contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendments requested involve no significant hazards consideration, the Commission may issue the amendments and make them immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendments.

If the final determination is that the amendments requested involve a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, by the above date. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and to Michael I. Miller, Esquire; Sidley and Austin, One First National Plaza, Chicago, Illinois 60690, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated September 2, 1997, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the local public document room located at the Wilmington Public Library, 201 S. Kankakee Street, Wilmington, Illinois 60481.

Dated at Rockville, Maryland, this 11th day of September 1997.

For the Nuclear Regulatory Commission.

**M. D. Lynch,**

*Senior Project Manager, Project Directorate III–2, Division of Reactor Projects, Office of Nuclear Reactor Regulation.*

[FR Doc. 97–24675 Filed 9–16–97; 8:45 am]

BILLING CODE 7590–01–P

---

## NUCLEAR REGULATORY COMMISSION

**[Docket No. 030–00001; License No. 24–04206–01; EA 97–155]**

## Mallinckrodt Medical, Inc. Maryland Heights, Missouri; Order Imposing Civil Monetary Penalty

### I

Mallinckrodt Medical, Inc. (Licensee) is the holder of Materials License No. 24–04206–01 which was first issued by the Nuclear Regulatory Commission (NRC or Commission) on January 6, 1975, and renewed in its entirety on October 12, 1990. The license authorizes the Licensee to prepare and package for distribution Mo–99/Tc–99m generators and other radioactive materials in accordance with the conditions specified therein.

### II

An inspection of the Licensee's activities was conducted during January 10–12, 1997, with continuing review through April 8, 1997. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written notice of violation and Proposed Imposition of Civil Penalty (notice) was served upon the Licensee by letter dated May 30, 1997. The Notice states the nature of the violation, the provision of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violation.

The Licensee responded to the notice in a letter dated June 30, 1997. In its response, the Licensee admitted that the violation occurred and agreed that a civil penalty is warranted. The Licensee contested the fact that the NRC categorized it as a ''b'' category, industrial processor, as listed in Table 1A-Base Civil Penalties of NUREG–1600, ''General Statement of Policy and Procedures for NRC Enforcement Actions.''

### III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violation occurred as stated and that the penalty proposed for the violation designated in the Notice should be imposed.

### IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, It is hereby ordered that:

The Licensee pay a civil penalty in the amount of $13,750 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852–2738.

### V

The Licensee may request a hearing within 30 days of the date of this Order. 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, D.C. 20555, and include a statement of good cause for the extension. A request for a hearing should be clearly marked as a ''Request for an Enforcement Hearing'' and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region III, 801 Warrenville Road, Lisle, Illinois 60532–4351.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order (or if written approval of an extension of time in which to request a hearing has not been granted), the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issue to be considered at such hearing shall be:

Whether on the basis of the violation admitted by the Licensee, this Order should be sustained.

Dated at Rockville, Maryland this 9th day of September 1997.

For the Nuclear Regulatory Commission.

**Mark A. Satorius,**

*Deputy Director, Office of Enforcement.*

**Appendix**

**Evaluation and Conclusion**

On May 30, 1997, a Notice of Violation and Proposed Imposition of Civil Penalty (notice) was issued for a violation identified during an NRC inspection. Mallinckrodt Medical, Inc. (Licensee) responded to the Notice in a letter dated June 30, 1997. The Licensee admitted the violation but requested mitigation of the proposed civil penalty based on its contention that the civil penalty was assessed at an inappropriate level. The NRC's evaluation and conclusion regarding the licensee's request is as follows:

*Restatement of Violation*

10 CFR 71.5(a) requires that a licensee who transports licensed material outside the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR parts 170 through 189.

49 CFR 173.441(a) requires, in part, with exceptions not applicable here, that each package of radioactive materials offered for transportation be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 200 millirem per hour at any point on the external surface of the package.

Contrary to the above, on December 30, 1996, the licensee delivered to a carrier for transport licensed material, a 12 curie Ultra Techna-Kow Mo–99 generator, in a package that arrived at its destination, Mallinckrodt Nuclear Pharmacy in Saginaw, Michigan, with a radiation level of 210 millirem per hour on contact with the outer surface of the package.

This is a Severity Level III violation (Supplement V). Civil Penalty—$13,750

*Summary of Licensee's Request for Mitigation*

The Licensee agrees in its June 30, 1997 letter that a civil penalty regarding this apparent violation is warranted. However, the Licensee contests the level at which the NRC categorized the civil penalty (i.e.; placement of Mallinckrodt Medical, Inc. into the ''b'' category (industrial processor) of Table 1A–Base Civil Penalties of Section VI.B.2.d. of the NRC Enforcement Policy, NUREG–1600).

The Licensee does not believe that its operations present the magnitude of risk implied by the examples of types of licensees listed in the ''b'' category. The Licensee indicates that category ''c'' or ''d'' of the referenced table is more appropriate for the nature of its operations.

*NRC Evaluation of Licensee's Request for Mitigation*

The NRC published a revised ''General Statement of Policy and Procedure for Enforcement Actions'' (Enforcement Policy) in the **Federal Register** on June 30, 1995 (60 FR 34381). A significant policy change incorporated into the revised Enforcement Policy was the strategy for assessing civil penalties. According to Table 1A-Base Civil Penalties of the NRC's Enforcement Policy, the current base civil penalty for fuel fabricators, industrial processors, and independent spent fuel and monitored retrievable storage installations is $27,500. The civil penalty for a Severity Level III violation is 50% of the base civil penalty—$13,750. For the purposes of this enforcement action, the staff has determined that the Licensee was properly classified as an industrial processor under category ''b'' of Table 1A-Base Civil Penalties and that the level of the proposed civil penalty was in accordance with the Enforcement Policy.

Mallinckrodt Medical, Inc. is a large organization that obtains or produces radiopharmaceuticals for worldwide distribution, and the Mallinckrodt Maryland Heights Production Facility is one of the largest manufacturing facilities of diagnostic and therapeutic radiopharmaceuticals in the United States. The Licensee is authorized to possess up to 100 curies of any byproduct material within atomic numbers 1 through 83. In addition, the Licensee may posses up to 10,000 curies of Molybdenum-99, 500 curies of Iodine-131, 200 curies of Selenium-75, 450 curies of Xenon-133, and 200 curies of Rhenium-186. The Licensee employs approximately 280 individuals at its Maryland Heights Production Facility and processes on average 4,000 curies of Molybdenum-99, 70–100 curies of Iodine-131, and 50 curies of Xenon-133 weekly.

Previously, when the Enforcement Policy was published as 10 CFR Part 2, Appendix C, the term ''industrial processors'' was defined as ''Large firms engaged in manufacturing or distribution of byproduct, source or special nuclear material'' in a footnote to Table 1A-Base Civil Penalties (e.g.; see footnote 3 to Table 1A-Base Civil Penalties on page 147 of 10 CFR Ch. I (1–1–94 Edition)). On page II.D–39 of the basis document for the revised Enforcement Policy, NUREG–1525, ''Assessment of the NRC Enforcement Program,'' the stated purpose for revising Table 1A-Base Civil Penalties was to simplify it by combining categories of licensees with the same base civil penalty amounts. The proposed Table 1A-Base Civil Penalty Amounts in NUREG–1525 contained a footnote describing industrial processors as ''Large firms engaged in manufacturing or distribution of byproduct, source or special nuclear material.'' Although the footnote that specifically defined the term industrial processors was omitted [1] when the Enforcement Policy was reprinted as NUREG–1600, there is no indication that the term means anything different now than it has in recent years.

Mallinckrodt Medical, Inc. fits the definition of an industrial processor as previously defined in the Enforcement Policy and is appropriately categorized as an industrial processor for purposes of assessing the civil penalty. On a daily basis, the Licensee manipulates, prepares, and/or distributes to hospitals and radiopharmacies multi-curie quantities of Molybdenum-99, Iodine-131, and other radioactive materials. As a large producer and distributor of radioactive materials, Mallinckrodt's operations involve greater nuclear material inventories and have a greater potential for adverse consequences, if not properly controlled, than many other material licensees (i.e.; those classified as category ''c'' or ''d'').

In accordance with the NRC's Enforcement policy, under the revised civil penalty assessment strategy, the base civil penalty for a violation is determined using Table 1A-Base Civil Penalties. Under the revised civil penalty assessment strategy, a violation involving transportation of radioactive materials can be assessed the same base civil penalty as a violation involving plant operations or health physics. This is a significant change from the NRC's prior strategy, which used both the category of the licensee and the type of activity being conducted (e.g.; plant operations, health physics, or transportation) to assess a base civil penalty. Under the prior civil penalty assessment strategy, the base civil penalty for a violation involving transportation of radioactive materials was different than the base civil penalty for a violation involving plant operations or health physics. In accordance with the Enforcement Policy, under the revised civil penalty assessment strategy, the staff does not consider the type of activity (e.g.; the magnitude of risk associated with a particular type of activity such as transportation of radioactive materials versus plant operations) when assessing a civil penalty.

*NRC Conclusion*

The NRC has concluded that an adequate basis for changing the penalty category was not provided by the Licensee. Consequently, the proposed civil penalty in the amount of $13,750 should be imposed.

[FR Doc. 97–24678 Filed 9–16–97; 8:45 am]

BILLING CODE 7590–01–P

[1] The footnote defining industrial processors as ''Large firms engaged in manufacturing or distribution of byproduct, source or special nuclear material'' was inadvertently left out of the June 30, 1995, **Federal Register** Notice.

## NUCLEAR REGULATORY COMMISSION

### Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Industrial Radiography Licenses, Availability of Draft NUREG

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of availability and request for comments.

**SUMMARY:** The Nuclear Regulatory Commission is announcing the availability of and requesting comment on draft NUREG–1556, Vol. 2, ''Consolidated Guidance about Materials Licenses: Program-Specific Guidance