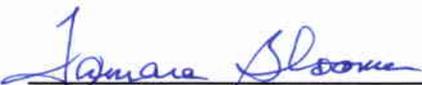



Geoffrey Warren, Health Physicist

Date 10/20/09

Approved 
Tamara Bloomer, Chief
Materials Inspection Branch

Date 10/20/09

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license)

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
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None

2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

A special inspection began in February 2008 and was initially documented in 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 in August 2009 with results documented in NRC Inspection Report No. 030-00001/09-02(DNMS) dated September 25, 2009. 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 the licensee received regarding the results of molybdenum-99 breakthrough tests conducted on technetium-99m generators and to evaluate the actions taken in response to the February 1, 2008, Confirmatory Action Letter (CAL 3-08-001).

As documented in NRC Inspection Report No. 030-00001/08-01(DNMS), the inspectors identified a violation of Condition 20 of NRC License No. 24-04206-01 involving failure to develop, implement, and maintain adequate Corrective Action Program (CAP) procedures. Specifically, the licensee's Product Quality CAP procedures did not 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; and 5) establishing time tables (milestones) for each provision, commensurate with the significance of the adverse condition. In addition to the violation, the inspectors identified a concern relative to the licensee's safety culture as it pertains to its response to the increased number of customer complaints.

As documented in NRC Inspection Report No. 030-00001/09-01(DNMS), the inspector identified a violation of Condition 20 of NRC License No. 24-04206-01 involving failure to develop Product Quality 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. In addition to the violation, the inspector identified concerns involving: (1) the licensee's method of conducting breakthrough testing on each generator prior to distribution; (2) the effectiveness of the licensee's corrective actions to prevent the breakthrough problem; and (3) licensee procedures that were written without sufficient detail or included inadequate information, resulting in an increased potential for misinterpretation and mistakes by individuals who may be responsible for implementing the procedures. The inspector also 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.

As documented in NRC Inspection Report No. 030-00001/09-02(DNMS), 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 inspectors determined that the new examples of the concern indicate a need for continued licensee focus on improving the overall safety culture at the Mallinckrodt facility. The inspectors also 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.

3. INCIDENT/EVENT HISTORY:

(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

NMED Item Number: 080595: Mallinckrodt reported the loss of a 0.69 GBq (18.7 mCi) I-131 capsule. On 9/19/2008, four I-131 capsules were packaged separately in shielded containers for shipment to Panama City, Panama. On 9/20/2008, the shipment departed on a flight from St. Louis, Missouri, to Miami, Florida. The packages were transferred to another flight that departed Miami and arrived in Panama City at approximately 1900 EDT on 9/20/2008. On 9/22/2008, Mallinckrodt was notified by the customer that one of the packages was not received in Panamanian Customs. Mallinckrodt requested a trace on the missing package. The airline's freight areas in St. Louis, Miami, and Panama City were searched. Mallinckrodt also pursued a search of the Panamanian Customs warehouse. All searches were negative. It was determined that the package was lost while in transit to South America. Mallinckrodt followed all procedures and no corrective actions are expected.

NMED Item Number: 080804: Mallinckrodt reported the loss of a radiopharmaceutical package with a single capsule containing 4.03 GBq (109 mCi) of I-131. Sixty packages of radiopharmaceuticals were shipped on 11/19/2008 from the Mallinckrodt facility to multiple customers in the Northeast United States. The packages were transferred by the initial courier to a charter aircraft courier that made stops in Richmond, Virginia,

Beltsville, Maryland, and Teterboro, New Jersey. At each location, freight was transferred to one or two additional couriers for ultimate delivery to customers. The missing package was destined for the Mallinckrodt Pharmacy in Folcroft, Pennsylvania. All of the couriers searched for the missing package without success and no customers reported receiving the package. To prevent recurrence, Mallinckrodt is working with the courier services to require signatures each time a package is transferred between courier services.

The above events were not reviewed during this inspection because this inspection was limited to a review of the licensee's biennial E.P. exercise. The above events will be reviewed during the next routine inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

The most senior licensee representative onsite was the Site Director. The Radiation Safety Officer (RSO) reported to the Site Director. The Maryland Heights facility had approximately 400 employees.

The locations of use were as authorized on the license. The bulk of the licensee's activities involved manufacture and distribution of radiopharmaceuticals. Mallinckrodt's main byproduct material of use was molybdenum-99 for the manufacture of molybdenum/technetium generators. Other isotopes of note, in descending order of quantity used each week, included iodine-131 and xenon-133. The licensee also operated six cyclotrons for the production of Thallium-201.

2. SCOPE OF INSPECTION:
(Identify the inspection procedure(s) used and focus areas evaluated. If records were reviewed, indicate the type of record and time periods reviewed)

Inspection Procedure: 88051
Inspection Focus Areas: 03.01-03.11, 03.13, and 03.14

The exercise scenario involved a vehicular accident near Building 400 and a resulting fire involving licensed material.

The following opportunities for improvement were identified during the exercise:

1. The licensee self-identified that it could improve communications regarding staging away from certain buildings.
2. The licensee self-identified that it could improve demarking of intermediately contaminated areas.
3. The licensee self-identified that it could reduce radio transmissions between the Emergency Manager and the Emergency Coordinator if all staff members with radios listen to all radio transmissions.

4. The licensee self-identified that it could improve communications regarding injured and/or contaminated personnel.
5. The licensee self-identified that it could have more promptly communicated when the fire was extinguished.
6. The licensee self-identified that it could reduce radio transmissions by positioning response teams closer together.
7. The licensee self-identified that it should have responded to victims more expeditiously.

The inspectors determined that the licensee's critique of the exercise was adequate.

The inspectors independently evaluated the licensee's dose estimates for the exercise by inputting applicable exercise scenario information into RASCAL, completing dose calculations, and comparing the RASCAL results with the licensee's results. The inspectors noted that their results were very comparable to the licensee's results.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:
(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

Since licensed material was not used during the inspection, the inspectors did not conduct independent or confirmatory measurements.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:
(State the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective action plan. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

None

5. PERSONNEL CONTACTED:
(Identify licensee personnel contacted during the inspection, including those individuals contacted by telephone.)

*Steve Duffy, Quality Director
 *Dorothy Gerner, Human Resources Manager
 *Dan Hoffman, RSO
 *Mark Van Horn, Engineering Manager
 *Roger Lewis, Senior Health Physicist
 *Craig Miller, Manufacturing Manager
 *Brad Nelson, Security and Emergency Response Supervisor
 *Mitzi Pennington, Site Director
 *James Schuh, Environmental Health and Safety Manager
 *Adam Washburn, B700 Health Physics/Operations Coordinator

Use the following identification symbols:

Individual(s) present at entrance meeting
* Individual(s) present at the exit meeting

-END-