September 25, 2009

CAL 3-08-001

Mitzi Pennington, Site Director
Mallinckrodt, Inc.
2703 Wagner Place
Maryland Heights, MO 63043

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 030-00001/09-02(DNMS) – MALLINCKRODT, INC.

Dear Ms. Pennington:

This refers to the special inspection that began in February 2008 and was initially documented in Nuclear Regulatory Commission (NRC) Inspection Report No. 030-00001/08-01(DNMS) dated May 22, 2008. The NRC conducted additional special inspections in January 2009, with results documented in NRC Inspection Report No. 030-00001/09-01(DNMS) dated February 19, 2009, and on August 24 through 28, 2009, at the Maryland Heights, Missouri facility. The purpose of the special inspection was to evaluate the facts, circumstances, and actions taken in response to the increased number of customer complaints that you received regarding the results of molybdenum-99 breakthrough (breakthrough) tests conducted on technetium-99m generators (generators) and to evaluate the actions taken in response to the February 1, 2008, Confirmatory Action Letter (CAL 3-08-001). Based on the results of the special inspection, the NRC has no further questions regarding the four CAL Items. We will inform you of our decision regarding the adequacy of your CAL Items under separate cover. The enclosed report presents the results of the inspection.

Based on your request to withhold proprietary information from public disclosure in accordance with the provisions of Title 10 Code of Federal Regulations (CFR) 2.390, the inspection report identifies components, equipment, chemicals, and other proprietary-related items in generic terms, such as Component 1 or Chemical 1.

The exit meeting to discuss the preliminary inspection findings was held with you and other members of your staff at the Maryland Heights, Missouri facility on August 28, 2009. On September 8, 2009, Robert Gattone of my staff contacted Dan Hoffman of your staff to discuss the inspection findings.

Based on the results of the inspection, no violations of NRC requirements were identified.

As described in Section 2.2.d. of this report, the inspectors identified new examples of the previously identified concern involving insufficient or inadequate information in some of your procedures, resulting in an increased potential for misinterpretation and mistakes by individuals who may be responsible for implementing the procedures. Therefore, within 30 days of the date of this report, please submit a response that describes the specific actions that have been or will be taken, which are in addition to those actions previously taken, to address the concern.

The inspectors identified that you implemented adequate actions to address the previously identified safety culture concern. However, the new examples of the concern regarding insufficient or inadequate information in some of the licensee's procedures, resulting in an increased potential for misinterpretation and mistakes by individuals who may be responsible for implementing the procedures, indicates a need for continued focus on improving the overall safety culture at the Mallinckrodt facility. In addition, it is important to be vigilant to sustain a good safety culture.

The inspectors previously identified a generic issue associated with the breakthrough problem. Generator users who comply with the NRC regulation for breakthrough testing and do not conduct breakthrough tests on each elution could conduct breakthrough tests on the first eluate with results that do not exceed the regulatory limit and then miss breakthroughs that may occur on subsequent elutions. The inspectors identified an additional generic issue associated with the breakthrough problem. Elevated levels of Chemical 1 in Component 1 used to produce generators could result in generators that produce elutions that exceed the breakthrough limit at either the first or a subsequent elution test.

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

Sincerely,

/ RA /

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

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

Enclosure:
Inspection Report 030-00001/09-02(DNMS)

cc w/encl: D. Hoffman, Radiation Safety Officer
J. Schuh, Manager of Environmental Health and Safety
M. Perry-Williams, FDA
State of Missouri

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Letter to Mitzi Pennington from Steven A. Reynolds dated September 25, 2009

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 030-00001/09-02(DNMS) – MALLINCKRODT, INC.

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-00001
License No.:	24-04206-01
Report No.:	030-00001/09-02(DNMS)
Licensee:	Mallinckrodt, Inc.
Facility:	2703 Wagner Place Maryland Heights, Missouri
Inspection Dates:	August 24 through 28, 2009
Exit Meeting:	August 28, 2009
Inspectors:	Robert G. Gattone, Jr. Senior Health Physicist Kevin G. Null Senior Health Physicist
Approved By:	Patricia J. Pelke, Chief Materials Licensing Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Mallinckrodt, Inc.
NRC Inspection Report 030-00001/09-02(DNMS)

On August 24 through 28, 2009, the inspectors continued the special inspection which began in February 2008 at Mallinckrodt, Inc.'s (licensee) Maryland Heights, Missouri facility and included continued special inspection activities on January 12 through 15, 2009. The special inspection was initially documented in Nuclear Regulatory Commission (NRC) Inspection Report No. 030-00001/08-01(DNMS) dated May 22, 2008, and it was subsequently documented in NRC Inspection Report No. 030-00001/09-01(DNMS) dated February 19, 2009. The purpose of the inspection was to evaluate the facts, circumstances, and the licensee's actions taken in response to the increased number of customer complaints it received associated with technetium-99m generators (generators) that failed the molybdenum-99 breakthrough (breakthrough) test. From approximately October 2006 through February 2007, and particularly in January 2008, the licensee received an increase in the number of customer complaints associated with generators that failed the breakthrough tests. Specifically, an increased number of generators produced elutions that exceeded the 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m regulatory limit in Title 10 Code of Federal Regulations (CFR) 35.204, "Permissible Molybdenum-99 Concentration" at either the first or a subsequent generator elution. The inspectors also evaluated the actions associated with Confirmatory Action Letter No. 3-08-001 dated February 1, 2008 (CAL). The NRC has no further questions regarding the licensee's commitments in the CAL.

No violations of NRC regulatory requirements were identified. The licensee implemented adequate corrective actions to prevent the previously identified violation of Condition 20 of NRC License No. 24-04206-01 involving failure to develop Corrective Action Program (CAP) procedures that established time tables (milestones) for: (1) identifying conditions that are adverse to radiation safety; and (2) reporting the conditions to appropriate management levels.

The licensee implemented adequate actions to address the previously identified concerns involving the licensee's method of conducting breakthrough testing on each generator prior to distribution, an assumption the licensee made about its method of assaying the radioactivity of molybdenum-99 during in-house breakthrough testing, and the effectiveness of the licensee's corrective actions to prevent breakthrough. However, the inspectors identified new examples of a previously identified concern involving insufficient or inadequate information in some of the licensee's procedures, resulting in an increased potential for misinterpretation and mistakes by individuals who may be responsible for implementing the procedures.

The licensee implemented adequate actions to address the previously identified safety culture concern. However, the new examples of the concern regarding insufficient or inadequate information in some of the licensee's procedures, resulting in an increased potential for misinterpretation and mistakes by individuals who may be responsible for implementing the procedures, indicates a need for continued focus on improving the overall safety culture at the Mallinckrodt facility.

Based on the licensee's request to withhold proprietary information from public disclosure in accordance with the provisions of 10 CFR 2.390, the report identifies components, equipment, chemicals, and other proprietary-related items in generic terms, such as Component 1 or Chemical 1.

The inspectors previously identified a generic issue associated with the breakthrough problem. Generator users who comply with the NRC regulation for breakthrough testing and do not conduct breakthrough tests on each elution could conduct breakthrough tests on the first eluate with results that do not exceed the regulatory limit and then miss breakthroughs that may occur on subsequent elutions. The inspectors identified an additional generic issue associated with the breakthrough problem. Elevated levels of Chemical 1 in Component 1 used to produce generators could result in generators that produce elutions that exceed the breakthrough limit at either the first or a subsequent elution test.

Report Details

1 Corrective Actions to Prevent the Previously Identified Violation

1.1 Inspection Scope

The inspectors interviewed selected Mallinckrodt, Inc. (licensee) management representatives and staff, and reviewed selected licensee procedures in order to evaluate the licensee's implementation of the corrective actions it took to prevent the violation that was previously identified during the special inspection and documented in the Notice of Violation (NOV) and Nuclear Regulatory Commission (NRC) Inspection Report No. 030-00001/09-01(DNMS) dated February 19, 2009.

1.2 Observations and Findings

Condition 20 of License No. 24-04206-01 required that the licensee maintain a Corrective Action Program (CAP) to identify and correct deficiencies associated with radiation safety, and that:

- It develop, implement and maintain procedures to assure that conditions adverse to radiation safety (CARS), such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and non-conformances that could reasonably affect exposures to workers or the public, or releases of radioactive material in effluents or to the sanitary sewer system, are promptly identified and corrected. In the case of significant CARS, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to radiation safety, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management. The procedures shall include appropriate quantitative or qualitative acceptance criteria for determining that the procedures have been satisfactorily accomplished; and

- The procedure(s) shall include provisions for: 1) defining conditions that are adverse to radiation safety; 2) identifying conditions that are adverse to radiation safety; 3) reporting the conditions to appropriate management levels; 4) investigating adverse conditions in sufficient detail to identify root causes; 5) developing and implementing corrective actions to address the identified root cause(s) and to prevent recurrence; and 6) establishing time tables (milestones) for each provision, commensurate with the significance of the adverse condition.

The NRC previously identified a violation of Condition 20 of License No. 24-04206-01 and issued an NOV to the licensee on February 19, 2009. The violation involved the licensee's failure to develop Product Quality CAP procedures that established time tables (milestones) for: (1) identifying conditions that are adverse to radiation safety; and (2) reporting the conditions to appropriate management levels. Specifically, the licensee's Standard Operating Procedure (SOP) 33-213, "Performing Complaint Investigations" did not establish time tables (milestones) for: (1) identifying conditions that are adverse to radiation safety; and (2) reporting the conditions to appropriate management levels. In addition, the licensee's SOP 33-23, "Exception and Deviation

Reporting" and the subsequent revision titled, "Exception Reporting," did not establish time tables (milestones) for identifying conditions that are adverse to radiation safety.

The licensee responded to the NOV by letters to the NRC dated March 20 and April 2, 2009. The licensee's letter dated March 20, 2009, states that the licensee modified SOP 33-213 and SOP 33-23 to specifically identify each provision of License Condition 20 and locate them in a single section of each procedure. The letter also stated that the modification was to insure that all required information is included within the text of the procedure. In addition, the licensee's letter dated April 2, 2009, states that the licensee separated the information required by License Condition 20 into a separate section of the procedures clearly identified as, "NRC Compliance." The letter also states that the NRC Compliance section lists each provision of License Condition 20 and the method that is utilized to ensure compliance to ensure that future procedure modifications retain the required information. Finally, the letter states that the licensee's Radiation Safety Officer (RSO) reviews proposed procedure revisions to ensure they are compliant with License Condition 20.

The inspectors noted that the March 20, 2009, revision of SOP 33-213 included an NRC Compliance section that specifically listed each provision of License Condition 20. In addition, the revised SOP included methods of how the procedure complied with each provision of License Condition 20. For example, the method for identifying conditions that are adverse to radiation safety included who was responsible for doing so, what information to review, and a time limit (milestone) for the responsible individual to identify conditions that are adverse to radiation safety. In addition, the method for reporting the conditions to appropriate management levels included a time limit (milestone) for doing so. The inspectors also noted that the NRC Compliance section referenced other specific sections of the procedure that described actions to comply with the provisions of License Condition 20 to ensure that future procedure modifications retain the required information.

The inspectors noted that the March 20, 2009, revision of SOP 33-23 included an NRC Compliance section that specifically listed each provision of License Condition 20. In addition, the revised SOP included methods of how the procedure complied with each provision of License Condition 20. For example, the method for identifying conditions that are adverse to radiation safety included who was responsible for doing so, what information to review, and a time limit (milestone) for the responsible individual to identify conditions that are adverse to radiation safety.

The inspectors reviewed licensee, "Management of Change" records that included documentation of the RSO's reviews of proposed revisions of SOPs 33-213 and 33-23 to ensure that the revised procedures were compliant with the provisions in License Condition 20. The inspectors noted that the licensee's inclusion of the NRC Compliance section in the procedures increased the efficiency and effectiveness of reviewing proposed procedure revisions, and ensured that they were compliant with the provisions of License Condition 20.

1.3 Conclusions

The licensee implemented corrective actions to achieve compliance with Condition 20 of License No. 24-04206-01. No violations of NRC regulatory requirements were identified.

2 Actions to Address Previously Identified Concerns

2.1 Inspection Scope

The inspectors observed licensee staff conduct in-house molybdenum-99 breakthrough (breakthrough) tests, interviewed selected licensee management representatives and staff, and reviewed selected licensee procedures in order to evaluate the licensee's implementation of actions it took to address four concerns that were previously identified during the special inspection and documented in NRC Inspection Report No. 030-00001/09-01(DNMS) dated February 19, 2009.

2.2 Observations and Findings

a. Concern 1 – Unsafe Method for In-House Molybdenum-99 Breakthrough Testing

The NRC previously identified a concern regarding the licensee's method of conducting breakthrough testing on each technetium-99m generator (generator) prior to distribution. During the breakthrough tests, vials containing between hundreds of millicuries and low curie quantities of technetium-99m within lead vial shields (shields) were placed into a plastic tray. The tops of the shields were not fastened to the shields; therefore, the tops would fall off the shields if they were inverted. After about eight shielded vials were placed into the plastic tray, an individual would hand carry the tray several feet to another area for molybdenum-99 measurements. The plastic tray had no handles; therefore, individuals usually carried the trays by grasping a plastic rim at the top of the tray. The loaded trays were heavy and awkward to carry. The inspector identified a concern that this step of the process had a high potential for a significant radioactive spill and/or injury to an individual. Specifically, if a loaded tray was dropped, one or more vials could break on the floor causing significant radioactive contamination and/or a shield(s) could fall on an individual and result in an injury.

In response to the NRC's concern, the licensee provided a letter dated March 29, 2009, that included specific actions that had been taken to address the concern. The letter stated that the licensee purchased carts that were now used for transporting the shielded vials from the generator manufacturing line to the molybdenum-99 assay station.

In follow-up to the concern, the inspectors noted that the licensee provided verbal training to applicable staff regarding the need to use carts to transfer the shielded vials from the manufacturing line to the molybdenum-99 assay station. In addition, the inspectors observed licensee staff use carts to transfer shielded vials that were within plastic trays from a generator assembly area to a molybdenum-99 testing area. The inspectors also noted that licensee staff moved the loaded carts carefully to reduce the potential of shielded vials falling off the cart.

b. Concern 2 – Untested Assumption Regarding Molybdenum-99 Breakthrough Testing

The NRC previously identified a concern regarding an assumption the licensee made about its method of assaying the radioactivity of molybdenum-99 during in-house breakthrough testing. Specifically, the licensee conducted insufficient testing to verify

that its assumption was correct. As previously discussed above, each vial of technetium-99m was within a shield. The licensee measured the radioactivity of molybdenum-99 while the vial was in the shield. The shields were not designed for conducting molybdenum-99 assays. The licensee assumed that the critical dimension of the shields for measuring the radioactivity of molybdenum-99 was consistent.

During testing of its method to conduct molybdenum-99 assays, the licensee randomly selected five shields out of more than 150 (a non-representative sample) to conduct measurements of a calibrated molybdenum-99 standard, in part, to determine if the critical dimension of the shield was consistent. In addition, the licensee did not measure the critical dimension of the five shields to assess potential variations. Therefore, the licensee did not provide sufficient justification to verify that its assumption about the critical dimension of the shields was correct. If the critical dimension of a shield(s) is thicker than the lead shield specification thickness beyond an unknown threshold, the measured molybdenum-99 radioactivity would be erroneously low, such that a vial could contain a molybdenum-99 concentration above the limit and still pass a breakthrough test.

In response to the NRC's concern, the licensee provided a letter dated March 29, 2009, that included specific actions that were taken to address the concern. The letter stated that the licensee defined the critical dimensions of the shields to be between a range of 0.26 inches to 0.30 inches, measured each shield, and eliminated any that did not have the critical dimensions. In addition, the licensee executed a protocol to determine the calculation factor (i.e., microcuries of molybdenum-99 per counts per minute) utilizing shields with the maximum thickness for the critical dimension. The letter also stated that use of the calculation factor will result in a conservative calculation of molybdenum-99 activity.

The licensee provided a letter to the NRC dated April 2, 2009, in response to the NRC's request for additional information. The letter stated that, to ensure that newly purchased shields are of the appropriate dimension, the licensee placed a unique mark on the shields that passed the dimensional check. The letter also stated that the licensee instructed operators to ensure that shields used for breakthrough tests have the unique mark. In addition, the letter stated that, for shields yet to be purchased, the licensee will supply the appropriate specification to the shield manufacturer and appropriate testing will be performed to ensure that the shields meet the defined specification.

In follow-up to the concern, the inspectors noted that the licensee's RSO and Site Quality Manager approved its protocol for determining the molybdenum-99 counting efficiency with the shields and appropriate instrumentation. The licensee used a tool to measure the thickness of the critical dimension of all of its shields. The inspectors observed the Environmental Health and Safety Manager demonstrate how the licensee measured the critical dimension of the shields to one thousandth of an inch. The measuring tool generated reproducible results. The licensee discarded shields with a critical dimension thickness that deviated from the acceptable 0.26 to 0.30 inch range.

The licensee developed standard samples of known molybdenum-99 activity with calibrated pipettes. The licensee determined the activity of the molybdenum-99 standard samples by counting them with a high purity germanium detector that was

calibrated by a traceable primary radioactive standard. The licensee employed a 5 percent tolerance limit of measured versus expected standard sample activity.

Based on counting the standard samples with specific instrumentation and shields with critical dimension thicknesses that were in the acceptable range, the licensee determined that the calculation factor differed by 15 percent relative to shields that were at the upper and lower limits of the acceptable range. As a conservative measure, the licensee used the 0.30 inch critical dimension thickness calculation factor for all shields used to conduct in-house breakthrough testing.

The inspectors observed that the licensee placed a unique mark on the lead shields that had critical dimension thicknesses that were in the acceptable range. During in-house breakthrough testing, the inspectors observed that licensee staff only used shields with the unique mark to conduct the tests. Licensee staff verified that shields had the unique mark during preparations taken before each generator manufacturing run, such as when the staff checked for shield warping. In addition, licensee staff verified that shields had the unique mark after each generator manufacturing run when the shield contents had decayed to safe radioactivity levels. Although the licensee had not purchased any new shields, it planned to supply the appropriate specification to the shield manufacturer, conduct appropriate testing to ensure that newly purchased shields are of the appropriate dimension, and apply the unique mark on those that have the appropriate dimension.

c. Concern 3 – Effectiveness of Actions to Prevent Molybdenum-99 Breakthrough

The NRC previously identified a concern regarding the effectiveness of the licensee's corrective actions to prevent breakthrough. Specifically, the inspector noted that the frequency of breakthrough complaints varied widely over several months, with a particularly increased frequency in January and February 2009. Considering the licensee's corrective actions that had been taken and the fact that the content of Chemical 1 in Component 1 used to produce generators had been very similar over the last several months, the inspector determined that it was reasonable to expect that the frequency of breakthrough complaints would be relatively constant. Therefore, the inspector concluded that the wide variation of breakthrough complaint frequency indicated that there may be another cause(s) for the breakthrough problem that the licensee was unaware of, thus rendering the licensee's corrective actions taken at that time less effective.

In response to the NRC's concern, the licensee provided a letter to the NRC dated March 20, 2009, that included specific actions that were taken to address the concern. The letter stated that the licensee developed an effectiveness check to determine if its corrective actions were successful in either preventing or mitigating the number of breakthrough events. The new effectiveness check will allow the licensee to evaluate the success of its corrective actions and, if it is determined that it has not been successful in preventing or significantly reducing the number of breakthrough events, then it will identify and implement additional corrective actions to address the issue. The letter also stated that the licensee continues to work on additional improvement opportunities in parallel with its corrective and preventative actions associated with breakthrough.

In follow-up to the concern, the inspectors noted that the licensee instituted an effectiveness check to determine if its corrective actions were successful in either preventing or mitigating the number of breakthrough events. The effectiveness check included an investigation to determine root cause and identify corrective actions when two breakthrough complaints are associated with any three consecutive generator lots.

The licensee reviewed the potential causes of the increased number of breakthrough complaints that it received in the late 2008 and early 2009 timeframe. For example, the licensee noted that a potential cause of the increased complaints may have been its initiation of a new label affixed to the top of its generators alerting customers to test each generator eluate for molybdenum-99 content before use. Specifically, the licensee suspected that the new label may have resulted in increased customer focus on breakthrough testing on each elution, which resulted in additional breakthrough complaints. The licensee also noted that it received bulk molybdenum-99 from different vendors more frequently during the timeframe in question. Based on consultation with experts inside and outside of its organization, the licensee considered its bulk molybdenum-99 as a potential cause of the breakthrough complaints.

On February 20, 2009, the licensee began to produce generators using Component 1 with Chemical 1 content that was much lower than that used during the previous several months. As a result, the breakthrough complaint frequency between February 20 and August 28, 2009, was less than the licensee's pre-January 2008 average.

d. Concern 4 – Insufficient Detail or Inadequate Information in Licensee Procedures

The NRC previously identified a concern regarding insufficient or inadequate information in some of the licensee's procedures, resulting in an increased potential for misinterpretation and mistakes by individuals who may be responsible for implementing the procedures. For example, SOP 33-213 defined, "Conditions Adverse to Radiation Safety," and it included examples. One example was "elevated breakthrough reports." The key individual responsible for identifying CARS knew the threshold for elevated breakthrough reports in the context of the SOP. However, other less experienced individuals who may fill in for the key individual and implement the procedure may have interpreted the word "elevated" incorrectly because it is not described in the SOP.

In addition, SOP 33-213 described actions to identify CARS, including, but not limited to, notifying a manager about all customer complaints associated with radioactive products. Although the manager knew he was responsible for evaluating each customer complaint associated with radioactive products to determine whether or not they are CARS, the SOP did not state that the manager is responsible for doing so.

Other examples of the concern were identified in the licensee's Standard Test Method (STM) Code 240-018, "Ultra Technekow Generator Testing." The section that included steps for calculating the results of in-house breakthrough tests was difficult to follow and contained inadequate information. Specifically, a step in the calculation called for entering the times that radioactivity measurements were made; however, the step did not indicate what units of time should be used. In the same section of the STM, the term, "Decay Correction" was erroneously used instead of, "Decay Factor" such that an individual following the calculation steps could be confused by different terms that meant the same thing.

In response to the NRC's concern, the licensee provided a letter to the NRC dated March 20, 2009, which included specific actions that were taken to address the concern. The letter stated that the licensee initiated applicable revisions to SOP 33-213 and STM 240-018. The letter also stated that, in order to address the concern in other areas, the licensee conveyed the importance of providing sufficient detail in procedures to all of its Supervisors, Superintendents, and Managers.

In follow-up to the concern, the inspectors noted that the licensee revised SOP 33-213 to address the concern. For example, the revised SOP defined, "Conditions Adverse to Radiation Safety," and it included, among other things, the molybdenum-99/technetium-99m concentration associated with customer complaints about breakthrough test results. In addition, the revised SOP stated that the RSO or designee was responsible for evaluating each customer complaint associated with radioactive products to determine whether or not they are CARS.

The inspectors noted that the licensee revised STM Code 240-018 to address the concern. For example, steps for calculating the results of in-house breakthrough tests that called for entering the times that radioactivity measurements were made indicated what units of time should be used. In addition, the revised STM replaced the terms, "Decay Correction" and "Decay Factor" with the term, "Decay Correction Value." The Decay Correction Value was clearly defined as a math formula to calculate the molybdenum-99 activity at the time of elution based on the molybdenum-99 activity measured after elution.

The inspectors reviewed an e-mail message from the RSO to Supervisors, Superintendents, and Managers that discussed the concern regarding insufficient or inadequate information in some of the licensee's procedures, resulting in an increased potential for misinterpretation and mistakes by individuals who may be responsible for implementing the procedures. The message included a reminder for management to beware of similar issues when reviewing, revising, and approving procedures.

Despite the licensee's implementation of actions to address the concern, the inspectors identified new examples of the concern. Revised SOPs 33-213 and 33-23 stated that the RSO or designee is responsible for identifying if customer complaints are CARS. However, the SOPs also stated that, once a customer complaint has been identified as a CARS, it will generally be communicated to the RSO or designee within 24 hours. Therefore, the SOPs inferred that the RSO or designee must be informed when a customer complaint has been identified as a CARS even though the RSO or designee is responsible for identifying if customer complaints are CARS.

A licensee manager stated that the intent of those sections of the SOPs was to communicate that the RSO is responsible for identifying if customer complaints are CARS and the RSO's designee is responsible for evaluating the significance of CARS and, if appropriate, notifying licensee management representatives about them within 24 hours. Therefore, the SOP contained inadequate information, resulting in an increased potential for misinterpretation and mistakes by individuals who may be responsible for implementing the SOP.

Additional examples of the concern involved STM Code 240-018 and SOP 5-204, "In-Process Testing (100%) of DTE Generators for Molybdenum-99 Breakthrough." Both of

the procedures included errors in how to calculate the molybdenum-99 activity at the time of elution. Specifically, the calculation did not include a step to convert the result of a 30 second background count into a 1 minute background count, which is ultimately used to calculate the net molybdenum-99 activity.

Several additional examples of the concern involved SOP 5-204. As discussed in Section 2.2.a. above, in response to the NRC's concern about hand carrying shielded vials of licensed material several feet to another area for molybdenum-99 measurements, the licensee began using carts to transfer the shielded vials from a generator assembly area to a molybdenum-99 testing area. However, due to an oversight, the SOP still stated that the shielded vials should be hand carried from a generator assembly area to a molybdenum-99 testing area. In addition, several sections of the SOP requested the results of counts measured without indication of the counting time, which should have been 30 seconds. Also, an SOP attachment, which functioned as a form to manually record radiation measurements, called for units of background in counts per minute; however, the attachment should have called for units of background in counts per 30 seconds. The inspectors determined that there were no adverse safety consequences associated with the new examples of the concern.

The licensee took actions to address the new examples of the concern. The inspectors reviewed final revisions of SOPs 33-213 and 33-23 that were effective on August 27, 2009, which stated that it is the responsibility of a designated member of the Health Physics group to identify CARS. The inspectors also noted that the revised procedures stated that the RSO or a designee will be informed within 24 hours of when a complaint has been identified as a CARS. In addition, the inspectors reviewed licensee documents indicating that actions were underway to revise SOP 5-204 and STM 240-018 to address the concern.

2.3 Conclusions

The licensee implemented adequate actions to address the previously identified concerns involving the licensee's method of conducting breakthrough testing on each generator prior to distribution, an assumption the licensee made about its method of assaying the activity of molybdenum-99 during in-house breakthrough testing, and the effectiveness of the licensee's corrective actions to prevent breakthrough. The inspectors identified new examples of the previously identified concern involving insufficient or inadequate information in some of the licensee's procedures, resulting in an increased potential for misinterpretation and mistakes by individuals who may be responsible for implementing the procedures.

3 Safety Culture/Safety Conscious Work Environment

3.1 Inspection Scope

The inspectors reviewed selected records and interviewed licensee management representatives, a member of the licensee's ombudsman service, and 17 members of the licensee's staff from various departments and levels within the organization in order to evaluate the licensee's implementation of actions it took to address the safety culture concern that was previously identified during the special inspection. The interviewees included staff members from the Environmental Health and Safety and Quality

Departments (including customer complaint staff), generator production line, cyclotron maintenance and engineering, product distribution, cold product packaging, and hot products.

3.2 Observations and Findings

As documented in NRC Inspection Report No. 030-00001/08-01(DNMS) dated May 22, 2008, the NRC identified examples of a concern about the licensee's safety culture pertaining to its response to molybdenum-99 breakthrough complaints that it received between October 2006 and February 2008. In a letter to the NRC dated June 8, 2008, the licensee described specific actions that were taken or planned to address the concern, including: (1) providing additional training to all radiation workers reminding them of their right and responsibility to report safety concerns; (2) reinforcing the avenues available to staff for reporting safety concerns; (3) reminding employees about protected activities and the prohibition of adverse actions or retaliation in response to individuals raising safety concerns; (4) holding an open forum with employees to communicate the NRC's concern relative to safety culture, the basis for the NRC concern, the key attributes associated with a Safety Conscious Work Environment (SCWE), and the need to maintain a "safety-first focus;" (5) providing additional training to Managers and Supervisors regarding behaviors that contribute to maintaining an effective SCWE; and (6) providing training to individuals responsible for investigating customer complaints associated with radioactive products, including the attributes associated with a SCWE.

The inspectors verified that the licensee implemented the actions described in its June 8, 2008, letter by interviewing a licensee manager and reviewing several documents as discussed below:

- The inspectors reviewed the slides used by the licensee to present, "Environmental Safety and Health Physics Training for Supervisors" in February 2008. The training included the role of the supervisor in improving safety culture and safety performance, the need for safety tours, supervisor behaviors that produce desired employee behaviors, the need to communicate safety expectations to employees, and the need to reward good performance.

- The inspectors reviewed the slides used by the licensee to present, "Maintaining an Effective SCWE" during a licensee Superintendent Meeting on July 10, 2008. The training included the examples of the safety culture concern, the NRC's definition of, "Safety Culture;" SCWE; avenues for reporting safety concerns; the right to raise safety concerns; prohibition of retaliation for raising safety concerns; protected activities; and management behaviors to improve the willingness to raise safety concerns that included open door policy, effective listening, and expressing appreciation to those who raise safety concerns.

- The inspectors reviewed the slides used by the licensee's RSO to provide, "Injury Reporting and NRC Update" training to all of the licensee staff in July 2008. The inspectors noted that it included, among other things, information in NRC Inspection Report No. 030-00001/08-01(DNMS), such as the violation of License Condition 20, the examples of the safety culture concern, and the avenues available to staff for reporting safety concerns. The training also included staff encouragement to raise

safety concerns to aid problem identification and correction, rights relative to raising safety concerns, and prohibition of retaliation for raising safety concerns.

- The inspectors reviewed the slides used by the licensee's Health Physics staff to provide High Radiation Door Controls/Incident Investigation/Root Cause Analysis/CAP Training to licensee staff in September 2008. The training included the examples of the safety culture concern, the NRC's definition of, "Safety Culture," SCWE, symptoms of poor safety culture, consequences of poor safety culture, and patient consequences that can result from poor safety culture.

- The inspectors viewed the "I Chose to Look the Other Way" training video that was shown to licensee staff. The video stressed the need to follow procedures and the significant consequences that can result from failure to do so. In addition, it emphasized the need to inform people if they are not following a procedure and that, by doing so, the practice will become commonplace.

In response to the concern, the inspectors interviewed a licensee manager to obtain information about how the licensee would respond to similar circumstances associated with the examples of the concern above if they were presented with them now. The licensee responded to the circumstances associated with each example of the concern as follows:

- Now the licensee would respond conservatively and not use a component to produce a product if the component was a suspected cause of a problem, despite conflicting data that was collected during its investigation of the problem.

- The licensee now attempts to retrieve every generator associated with breakthrough complaints for investigation of the cause of the complaint in accordance with direction from corporate management.

- The licensee now includes extent of condition as part of its incident investigation/problem solving training.

- The licensee revised its applicable procedure to require performance testing on replacement of like-for-like parts to ensure that the replacement parts perform just like the parts they are replacing.

- The licensee revised its customer complaint receipt form to include what elution test resulted in breakthrough test failure.

- The licensee's Corporate Product Monitoring staff now conducts monthly customer complaint trend reports on products. For example, the licensee is implementing its effectiveness check (discussed in Section 2.2.c. above) to identify breakthrough trends.

Interviewees were very positive in terms of the licensee's enhancement of its safety culture and maintenance of a SCWE. Licensee staff expressed a willingness to report safety concerns to management, and indicated that management has been very open in receiving and handling safety issues raised by staff. Likewise, interviews of licensee management representatives indicated that they take reports of safety concerns from

staff very seriously, and that they have high expectations of staff to report safety concerns.

Interviewees provided examples of improvements in safety culture that included improved licensee response to safety issues, receipt of training regarding employee rights associated with reporting safety concerns to licensee management and the NRC, and options available to report safety concerns. In addition, several of the interviewees stated that they were provided with lessons learned as a result of licensee investigations or audits to resolve problems.

Some of the interviewees stated that they had reported safety concerns to the licensee by using some of the options available to report the concerns. In each case, the interviewee was satisfied with the quality of the licensee's response. Interviewees also stated that they were satisfied with management's timely response to their concerns. In addition, none of the interviewees stated that they experienced retaliation as a result of reporting safety concerns to the licensee.

The licensee contracted an Ombudsman service to provide one of several options for its staff to report safety concerns. The Ombudsman is available at a toll-free number 24 hours per day. The Ombudsman offered an "anonymous option" for employees who request identity protection when they report safety concerns. The Ombudsman collected and documented detailed facts regarding reported concerns, including whether or not the concerns were previously reported to the licensee. The Ombudsman forwarded information regarding concerns to licensee management for action.

The inspectors noted several licensee initiatives that were indicators of its focus on safety culture. Examples of programs instituted by the licensee to improve its safety culture include, but are not limited to: (1) a hazard observation program that provides incentives to staff to find and report safety concerns; (2) daily morning "Admiral's Call" meetings where, among other topics, safety issues are raised and discussed; (3) departmental Quality Improvement Program boards where safety issues received by staff are logged and tracked for resolution; and (4) "skip" meetings that provide the opportunity for staff to meet directly with a next level supervisor to discuss safety issues or other concerns.

As described in Section 2.2.d. above, the inspectors identified new examples of the previously identified concern regarding insufficient or inadequate information in some of the licensee's procedures, resulting in an increased potential for misinterpretation and mistakes by individuals who may be responsible for implementing the procedures. The new examples of the concern indicate a need for continued focus on improving the overall safety culture at the Mallinckrodt facility.

3.3 Conclusions

The licensee implemented adequate actions to address the previously identified safety culture concern. However, the new examples of the concern regarding insufficient or inadequate information in some of the licensee's procedures, resulting in an increased potential for misinterpretation and mistakes by individuals who may be responsible for implementing the procedures, indicate a need for continued focus on improving the overall safety culture at the Mallinckrodt facility.

4 Implementation of Actions Described in CAL 3-08-001

4.1 Inspection Scope

The inspectors continued their review of the licensee's actions taken to address the Confirmatory Action Letter (CAL) dated February 1, 2008. The inspectors interviewed licensee staff and reviewed selected documents, including records of customer complaints of breakthrough that were received since January 2009.

4.2 Observations and Findings

a. CAL Items 1 and 2

Item 1 of the CAL addressed the licensee's commitment to conduct an investigation into the problem of increased breakthrough complaints, and Item 2 of the CAL addressed the licensee's commitment to identify and implement immediate, short, and long term corrective actions regarding the breakthrough problem. In letters to the NRC dated May 19, 2009, and July 28, 2009, the licensee submitted responses to CAL Items 1 and 2. The licensee identified that the root causes of the breakthrough problem were an elevated level of Chemical 1 in Component 1, and manufacturing and assembly process issues associated with generator production. The licensee also identified and implemented immediate, short, and long term corrective actions to address the causes and prevent recurrence. The licensee determined that it had completed Items 1 and 2 of the CAL on February 20, 2009, when it implemented its last corrective action by using Component 1 with much lower levels of Chemical 1 to produce generators.

Examples of immediate, short, and long term corrective actions taken included distributing an Important Product Notification (IPN) in all generator shipping packages to request breakthrough testing of each elution (immediate); requesting that customers return affected generators for cause analysis (immediate); increasing the percent of generators that are breakthrough tested prior to shipment (short term); searching for a new supplier of Component 1 with a lower level of Chemical 1 (short term); performing tests on the impact of various levels of Chemical 1 in Component 1 on breakthrough (short term); obtaining and incorporating into the generator production process a new lot of Component 1 with a lower level of Chemical 1 (long term); revising procedures regarding the manufacturing and assembly processes of Component 2 (long term); and increasing molybdenum-99 breakthrough testing of outgoing generators to 100 percent (long term).

In its May 19 letter, the licensee stated that it had completed validation runs with the new Component 1 containing lower levels of Chemical 1, and that the results of the runs were submitted to the Food and Drug Administration (FDA) in January 2009. The licensee conducted breakthrough tests on the first elutions of all 81 generators in three consecutive lots (27 generators in each lot), followed by breakthrough tests on 10 subsequent elutions of nine generators from each lot. All elutions passed the breakthrough test with the exception of one generator which had a breakthrough value that exceeded 0.15 microcuries at 12 hours post-elution on both the first and second elutions. The remaining nine elutions for that generator were within acceptable limits. The licensee forwarded its test results to the FDA on January 20, 2009.

The licensee began to use new Component 1 with lower levels of Chemical 1 for generator production on February 20, 2009, and it initiated a 12 month effectiveness check. From February 20 to August 28, 2009, the rate of breakthrough complaints was less than the pre-January 2008 breakthrough complaint rate. Since February 20, 2009, the licensee received two breakthrough complaints within three consecutive lots of generators that were produced on July 17 and 20, 2009. Therefore, in accordance with its effectiveness check policy, the licensee initiated an investigation into the cause of the breakthrough complaints. The investigation was in progress during the inspection, and as of the date of this inspection, the licensee has not identified any new causes. The licensee expects that their investigation will be completed in early October 2009.

b. CAL Item 3

Item 3 of the CAL addressed the licensee's commitment to conduct an evaluation of the reportability of the breakthrough problem pursuant to Title 10 Code of Federal Regulations (CFR) Part 21 and provide the NRC with the results of the evaluation. As documented in NRC Inspection Report No. 030-00001/09-01(DNMS) dated February 19, 2009, the NRC determined that the breakthrough events that occurred between January 1, 2008, and January 6, 2009, did not constitute a "substantial safety hazard" as defined in 10 CFR Part 21.3. Therefore, the licensee was not required to report those breakthrough events to the NRC pursuant to 10 CFR Part 21. As such, the Open Item was closed. However, the licensee is required to evaluate future breakthroughs for reportability pursuant to 10 CFR Part 21 on a case-by-case basis.

In addition, the NRC reviewed the reportability of the breakthrough problem relative to 10 CFR Part 30 reporting requirements. Specifically, Section 30.50(b)(2) requires a 24 hour report after discovery of an event in which equipment is disabled or fails to function as designed when: (i) the equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident; (ii) the equipment is required to be available and operable when it is disabled or fails to function; and (iii) no redundant equipment is available and operable to perform the required safety function.

The NRC determined that the breakthrough events did not meet the reportability requirements of 10 CFR 30.50. Section 30.50(b)(2) requires, in pertinent part, that an event be reported in which equipment fails to function as designed "when the equipment is required by regulation or license condition to prevent exposures to radiation and radioactive materials exceeding regulatory limits." The NRC concluded that the regulations do not require the use of generators to prevent exposures to radiation, and there is no license condition that requires the use of generators to prevent exposures to radiation.

c. CAL Item 4

Item 4 of the CAL addressed the licensee's commitment to continue distribution of the IPN to its customers and, prior to discontinuing IPN distribution, contact the NRC to discuss: (1) why distribution of the IPN is no longer necessary; (2) its understanding of the FDA's perspective on whether or not distribution of the IPN is no longer necessary;

and (3) whether or not it has completed all of the corrective actions necessary to prevent recurrence. The licensee continued to include the IPN with the shipment of each generator. In addition, the licensee continued to affix a label to the outer lid of each generator which re-emphasized that each elution must be tested for breakthrough before use.

In its letter to the NRC dated May 19, 2009, the licensee stated that it believes that the IPN is no longer necessary because its corrective actions have successfully addressed the breakthrough problem. The letter also indicated that the FDA had determined that the IPN could be discontinued. The licensee plans to discontinue IPN distribution and continue use of the generator label. The inspectors contacted an FDA representative who confirmed the FDA's position that the IPN could be replaced with the label.

4.3 Conclusion

The licensee continued to make progress in addressing open CAL Items 1, 2, and 4. In addition, for CAL Item 3, the NRC determined that the licensee was not required to report the breakthrough events to the NRC pursuant to 10 CFR Parts 21 or 30.

5 Potential Generic Issues Relative to the Breakthrough Problem

5.1 Inspection Scope

The inspectors interviewed selected licensee staff, including the RSO and licensee management; reviewed selected records, including SOPs and licensee correspondence with the NRC; and observed licensee staff conduct breakthrough tests as a means of identifying potential generic issues associated with the breakthrough problem.

5.2 Observations and Findings

As documented in the previous NRC Inspection Report No. 030-00001/09-01(DNMS) dated February 19, 2009, the NRC identified a generic issue associated with the breakthrough problem. Specifically, a number of generators were reported to have produced elutions that exceeded the limit in 10 CFR 35.204(a)(1) at either the first or a subsequent elution test. Several breakthrough complaints involved breakthrough tests results that did not exceed the limit for the first eluate of a given generator, and then exceeded the limit based on a breakthrough test on a subsequent elution of that generator.

The inspectors identified an additional generic issue associated with the breakthrough problem. Specifically, elevated levels of Chemical 1 in Component 1 used to produce generators could result in generators that produce elutions that exceed the limit at either the first or a subsequent elution test, with the potential of having breakthrough test results that do not exceed the limit for the first eluate of a given generator, and then exceed the limit based on a breakthrough test on a subsequent elution of that generator.

5.3 Conclusions

The inspectors identified another generic issue associated with the breakthrough problem. Elevated levels of Chemical 1 in Component 1 used to produce generators could result in generators that produce elutions that exceed the limit at either the first or a subsequent elution test. The licensee has implemented adequate corrective actions to address this issue.

6 Exit Meeting

The inspectors discussed the preliminary conclusions described in this report with licensee management during an exit meeting conducted at the licensee's facility on August 28, 2009. The inspectors discussed the inspection findings described in this report with the RSO during a teleconference conducted on September 8, 2009.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Julia Balliet, Quality Assurance Systems Manager
Matt Biangardi, Maintenance
Erik Blake, Manager, Operational Excellence Manager
Tim Boger, Radioactive Hot Products Supervisor
David Canepa, Distribution
April Chance, Manager of Radiological Affairs/Radiation Safety Committee Chair
Terazina Cornell, Laboratory Technician
Steven Duffy, Quality Site Director
Keith Edwards, Environmental Compliance Supervisor
Mike Engdale, Materials Manager
Dorothy Gerner, Human Resources Manager
Dawn Heigel, Cold Products Packaging
Eric Hill, Health Physics
Chris Hoerchler, Assistant Human Resources Manager
#* Dan Hoffman, Radiation Safety Officer
Kandiss James, Manufacturing Laboratory Hot Products Technician
Melissa Kirkpatrick, Director, Quality
Vladimir Kmonicek, Senior Chemistry Technician
Stephanie Kramer, Training and Document Control Supervisor
Bob Krzyanowski, Manufacturing Coordinator
Corey Lamb, Health Physics Technician
John Lehnhoff, Quality Control Supervisor
Tracy Lore, Distribution Technician
Bryan Lowery, Production Superintendent
Sterling Marshall, Quality Engineer
Russell Maschek, Quality Assurance Engineer
Kevin McCarthy, Process Engineer
Tom McCormack, Distribution Superintendent
Craig Miller, Manager, Manufacturing
Darren Moore, Radiation Safety Committee Member
Brad Nelson, Environmental Health and Safety
Esther Onyango, Quality Technician II
Mitzi Pennington, Site Director
Jim Schuh, Manager of Environmental Health and Safety
Richard Sparks, Plant Controller
Dirk Stevens, Vice President of Quality
Randy Thomas, Safety and Environmental Manager
Mark Van Horn, Engineering Manager
Adam Washburn, Health Physics
Rich Watkins, Laboratory Technician
Michael Witte, Production Supervisor
Travion Woods, Quality on the Floor

participated in onsite exit meeting on August 28, 2009
* contacted by telephone on September 8, 2009, regarding final inspection findings

LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
CARS	Conditions Adverse to Radiation Safety
CAL	Confirmatory Action Letter
CAP	Corrective Action Program
CFR	Code of Federal Regulations
DNMS	Division of Nuclear Materials Safety
FDA	Food and Drug Administration
IPN	Important Product Notification
NRC	Nuclear Regulatory Commission
NOV	Notice of Violation
RSO	Radiation Safety Officer
SCWE	Safety Conscious Work Environment
SOP	Standard Operating Procedure
STM	Standard Test Method