

8/4/11

MEMORANDUM TO: File
Mallinickrodt, Inc.
License No. 24-04206-01
Docket #: 030-00001

FROM: Robert G. Gattone, Jr., Senior Health Physicist, Materials Inspection
Branch, Region III *Robert G. Gattone, Jr.*

SUBJECT: Notice to Next Inspector

Please review the issues summarized in the attached documents during the next routine inspection.

CONVERSATION RECORD

TIME | DATE

VISIT

CONFERENCE

TELEPHONE

8/4/11

INCOMING

OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

Dan Hoffman, RSO

ORGANIZATION (OFFICE, DEPT.ETC.)

Mallinckrodt, Inc.

TELEPHONE NO.

314-654-7906

SUBJECT

EN 47106

IMBA Internal Dosimetry Software

SUMMARY

Regarding EN 47106, spent Tc-99m generators were shipped from the licensee's clients to the licensee and they were lost in transit. The licensee is continuing its investigation and will submit the required written report.

The licensee will begin using new internal dosimetry software (i.e., IMBA) that is based off of ICRP-68; however, 10 CFR 20 is based off of ICRP-30. Therefore, the licensee asked if it needed to obtain license amendment approval to use the IMBA software.

The inspector stated that the 10 CFR 20 regulations stand (e.g., ALIs, occupational dose limits, etc.). The inspector also reminded the licensee that 10 CFR 20.1501(a) requires that licensees conduct reasonable surveys to comply with 10 CFR 20. As long as the IMBA methodology is a reasonable survey to comply with 10 CFR 20 and use of it doesn't conflict with the licensee's NRC license conditions, amendment authorization to use the IMBA methodology doesn't appear necessary. However, the licensee can submit a license amendment request to use the IMBA methodology if it desires.

ACTION REQUIRED

Place in ADAMS.

Follow-Up on the above information during the next inspection.

NAME OF PERSON DOCUMENTING CONVERSATION

Bob Gattone

SIGNATURE

Robert B. Gattone, Jr.

DATE

8/4/11

ACTION TAKEN

SIGNATURE

TITLE

DATE