

FEB 4 1994

IE-07
PUBLIC

Mallinckrodt Medical, Inc.
ATTN: Warren Fadling
Director DIS/NMA Operations
P. O. Box 5840
St. Louis, MO 63134

License No. 24-04206-10MD
Docket No. 030-29675

Dear Mr. Fadling:

This refers to the routine safety inspection conducted by Evelyn R. Matson of this office on December 22, 1993, of activities at your Warren, Michigan radiopharmacy authorized by NRC Byproduct Material License No. 24-04206-10MD, and to the discussion of our findings with Mr. Grawburg at the conclusion of the inspection. This also refers to our telephone conversation with you, Dennis Davis, and Mr. Grawburg on February 3, 1994, to emphasize the importance of our findings regarding the effectiveness of your internal assessment follow up and client license programs.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. The inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel.

During this inspection, certain of your activities were found to be in violation of NRC requirements, as specified in the enclosed Notice. A written response is required.

The violation described in the enclosed Notice was originally identified through an internal audit by your office; however, the audit finding was not corrected and a broader concern regarding the effectiveness of your program to maintain and use current client license files was not resolved. We are concerned with your failure to assure: (1) that root causes of problems are thoroughly evaluated and lasting corrective actions are identified; (2) that corrective actions are implemented; and (3) that corrective actions are effective to prevent recurrence.

An effective self-assessment program is essential to continued safe operations of your radiopharmacy. Therefore, in addition to your response to the violation, please describe what actions you will take to strengthen your response to audit findings to assure that corrective actions to improve program weaknesses are appropriate, implemented and effective.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosure, and your response to this letter will be placed in the NRC Public Document Room.

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The response directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

John A. Grobe, Chief
Nuclear Materials Inspection
Section 2

Enclosure: Notice
of Violation

cc w/enclosure:
Michael Grawburg, Radiation Safety Officer
Mallinckrodt Medical, Inc.
2252 E. 14 Mile Road
Warren, MI 48092

bcc w/enclosure:
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YDA
RIII
EMH
Matson/bt
02/3/94

JAG
Grobe
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