviewed selected licensee staff including the RSO, health physicists and technicians, the individual, and production laboratory personnel. In addition, the inspectors observed a reenactment of the incident.

3.2 Observations and Findings

On December 8, 2014, an individual, while working in the Ultra-Technekow® dry top eluting (DTE) V3 generator production line, directly handled a generator column containing 7.5 curies of molybdenum-99. The licensee immediately initiated an investigation of this incident and entered it as a Category 2 incident into the CAP.

The individual was assigned to work at various work stations within the production laboratory and tasked with labeling columns, recovering generator canisters and removing labeling from rejected generators. While working in the laboratory, the staff could be assigned to work between various work stations based on the generator production line needs. The reprocessing/rework area involved minor repairs to generators that failed quality assurance/quality control tests. Occasionally, this rework required removal of the generator column from the generator shielding or safe and was performed within the hot cell. The licensee established SOP 5-190, "Reprocess of Ultra-Technekow® DTE Generator," effective date April 23, 2012. The SOP provided step-by-step procedures for performing rework on generators.

The individual retrieved a generator from the shielded storage bunker and placed it on a workspace to remove the labels and the canister. The individual removed the generator hood for preparation to transfer the generator into the hot cell for reprocessing; removal of the hood exposed the inlet needles. The individual returned to another work station and resumed duties. A coworker questioned the individual about the exposed inlet needles and expressed concern about a potential unsafe condition. The individual returned to the generator re-work station and proceeded to disassemble the generator. Using needle-nose pliers in his left hand, the individual removed the shielded plug (with the generator column attached) causing his personal electronic dosimeter to alarm. The individual reacted to the audible alarm from his electronic dosimeter and recognized that he needed to immediately shield the exposed generator column. The individual took the

column from the needle-nose pliers with the thumb and forefinger of his right hand and placed the column in a nearby plastic “sharps” container (unshielded). The laboratory area frisker also continuously alarmed during this time and alerted the personnel of the elevated radiation area. The production staff left the immediate area and notified the health physics office.

A health physics technician responded to the incident and secured the unshielded sharps vessel that contained the generator column within the hot cell. The production lab resumed operations. The licensee held the generator column for decay within the hot cell.

The licensee restricted the individual from further occupational exposure until completion of the investigation. The licensee staff conducted a dose assessment for the individual using Microshield® codes in addition to the information obtained from the event re-enactment to calculate the dose to the individual’s right hand. The licensee estimated that the individual handled the generator column for approximately 3.8 seconds. Based on the licensee’s re-enactment and dose assessment, the licensee assigned a shallow-dose equivalent of 7,413 millirem (mrem) to the individual’s right hand; the licensee determined that the individual received a whole body exposure of 22 mrem from this incident. 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 also performed an independent dose assessment for the individual using Microshield® and Varskin® 4 codes; the NRC’s results were in close agreement with the licensee’s dose assessment.

The licensee determined that the root causes of this incident included lack of training, fatigue, limited SOP guidance on the task the individual was assigned, lack of direct supervision of the individual, and multi-tasking. The licensee’s corrective actions included providing training to its personnel with focus on handing procedures for “hot” generator columns and decayed or “cold” columns, establishing a work schedule/qualification matrix to ensure that individuals were trained on their assigned to work stations, and revising the SOP related to rejected generators.

The inspectors attributed the root cause of this incident to inadequate training for the individual. Although, the individual routinely worked at various stations within the production laboratory, the individual was neither trained on SOP 5-190 nor did the individual receive on-the-job training for reprocessing generators. Interviews with licensee training personnel and a review of the individual’s training file confirmed that the individual was not specifically trained to reprocess generators. The individual was accustomed to working on and dismantling returned generators that decayed to background levels and treated as “cold” or nonradioactive. These returned generator dismantling efforts included removal of the column which could be handled directly.

Condition 22. of License Number 24-04206-01 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in letter dated November 15, 2013. Item 3, of letter dated November 15, 2013, states in part that the licensee will develop, implement, and maintain procedures associated with areas including Operating Procedures (Bullet 6). The licensee developed an operating procedure, SOP 5-190, “Reprocess of Ultra-Technekow® DTE Generator,” effective date April 23, 2012. The second note in Section VI, Generator Reprocessing in the hot cell, of this SOP states, “Under no

circumstances are [generator] columns to be removed from the safe outside of the DTE hot cell."

The licensee's failure to implement its Operating Procedures in SOP 5-190, "Reprocess of Ultra-Technekow® DTE Generator" is a violation of License Condition 22. Specifically, the licensee failed to implement its Operating Procedures in SOP 5-190, when the licensee removed a generator column containing approximately 7.5 curies of molybdenum-99 and 1 curie of technetium-99m from the safe [generator shield] outside of the DTE hot cell.

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

3.3 Conclusions

The licensee's dose assessment for the individual was accurate, within the identified limitations of such assessments. The dose assessment was technically sound and reasonable, and to the extent practical, included consideration of individual practices. NRC's independent calculations agreed with the licensee's estimates in the generator column handing exposure incident.

One violation of NRC requirements was identified for the licensee's failure to implement its Operating Procedures in SOP 5-190, "Reprocess of Ultra-Technekow® DTE Generator" as required by License Condition 22. The licensee identified this incident and entered it into the CAP. This non-repetitive, licensee-identified, non-willful, and corrected violation is being treated as a noncited violation, consistent with Section 2.3.2 of the NRC Enforcement Policy.

4 Elevated Radiation Exposure Rates from a Contaminated Shipping Cask (Incident No. 15-0025)

4.1 Inspection Scope

The inspectors reviewed the circumstances of an incident involving elevated radiation exposure rates from a contaminated shipping cask. The inspectors reviewed selected records including the incident report, the SOP related to the task performed by the licensee staff, dosimetry badge records, and dose assessment records. The inspectors interviewed selected licensee staff including the RSO, health physicists and technicians, and lab technicians. In addition, the inspectors observed a reenactment of the incident.

4.2 Observations and Findings

Hot Cell Work Activities

The licensee received its molybdenum-99 from the vendor in Type B shipping casks; the majority of its material and casks was received from the research reactor in Petten, Netherlands. The shipping cask consisted of a series of robust containers with the raw molybdenum-99 liquid contained within the innermost flask. The top of the flask was secured within a "plug" to facilitate removal of the raw material within the hot cell. The flask was further secured and shielded within the cask with a metal "R2" sleeve or liner.

Upon removal of the flask from the cask, the R2 sleeve typically adheres to the flask; the user can remove the R2 sleeve from the flask and process the molybdemun-99 liquid. The flask and the R2 sleeve remain in the hot cell for decay prior to return to the vendor.

On February 28, 2015, an individual unexpectedly encountered a high radiation area while cleaning and preparing a shipping cask for return to the vendor. The inner cask was released from the hot cell, where the staff failed to identify residual molybdenum-99 contamination within or on the surface of the R2 sleeve which remained within the cask. Based on interviews with the staff and demonstrations of the hot cell procedures, the licensee did not perform certain steps of its SOP. Specifically, the licensee hot cell staff did not confirm that the R2 sleeve was removed from the cask as required by Item F. of the SOP.

Additionally, the inspectors noted that item M. of SOP 15-40 requires, in part, to record the gross dose rate [measured at 12 inches from the cask], in Roentgen (R) per hour, on the "Mo-99 Cask Tracking Sheet." Item N. states, "Place the inner container with flask into the open cask and place the shield lid back on the cask." However, these steps were not performed because the licensee changed the associated work practices without revising the SOP.

Condition 22. of License Number 24-04206-01 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in letter dated November 15, 2013. Item 3, of letter dated November 15, 2013, states in part that the licensee will develop, implement and maintain procedures associated with areas including Operating Procedures (Bullet 6). The licensee developed an operating procedure, SOP 15-40, "Preparation of Petten, Nordian, and Beatrice Mo-99 Shipping Casks for Return," effective date January 9, 2013. Section VIII., "Radioactive Assay of Midus (Petten Cask) Inner Flask" of SOP 15-40 describes step-by-step procedures for the preparation and survey of Mo-99 shipping casks within the hot cell prior to transferring the casks to the Waste Management department. Item F, requires, if the R2 inner container remains inside the cask after flask removal, remove the R2 inner container once the flask is secured." The licensee's failure to implement its procedures for preparation of shipping casks within the hot cell in Item F. of SOP 15-40, is a violation of License Condition 22.

Waste Management Work Activities

Following generator production, the hot cell staff released the cask with the inner R2 sleeve to waste management who in turn prepared the cask assembly for return to the vendor. Once the cask was received by waste management, an individual removed the inner cask lid and started to remove the shipping plug which had the R2 sleeve attached. The individual noted that his personal electronic dosimeter alarmed and the survey meter was reading off scale. The individual recognized the elevated radiation levels in the general area and proceeded to remove the plug and the sleeve, placing the sleeve in a bucket on the workbench and the plug within the cask with the lid secured. The individual notified the supervisor of the alarming dosimeter because he believed that the cask was contaminated. The licensee staff surveyed the cask and the sleeve and determined that the sleeve was reading approximately 70 R per hour at the surface of the bucket. The licensee secured the sleeve within an over pack and placed it in a secured waste storage area for decay. Based on the exposure rate, the licensee estimated that the R2 sleeve was contaminated with approximately 1.4 curies of

molybdenum-99. The individual received 15 mrem whole body and 31 mrem extremity from this elevated exposure incident.

The licensee determined that the root causes of this incident were attributed to inadequate surveys (by the hot cell staff), lack of training, and limited SOP guidance for the waste management staff. The inspectors attributed the root cause of this incident to the licensee's inadequate methods for surveying the cask within the hot cell. The inspectors noted that the licensee's method of identifying contamination within the cask by visual examination for liquid was flawed because the contamination could not be quantified without a radiation survey.

The licensee's corrective actions included providing training to its personnel, revising its SOP related to casks cleaning/return. The licensee noted that this incident was similar to a previous incident that occurred in 2012 (Incident No. 12-0070). Corrective actions for the 2012 incident included the development of a vacuum "retrieval tool" for use by the hot cell staff to remove the R2 sleeve from the cask. The production staff was also instructed to visually inspect the interior of the R2 container for residual liquid (molybdemun-99) prior to releasing a cask from the hot cell. According to the licensee's investigation, the whereabouts of the vacuum "retrieval tool" was unknown. The licensee's corrective actions for the 2015 incident were revised to include the use of a custom tool in the new V4 hot cell production line to aid in the retrieval of a lodged R2 sleeve within the cask.

Condition 22. of License Number 24-04206-01 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in letter dated November 15, 2013. Item 3, of letter dated November 15, 2013, states, in part, that the licensee will develop, implement, and maintain procedures associated with areas including Operating Procedures (Bullet 6). The licensee developed an operating procedure, SOP 15-40, "Preparation of Petten, Nordian, and Beatrice Mo-99 Shipping Casks for Return," effective date January 9, 2013. Section X., "Cleaning of Mo-99 Casks," describes step-by-step procedures used by the waste management department in items A. through N. to clean molybdenum-99 casks in preparation for transfer to the vendor. As described above, the inspectors noted that items M. and N. of Section VIII of SOP 15-40 requires, were not performed because the licensee changed the associated work practices without revising the SOP. The licensee's failure to maintain its SOP 15-40, "Preparation of Petten, Nordian, and Beatrice Mo-99 Shipping Casks for Return," for performing tasks for returning shipping casks is another example of a violation of License Condition 22. Specifically, the licensee changed its process, methods, and timing for returning casks to the vendor without revising the operating procedure to reflect the new practice within the waste management department.

The licensee identified this incident and entered it into the CAP. These non-repetitive, licensee-identified, non-willful, and corrected violations are being treated as noncited violations, consistent with Section 2.3.2 of the NRC Enforcement Policy.

4.3 Conclusions

The inspectors identified two violations of NRC requirements involving the licensee's failure to implement Section VIII., Item F. and maintain Section VIII., Items M. and N. (hot cell) as well as Section X. (waste management) of its SOP 15-40, "Preparation of Petten, Nordian, and Beatrice Mo-99 Shipping Casks for Return" as required by License Condition 22. These non-repetitive, licensee-identified, non-willful, and corrected violations are being treated as a noncited violations, consistent with Section 2.3.2 of the NRC Enforcement Policy.

5 Elevated Extremity Exposure from Direct Handling of a Contaminated Cyclotron Component (Incident No. 15-0037)

5.1 Inspection Scope

The inspectors reviewed the circumstances of an incident involving an elevated extremity exposure from the direct handling of a contaminated cyclotron component. The inspectors reviewed selected records including the incident report, Radiation Safety Committee meeting minutes and approvals, and dosimetry reports. The inspectors interviewed selected licensee staff including the RSO, health physicists, and technicians.

5.2 Observations and Findings

On April 29, 2015, during a review of dosimetry reports, the radiation safety staff identified that an individual received an extremity exposure of 4,765 mrem for the March 2015 monitoring period. The licensee staff determined that the individual performed rebuild work on a scatter plate used in the cyclotron for the production of germanium-68. Although this contaminated component was stored for decay in a bunker for nine months, germanium-68 (half-life 271 days) is a positron emitter with a long-lived energetic shallow dose contribution. The individual initially surveyed the scatter plate with a telescoping radiation survey meter for gamma only and measured that the plate was indistinguishable from background. The individual proceeded to rebuild the scatter plate for re-introduction into the cyclotron unit for production. These rebuild efforts were performed within a bench top glove box isolation unit with direct handling of the scatter plate over a period of several days in March 2015. The licensee stated that this rebuild work required more time than originally anticipated. As a result, the individual received an elevated extremity exposure. Previous manipulations of germanium-68 were performed within a hot cell with remotely handling tools and did not require direct handling by the licensee staff.

The licensee authorized the development of a new product that utilized new radionuclides and manufacturing techniques without evaluating the potential radiological impact on occupational dose created by the new process. This resulted in a condition where the cyclotron scatter plate unexpectedly became heavily contaminated with removable germanium-68, a beta emitting radionuclide. This was only discovered after an individual was exposed to the contamination and the personal dosimeter was processed revealing an occupational dose to the extremity reported as 4,765 mrem SDE in a 1-month period.

The licensee determined that the root causes of this incident included a lack of awareness of the radiological properties of germanium-68. The licensee stated that the

literature on this isotope was limited based on its limited use. The licensee also stated that information on this isotope was not readily shared by other institutions that researched and used germanium-68. The licensee's corrective actions included providing training to its personnel and survey instrumentation with beta measuring capabilities. The licensee continued to research the use of beta monitoring personnel electronic dosimeters. The inspectors determined the licensee authorized the development of a new product that utilized new radionuclides and manufacturing techniques without evaluating the potential radiological impact on occupational dose created by the new process. This resulted in a condition where the cyclotron scatter plate unexpectedly became heavily contaminated with germanium-68, a beta emitting radionuclide. The licensee applied its corrective actions from this incident to a planned hot cell remediation effort (germanium-68 contamination) in April 2015. In this remediation effort (Incident No. 15-0038), the licensee anticipated that four employees could receive elevated extremity exposures. The licensee staff conducted surveys for gamma and beta radiation in order to properly characterize any adverse radiation safety conditions. As a result, the licensee personnel received extremity exposures significantly less than the previous incident with results ranging from 272-886 mrem.

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 10 CFR Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or 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 the 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 that were necessary to comply with the regulations in 10 CFR Part 20.1201 and were reasonable under the circumstances to evaluate the extent of radiation levels is a violation of 10 CFR 20.1501. Specifically, in March 2015, the licensee authorized the development of a new product that utilized new radionuclides and manufacturing techniques without evaluating the potential radiological impact on occupational dose created by the new process. This resulted in a condition where the cyclotron scatter plate unexpectedly became heavily contaminated with germanium-68, a beta emitting radionuclide. This was only discovered after workers were exposed and personal dosimeters were processed when the occupational dose to the extremity of an individual reported 4,765 mrem shallow-dose equivalent in a one month period.

The licensee identified this incident and entered it into the CAP. This non-repetitive, licensee-identified, non-willful, and corrected violations are being treated as noncited violations, consistent with Section 2.3.2 of the NRC Enforcement Policy.

5.3 Conclusions

The inspectors identified one violation of NRC requirements involving the licensee's failure to conduct adequate radiation surveys, as required by 10 CFR Section 20.1501, when the licensee authorized the development of a new product that used new radionuclides and manufacturing techniques without evaluating the potential radiological impact on occupational dose created by the new process. The licensee identified this incident and entered it into the CAP. This non-repetitive, licensee-identified, non-willful, and corrected violation is being treated as a noncited violation, consistent with Section 2.3.2 of the NRC Enforcement Policy.

6 Exit Meeting Summary

The NRC inspectors presented the inspection findings via telephone on February 19, 2016. 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
Lori Bloomfield, V4 Supervisor
*#David Boozer, Engineering Manager
*#+Manuel Diaz, Radiation Safety Officer/Health Physics Manager
*#Janet Dohm, EHS Admin Coordinator
*#Gerald Fuller, Human Resources Manager
*Ernest Glaneman, Senior EHS Specialist
*#Leoul Hagoss, Senior Health Physics Technician
#Eric Hill, Senior Health Physicist
#Reonda Hurt, Health Physicist
#Sarah Jaeger, Materials Manager
*#Shaun Kelly, Principal Health Physicist
*#Edward Keppel, Performance Excellence Manger
*#Steve King, Senior Health Physics Technician
*Corey Lamb, EHS Specialist
*#Bryan Lowery, Operations Manager
Dustin Martin, Health Physics Technician
Charles McCullum, Senior Health Physics Technician
*#Brad Nelson, Senior Production Health Physicist/Emergency Manager
Jenny Nickels, Training Specialist
#Whitney Sandberg, Quality Director
*#+Jim Schuh, Director EHS-Nuclear Operations
*#Sumit Verma, Site Director
*Kevin White, RHP Production Manager

Numerous production and waste management 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.

*Individuals at entrance meeting
#Attended exit meeting on January 15, 2016
+Individuals contacted on February 19, 2016 for final telephonic exit meeting

INSPECTION PROCEDURES USED

IP 87125 "Materials Processor/Manufacturer Programs"