

CONVERSATION RECORD

TIME | DATE

10/16/08

☐ VISIT☐ CONFERENCE☒ TELEPHONE☒ 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

Molybdenum-99 Breakthrough Complaint

SUMMARY

The licensee stated that it received a molybdenum-99 breakthrough complaint letter from a generator customer in the Dominican Republic on 10/14/08, and it was translated on 10/16/08. The licensee determined that the molybdenum-99 breakthrough complaint is physically impossible.

The complaint involves a 2 Ci generator that was calibrated for noon on 10/3/08. The customer reported that, on 10/8/08, the eluate contained 2.2 Ci of molybdenum-99 and 307 mCi of technetium-99m; however, the most molybdenum-99 that could remain in the generator would be 570 mCi, based on decay. The licensee has high confidence that the generator contained 2 Ci of molybdenum-99 at noon on 10/3/08 based on checks and balances, including an assay of the column before insertion into the generator.

The licensee contacted the customer physician who conducted the breakthrough test, and the customer will have its dose calibrator tested for proper operation. In addition, the licensee forwarded its standard molybdenum-99 breakthrough complaint questionnaire to the customer. The licensee suspects that the event is due to dose calibrator malfunction or operator error.

On 10/20/08, the licensee notified the NRC that it is sending a pharmacist and a transportation specialist to the customer in an effort to ship the generator back to the licensee's facility so Mallinckrodt can investigate the generator. In addition, the licensee reported that the event occurred during the customer physician's first ever molybdenum-99 breakthrough test. The licensee planned to contact the NRC with the findings of its investigation.

ACTION REQUIRED

Place in ADAMS.

Briefed Patty Pelke, Steve Reynolds, Jim Anderson

cc: Patty Pelke, Kevin Null

NAME OF PERSON DOCUMENTING CONVERSATION

Bob Gattone

SIGNATURE



DATE

10/22/08

ACTION TAKEN

SIGNATURE

TITLE

DATE