

June 9, 2000

EA-00-143

Mr. Richard Johnson
Vice President, Imaging Operations
Mallinckrodt, Inc.
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Dear Mr. Johnson:

This refers to a June 8, 2000, telephone call between you and Ms. Cynthia Pederson, and other members of our respective staffs. The purpose of the call was to discuss the Confirmatory Order Modifying License (Order) that the NRC intends to issue to Mallinckrodt, Inc. The Order would resolve certain concerns the NRC has with the recently identified exposures in excess of the regulatory limits in 10 CFR Part 20 and with radiation safety practices at Mallinckrodt, Inc., and would become effective immediately upon issuance. During the telephone call, we discussed various corrective and remedial actions that Mallinckrodt, Inc., could implement to improve its radiation safety program and resolve NRC staff concerns. Based on our conversation, we propose that the conditions stated below be incorporated in the Order. The requirements of the Order would be satisfied upon submittal of the described information.

- A. Mallinckrodt shall retain the services of one or more independent individuals or organizations capable of evaluating radiation safety program implementation and manufacturing processes associated with radioactive materials at large facilities to perform the following:
1. An assessment of Mallinckrodt's radiation protection program. At a minimum the assessment shall include the following:
 - a. Roles and responsibilities of the Radiation Safety Office and Officer;
 - b. Effectiveness of Mallinckrodt's Radiation Safety and Dose Reduction Committees;
 - c. Current radiation protection organization staffing levels to determine if sufficient resources are available to support plant operations;
 - d. Effectiveness of the occupational exposure monitoring program (deep-dose equivalent; shallow dose equivalent, whole body and maximum extremity; and committed effective dose equivalent) to assure that all recorded exposures (e.g., finger and hand exposures) are representative of maximum exposures received;

- e. Effectiveness of Mallinckrodt in resolving previous radiation protection issues; and
 - f. Effectiveness of Mallinckrodt's radiation safety training program, including on the job training for radiation workers.
2. A radiation safety assessment of Mallinckrodt's radioactive materials manufacturing processes. At a minimum the assessment shall include the following:
- a. The radiation safety practices and related engineering controls associated with Mallinckrodt's processes involving radioactive materials;
 - b. Adequacy of and adherence to Standard Operating Procedures affecting radiation safety; and
 - c. The process that Mallinckrodt uses for evaluating radiation safety issues associated with new and modified product lines involving radioactive materials.

Mallinckrodt shall inform NRC Region III of the individual(s) or organization(s) hired for each of these assessments. These notifications shall be made within seven days of the date of the Order, and include the audit plan. Each assessment shall be completed within 60 days of the date of the Order. Within 90 days of the date of the Order, Mallinckrodt shall ensure that the individual(s) or organization(s) conducting each assessment submit to Mallinckrodt and NRC Region III, at the same time, the results of each assessment, including the deficiencies identified.

Mallinckrodt shall evaluate the root causes and develop corrective actions associated with any identified findings and submit to NRC Region III the schedules to implement those corrective actions. Mallinckrodt shall provide to NRC Region III the radiation protection program assessment corrective actions within 150 days of the date of the Order. Mallinckrodt shall provide to NRC Region III the corrective actions to the radiation safety assessment of the radioactive materials manufacturing processes within 180 days of the date of the Order. Should Mallinckrodt disagree with any assessment finding or plan not to initiate any corrective action arising from the assessments, Mallinckrodt must provide a written explanation of the rationale for such disagreement to NRC Region III within the respective 150-day or 180-day period.

- B. Mallinckrodt shall provide to NRC Region III, a written statement that all applicable Mallinckrodt workers have been trained and that Mallinckrodt has assessed the effectiveness of the training to ensure workers understand the procedures and practices in place to maintain radiation exposures as-low-as-is-reasonably-achievable. This written assurance shall be submitted to NRC Region III within 15 days of the date of the Order.

- C. Mallinckrodt shall develop a plan to review past operations to determine if any individuals could have received radiation exposures in excess of the applicable NRC limits in 10 CFR Part 20. This review shall encompass activities for a period of five years prior to the date of this Order. Mallinckrodt shall provide NRC Region III the plan and implementing schedule within 90 days of the date of the Order. The provisions of this Order do not relieve Mallinckrodt from complying with the reporting requirements in 10 CFR Part 20 should an exposure in excess of regulatory limits be identified during the review.

- D. Mallinckrodt shall request an amendment to its license incorporating a program that will identify and correct deficiencies associated with radiation safety. This program shall include, as a minimum, provisions for: (1) worker identification of radiation related safety issues; (2) prompt notification to management of significant issues; (3) root cause analysis, including associated training for all managers, supervisors, and radiation protection staff involved with performing and reviewing root cause evaluations; and (4) tracking of identified deficiencies. This amendment request shall be submitted to NRC Region III within 90 days of the date of the Order.

Please inform us whether Mallinckrodt, Inc., will consent to a Confirmatory Order with the above outlined conditions. Please provide your written response to me, NRC Region III, 801 Warrenville Road, Lisle, Illinois, 60532-4351 within five working days of the date of this letter. In addition, we would appreciate that Mallinckrodt, Inc., waive their right to a hearing on this Confirmatory Order by signing the enclosed Hearing Waiver form. After receiving your written consent, the NRC will issue the aforementioned Order. Issuance of the Order does not preclude the NRC from taking other enforcement actions in this matter.

Should you have any questions or wish to schedule another meeting to discuss the above provisions, please call Ms. Cynthia Pederson at (630) 829-9802.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be made available to the Public.

Sincerely,

/RA/ Cynthia D. Pederson for

J. E. Dyer
Regional Administrator

Enclosure: Hearing Waiver Form

FILE NAME:G:\eics\00-143 order items ltr.wpd *SEE PREVIOUS CONCURRENCE

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HEARING WAIVER FORM

Mallinckrodt, Inc., hereby agrees to comply with the commitments described in this letter and agrees to incorporation of these commitments into a Confirmatory Order that will be immediately effective upon issuance. I recognize that by signing below, Mallinckrodt, Inc., consents to the issuance of the Confirmatory Order, effective immediately, with the commitments described on pages 1 and 2 of this letter and, by doing so, pursuant to 10 CFR 2.202(a)(3) and (d), Mallinckrodt, Inc., waives the right to request a hearing on all or any part of the Order.

Richard Johnson
Vice-President, Imaging Operations
Mallinckrodt, Inc.

Date_____