

NUCLEAR REGULATORY COMMISSION

[Docket No. 030-00001; License No. 24-04206-01; EA-00-143]

Mallinckrodt, Inc., St Louis, Missouri; Confirmatory Order Modifying License

I

Mallinckrodt, Inc. (Mallinckrodt), is the holder of NRC License No. 24-04206-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR part 30. The license authorizes Mallinckrodt to use byproduct materials in manufacturing, processing and packaging of radiopharmaceuticals and radiochemicals for distribution to holders of a specific license issued by the Commission or an Agreement State. The license also authorizes Mallinckrodt to use byproduct material for research and development of radiopharmaceuticals. The license was issued on October 8, 1958, was most recently amended on March 27, 1998, and is currently in the renewal process.

II

On April 13, 2000, Mallinckrodt identified a potential extremity exposure in excess of regulatory limits to an individual working on the molybdenum/technetium generator manufacturing line and immediately notified the NRC of the incident. The NRC initiated a special inspection on April 14, 2000, to review the circumstances, and root and contributing causes of the event. On April 28, 2000, Mallinckrodt identified additional potential exposures in excess of regulatory limits involving additional processing areas. Based on the additional potential exposures and the complexity of the processes, the NRC expanded the special inspection to an Augmented Inspection Team (AIT). The AIT inspected Mallinckrodt between May 4 and May 26, 2000.

Based upon the AIT results, the NRC concluded that programmatic deficiencies exist in Mallinckrodt's ability to conduct: (1) Comprehensive assessments of its radiation protection program; (2) accurate root cause determinations for deficiencies identified through its problem identification program; and, (3) radiological evaluations of manufacturing processes. The results of these deficiencies included the failure to identify that significant differences existed in dose rates between fingertips and extremity monitoring devices when handling unshielded containers of radioactive material, the identification

that operating procedures did not reflect actual work practices, and that supervisors overseeing laboratory activities did not recognize the potential radiological consequences of work habits in their area. The NRC is concerned that inadequate controls over the safe use of licensed material continue to exist. NRC concerns along with various remedial and corrective actions, designed to improve Mallinckrodt's radiation safety program, were discussed with Mallinckrodt during a telephone call between members of NRC and Mallinckrodt staff on June 8, 2000. By letter dated June 9, 2000, NRC proposed conditions that could be taken to identify and correct the licensee's programmatic weaknesses. By letter dated June 16, 2000, Mallinckrodt agreed to implement the proposed conditions with minor modifications. These modifications have been incorporated into this Order.

III

By letter dated June 16, 2000, Mallinckrodt has agreed to:

- (1) Retain an independent organization to assess the radiation safety program and the radiation safety aspects of its radioactive material manufacturing processes;
- (2) Provide written assurance that workers have received training and understand procedures and practices in place to maintain radiation exposures as low as is reasonably achievable;
- (3) Develop a plan to review operations for the last five years to determine if any individuals have received exposures in excess of regulatory limits; and,
- (4) Request an amendment to its license incorporating a program that will identify and correct deficiencies associated with radiation safety.

On June 16, 2000, Mallinckrodt consented to issuance of this Order with the commitments, as described in Section IV below. Mallinckrodt further agreed in its June 16, 2000, letter that this Order is to be effective upon issuance and has waived its right to a hearing. Implementation of these commitments will provide enhanced assurance that sufficient attention will be applied to the radiation safety program, and that the program will be conducted safely and in accordance with NRC requirements.

I find that Mallinckrodt's commitments as set forth in Section IV are acceptable and necessary. Further, I conclude that with these commitments, the public health and safety are reasonably assured. In view of the foregoing, I have determined that the public health and safety require that

Mallinckrodt's commitments be confirmed by this Order. Based on the above and Mallinckrodt's consent, this Order is immediately effective upon issuance.

IV

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR part 30, *It Is Hereby Ordered, Effective Immediately, That License No. 24-04206-01 Is Modified As Follows:*

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:
 - 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:

- 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 this Order, and include the audit plan. Each assessment shall be completed within 60 days of the date of this Order. Within 90 days of the date of this 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 this 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 this 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 this 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 this 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 180 days of the date of this Order.

The Regional Administrator, Region III, may relax or rescind, in writing, any of the above conditions upon a showing by Mallinckrodt of good cause.

V

Any person adversely affected by this Confirmatory Order, other than Mallinckrodt, may request a hearing within 20 days of its issuance. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be made in writing to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Rulemakings and Adjudications Staff, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Materials Litigation and Enforcement at the same address, to the Regional Administrator, NRC Region III, 801 Warrenville Road, Lisle, Illinois, and to Mallinckrodt. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the

provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received. An answer or a request for hearing shall not stay the immediate effectiveness of this order.

Dated this 22nd day of June, 2000.

For the Nuclear Regulatory Commission.

R.W. Borchardt,

Director, Office of Enforcement.

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NUCLEAR WASTE TECHNICAL REVIEW BOARD

Board Meeting: August 1-2, 2000—Carson City, NV: Discussions of a Total System Performance Assessment for a Potential Yucca Mountain, Nevada, Repository for Spent Nuclear Fuel and High-Level Radioactive Waste; Update on Scientific and Engineering Studies Undertaken at the Yucca Mountain Site; and Update on the DOE's Development of a Safety Strategy for a Potential Yucca Mountain Repository

Pursuant to its authority under section 5051 of Public Law 100-203, Nuclear Waste Policy Amendments Act of 1987, on Tuesday, August 1, Wednesday, August 2, the Nuclear Waste Technical Review Board (Board) will meet in Carson City, Nevada, to discuss technical and scientific issues related to evaluating a possible site for a repository for spent nuclear fuel and high-level radioactive waste at Yucca Mountain, Nevada. Among the issues that will be discussed are a total system performance assessment (TSPA), a safety strategy for the potential repository, and scientific and engineering studies being conducted to evaluate the suitability of the Yucca Mountain site. The Board is charged by Congress with reviewing the technical and scientific aspects of the Department of Energy's (DOE) civilian radioactive waste management program, including disposing of, packaging, and transporting the waste.

The Board meeting will be held at Pinon Plaza Resort (Best Western), 2171 Hwy 50 East; Carson City, NV 89701. The telephone number is (775) 885-9000; the fax number is (775)-888-8018. The meeting will start at 8:30 a.m. on both days and will be open to the public.

On Tuesday, August 1, the DOE's Office of Civilian Radioactive Waste Management will present a general overview of the status of the program. The overview will be followed by