

---

CONVERSATION RECORD

|TIME |DATE

6/26/08

---

VISIT

CONFERENCE

TELEPHONE

6/26/08

INCOMING

OUTGOING

---

NAME OF PERSON(S) CONTACTED OR IN CONTACT  
Jim Schuh, RSO

ORGANIZATION (OFFICE, DEPT. ETC.)  
Mallinckrodt, Inc.

TELEPHONE NO.  
314-654-7981

---

SUBJECT

Draft Revised Important Product Notification

---

SUMMARY

On 6/23/08, the licensee provided courtesy notification that it received two molybdenum-99 breakthrough complaints that involved much higher molybdenum-99 concentrations than previously identified (reference conversation record dated 6/23/08 for additional details). In response to the complaints involving higher molybdenum-99 concentrations, the licensee provided the attached draft, "UPDATED Important Product Notification," dated June 25, 2008, to the NRC and the FDA for review and comment/approval.

Kevin Null, Acting Chief, Materials Licensing Branch and Bob Gattone, Senior Health Physicist, reviewed the proposed revision.

The RSO confirmed that the final UPDATED Important Product Notification will be mailed to generator customers and it will also be included in the boxes containing each generator. In addition, the RSO confirmed that any future revisions to the UPDATED Important Product Notification will be forwarded to the NRC for review and comment/approval prior to issuance.

The RSO was informed that the NRC had no questions or concerns regarding the draft UPDATED Important Product Notification. In addition, the RSO was informed that the NRC will note the final date of the UPDATED Important Product Notification on the docket with reference to Item 4 of Confirmatory Action Letter 3-08-001.

---

ACTION REQUIRED

Place in ADAMS.

---

NAME OF PERSON DOCUMENTING CONVERSATION  
Bob Gattone

SIGNATURE

*Robert J. Gattone*

DATE

6/26/08

---

ACTION TAKEN

SIGNATURE

TITLE

DATE

UPDATED



COVIDIEN

## Important Product Notification

June 25, 2008

Dear Covidien Imaging Solutions Pharmacy Customer:

Since January 27, 2008, Covidien has included a letter in each Ultra-TechneKow<sup>®</sup> DTE generator shipment to make you aware of reports received from our customers of elutions in which the concentration of molybdenum Mo 99 to technetium Tc 99m exceeds the 12 hour expiration limit as stated in our package insert. Additionally, the letter serves as a reminder to follow the Covidien package insert and USP guidelines for the Ultra-TechneKow DTE Generator.

We continue to receive sporadic reports from our customers of elutions in which the concentration of molybdenum Mo 99 to technetium Tc 99m exceeds the 12 hour expiration limit as stated in our package insert. This includes two recent reports in which the reported concentration of molybdenum Mo 99 to technetium Tc 99m was higher than the USP guideline and higher than any previously reported incident. At the level indicated in these two reports, patient injections formulated with these elutions could potentially increase the possibility of an adverse health effect. **These occurrences reemphasize the need for customers to follow the package insert requirements to perform the Mo 99 breakthrough test on each generator elution.** Since scientific evidence does not conclusively demonstrate whether there is an adverse health effect at doses that could be expected if injections prepared with these elutions were administered to patients, it is important for customers to specifically follow the requirements of the Covidien package insert and USP guidelines for Ultra-TechneKow DTE Generator and sample each elution prior to patient administration.

Per our package insert, the expiration time of the Sodium Pertechnetate Tc 99m solution is no later than 12 hours after time of elution. Additionally, each eluate of the generator should not contain more than the USP limit of 0.15 microcuries molybdenum Mo 99 per millicurie technetium Tc 99m per administered dose at the time of administration (0.15uCi Mo99/mCi Tc99m).

Covidien has been in communication with both the United States Food and Drug Administration and the Nuclear Regulatory Commission regarding this matter. We are continuing to investigate these incidents.

In order to ensure that there are no patient safety or adverse health issues, we urge you to follow the Covidien package labeling and USP guidelines for the Ultra-TechneKow DTE Generator.

**Each eluate of the generator should be tested and should not contain more than the USP limit of 0.15 microcuries molybdenum Mo 99 per millicurie technetium Tc 99m per administered dose at the time of administration (0.15uCi Mo99/mCi Tc99m). If the concentration does not meet these requirements, the eluate should never be used to prepare a dose.**

We are requesting that you report all instances of Mo 99 in excess of 0.15 microcuries per millicurie technetium at 12 hours post elution to our Product Monitoring Department at 800-778-7898. Please also contact us with any questions or concerns.

Sincerely,

Dirk E. Stevens, Ph.D.  
Vice President, Quality

675 McDONNELL BOULEVARD  
HAZELWOOD, MO  
63042