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JAN 28 1994

Mallinckrodt Inc.
ATTN: Mr. Louis Schmuckler
Director of Manufacturing
2703 Wagner Place
Maryland Heights, MO

License No. 24-04206-01
Docket No. 030-00001

Dear Mr. Schmuckler:

This refers to the routine safety inspection conducted by Messrs John D. Jones and Mark Mitchell accompanied by John A. Grobe of this office from December 15, 1993, through January 19, 1994, of activities authorized by NRC Byproduct Material License No. 24-04206-01, and to the discussion of our findings with you and Mr. Ashok Dhar at the conclusion of the inspection.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and 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, personnel interviews, and independent measurements.

In addition to the above areas, the inspector examined actions described in your letters dated March 2, 1993, June 1, 1993, August 13, 1993, and November 1, 1993, regarding violations found during our February 22 through March 2, 1993, inspection.

Within the scope of this inspection, no violations were observed. However, several concerns were identified that we believe warrant your attention:

- **Technical and Professional Health Physics Staffing** - The technical and professional health physics staffing in the Radiation Safety Department may not be sufficient to effectively implement the radiation safety program. This concern was derived after considering several issues that could have been identified and resolved in a more timely manner:
(1) the tank spill clean-up issue; (2) air sample line maintenance; (3) extended time (over 18 months) to evaluate and install real time monitoring; (4) extended time (seven months) to prepare a report on a high thyroid measurement, (5) extended time to resolve the design and install the stack monitoring system; and (6) failure to provide an acceptable inventory of Tc-99. Staffing should be evaluated and adjusted as necessary.
- **Personnel Protection when Handling High Level Solid Waste** - The technicians entering Building 250 (a high radiation area and solid radioactive waste facility) are entering without the physical presence

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of a person at the entrance to the facility to provide assistance should the technician for any reason become incapacitated. Procedures for access to this facility should be evaluated and modified as necessary.

- **Radiological Protection Equipment Material Condition**

Air Sampler Flow Rates - The flow rate through the air samplers located in the penthouse of building 600 may not be sufficient and may result in measurements that are not representative of the sampled air due to partially or fully collapsed plastic sample lines near the filter port.

Sampler Power Cables - Power cables running along the perimeter fence for remote samplers may be unnecessarily stressed and could become damaged due to breaks in the conduits transferring the cables.

Radwaste Shredder Ventilation System - A tear in the shredder ventilation line, that could have materially affected the unit negative pressure, went undetected.

Preventative maintenance practices for radiological protection equipment should be evaluated and modified as necessary.

- **Radioactive Waste Inventory and Decommissioning Financial Assurance** - At the time of the inspection, spent generator columns containing residual technetium-99 (Tc-99) had been placed in drums awaiting receipt of a waste disposal license and shipment for disposal. On January 19, 1994, the RSO confirmed in a telephone conversation that a waste shipment had occurred during the first week of January. The Tc-99 inventory in the drums was estimated at 7.5 millicuries. The licensee could not demonstrate quantitatively that the Tc-99 inventory in the facility and ready for waste shipment did not exceed 10 millicuries, the limit requiring decommissioning financial assurance under 10 CFR 30.35. Procedures for controlling waste inventory and calculational techniques for monitoring Tc-99 inventory should be evaluated and upgraded as necessary.

- **Control of Liquid Wastes** - The inspectors expressed concern regarding the use of the floor of the liquid radioactive waste tank room in building 500 as a temporary hold-for-decay area following an accidental siphonage of one of the holding tanks during December 1993. Liquid waste handling practices should be evaluated and revised as necessary.

- **Radiation Safety Committee Review of Events** - During the Radiation Safety Committee meeting in April 1993, an incident was reviewed that occurred on March 2, 1993, involving an employee who had an elevated thyroid burden resulting from an estimated 40 MPC hours I-131 exposure. Very little information regarding root cause, and/or corrective action was provided in the minutes. The formal report of the incident was not

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completed until October, 1993. The timeliness of the incident report, and the limited detail provided in the minutes raises a concern regarding the depth of review and evaluation of the event and corrective actions by the committee. The effectiveness of committee reviews of events and documentation of those reviews should be evaluated and upgraded as necessary.

We request that you respond within 30 days to this letter. In your response, please describe your assessment of our concerns and what actions you will take to resolve these issues.

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

The response directed by this letter is 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.

Sincerely,

John A. Grobe, Chief
Nuclear Materials Inspection
Section 2

cc: W. Petty, Manager of
Regulatory Compliance
A. Dhar, Radiation Safety Officer

bcc: PUBLIC

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