

Enclosure 6 – Inspection Record

Region III Inspection Report No. 2011-002 License No. 21-04177-01
Docket No. 030-02049

Licensee (Name and Address):

Mallinckrodt, Inc.
2703 Wagner Place
Maryland Heights, MO 63043

Location (Authorized Site) Being Inspected: Same as above

Licensee Contact: Dan Hoffman, RSO Telephone No. 314-654-7906

Priority: 2 Program Code: 03211

Date of Last Inspection: 1/10-14/2011 Date of This Inspection: 09/13/2011

Type of Inspection: () Initial (X) Announced () Unannounced
(X) Routine Biennial E.P. Exercise () Special

Next Inspection Date: The biennial E.P exercise inspection does not change the next routine inspection date. () Normal () Reduced

Justification for reducing the routine inspection interval: N/A

Summary of Findings and Actions:

- (X) No violations cited, clear U.S. Nuclear Regulatory Commission Form 591 or regional letter issued
- () Non-cited violations (NCVs)
- () Violation(s), Form 591 issued
- () Violation(s), regional letter issued
- () Follow-up on previous violations

Inspector(s) Kenneth Lambert
(Name)

Date 11/18/11

Kenneth Lambert
(Signature)

Approved Tamara Bloomer
(Name)

Date 11/17/11

Tamara Bloomer
(Signature)

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

1. AMENDMENTS AND PROGRAM CHANGES:

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

2. INSPECTION AND ENFORCEMENT HISTORY:

A routine inspection was conducted January 10-14, 2011, with in-office review through January 28, 2011 (Inspection Report No. (IR) 030-0001/11-01(DNMS)). The inspection results documented a non-cited violation that occurred on August 16 and 17, 2011, involving the licensee's failure to ensure that the door to a high radiation area was locked or provide positive control over entries when the door was unlocked.

A routine inspection was conducted on November 2-6, 2009, with no violations identified (IR 030-0001/09-04 (DNMS)).

A routine inspection was conducted on September 20, 2009, to observe and evaluate the biennial emergency preparedness exercise (IR 030-0001/09-03 (DNMS)). No violations were identified.

A special inspection began in February 2008 and was initially documented in IR 030-00001/08-01 (DNMS), dated May 22, 2008. The NRC conducted additional special inspections in January 2009, with results documented in IR 030-0001/09-01 (DNMS), dated February 19, 2009, and in August 2009, with results documented in IR 030-0001/09/02 (DNMS), dated September 25, 2009. The purpose of the special inspections 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 take in response to the February 1, 2008 Confirmatory Action Letter (CAL-3-08-001).

3. INCIDENT/EVENT HISTORY:

EN 47236 On September 2, 2011, Mallinckrodt reported the loss of an OctreoScan dosage containing 18 mCi of In-111. The dosage was shipped on 8/7/2011 to a customer's facility in Rochester, NY. The courier contacted Mallinckrodt on 8/7/2011, to report that they had three bills of lading for the customer, but only two packages to deliver. Mallinckrodt began an investigation and contacted customers along the courier's route, but were unable to locate the missing material and reported the package lost on 9/2/2011.

EN 47106 On July 28, 2011, Mallinckrodt reported the loss of three TC-99m generator shields, each containing 8 mCi of depleted uranium. The shields were being returned to Mallinckrodt between April and June 2010. Two generators had been shipped to Ohio State University Medical Center, Ohio, and one to Tripler Army Medical Center, Hawaii. The facilities indicated they were returned to Mallinckrodt, but Mallinckrodt has no record of receiving the generator shields. All facilities

searched for the missing generator shields, but they were not located. The shields were discovered missing on July 27, 2011.

EN 46615 On February 15, 2011, Mallinckrodt reported the loss of a Mo-99/Tc-99m generator which was contained in a 49 pound depleted uranium cask. The generator was shipped on 2/13/2011 to a customer in Port Huron, MI. Mallinckrodt worked with the courier, the airline shipping the package, and customers along the delivery route in an attempt to find the shipment. The shipment was declared lost on 2/15/2011.

Since this inspection only reviewed the activities associated with the biennial exercise, the above events will be reviewed during the next routine inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

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

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

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 88051

Focus Areas Evaluated: 03.01-03.11, 03.13, and 03.14

The exercise scenario involved a vehicular accident with a parked semi tractor trailer and resulting in a fire involving licensed material in the trailer. The licensed material in the trailer was 665 Ci of Mo-99 and 1.5 Ci of I-131.

The inspector noted the following during the exercise and post-exercise critique.

1. The short exercise duration limited NRC participation at the Regional office.
2. The exercise participants did not simulate surveys of the vehicle and surrounding area and medical assistance to the vehicle driver.
3. Fire Department entered the site from the normal site access, which was downwind of the fire. The licensee could have made the exercise more realistic by having the fire department access the site from the upwind direction, which would have been through a gate that is normally locked. This would have allowed the licensee to test whether the locked gate could have been opened in a reasonable time frame.

4. Exercise Controllers need to control the exercise and ensure the developed timelines were followed. The exercise was estimated to take a minimum of 1.5 hours, however was completed in less than 45 minutes.
5. The licensee's critique of the exercise was self critical and resulted in the identification of several items that were to be entered into the licensee's corrective action program.

The inspector noted that the licensee's dose estimated during the exercise was significantly greater than those developed by the NRC base team dose assessor. The licensee's input data to its dose assessment program was provided to the NRC for evaluation and comparison to the input data NRC used in RASCAL. From the analysis of the data by NRC staff in headquarters involved with the development and upgrades to RASCAL, it was determined that several factors were involved in causing differences in the dose data. The NRC determined that the difference in the doses was due primarily to the licensee's program assuming all activity involved with the fire went airborne with the first hour of the fire, whereas RASCAL assumed 1 percent of the Mo-99 and 50 percent of the I-131 went airborne. Other factors that had less impact on the difference were RASCAL used a release height of 30 feet, the differences in atmospheric dispersion models between the two programs, and the uncertainties in the RASCAL for dose projections less than 0.1 miles. The licensee's radiation safety officer stated that they will be reviewing their dose assessment program and deciding whether to continue its use or to use the newer RASCAL program. This will be followed up during future inspections.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

None. Since licensed materials were not used during the EP exercise, the inspector did not conduct independent or confirmatory measurements.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

None

5. PERSONNEL CONTACTED:

- *Dale Eyman, Site Director
- *Dorothy Gerner, Human Resources Manager
- # *Dan Hoffman, Radiation Safety Officer
- *Shaun Kelley, Health Physicist
- *Bryan Lowery, Environmental Health and Safety Manager
- *Jim Schuh, Radiological Programs Director
- *Gwen Steavens, Production Manager
- *Mark VanHorn, Engineering Manager
- *Carol Walker, Site Quality Director
- *Kay Yoder, Director Environmental Health and Safety

Use the following identification symbols:

- * Individual(s) present at onsite preliminary exit meeting
- # Individual present at final exit meeting