

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 possess 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 omitted¹ 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

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.

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]

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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

about Industrial Radiography Licenses," dated August 1997.

NRC is consolidating and updating numerous guidance documents into a series of program specific guidance documents to be published in a NUREG format. All NUREGs in the series will carry the number and title: NUREG 1556, Volume X, "Consolidated Guidance About Materials Licenses." Each specific guidance document will have an identifying volume number, and the title of the specific guidance will appear as the sub-title of the NUREG. This draft NUREG is the second guidance document to be published in this series; therefore it is listed as Volume 2.

This draft NUREG report is intended for use by applicants, licensees, NRC license reviewers, and other NRC personnel. This guidance corresponds with the revision to 10 CFR part 34 published in May 1997. It combines and updates the guidance for applicants and licensees previously found in draft Regulatory Guide FC 401-4, "Guide for the Preparation of Applications for the Use of Sealed Sources and Devices for Performing Industrial Radiography," (dated October 1984), and the guidance for licensing staff previously found in Policy and Guidance Directive FC 84-15, "Standard Review Plan for Applications for the Use of Sealed Sources and Devices for Performing Industrial Radiography," dated October 1994. In addition, this draft report also contains information found in pertinent Technical Assistance Requests and Information Notices. This draft report takes, where applicable, a more graded (or risk-informed) and performance-based approach to licensing industrial radiography consistent with the current regulations.

This draft NUREG report has been distributed for comment to encourage public participation in its development. It represents the current position of the NRC staff, which is subject to change after the review of public comments. Comments received will be considered in developing the final NUREG report that represents the official NRC staff position. Until the final NUREG report is published, this draft NUREG report represents the best available guidance, and may be used when preparing requests for licensing actions. Once the final NUREG report is published, NRC staff will use it in its review of requests for licensing actions. The draft and final NUREG reports may differ. If a license was issued or amended based on recommendations in the draft NUREG report and the final guidance is believed to be more advantageous, licensees may choose to request an amendment.

DATES: The comment period ends November 17, 1997. Comments received after that time will be considered if practicable.

ADDRESSES: Submit written comments to: Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Hand deliver comments to 11545 Rockville Pike, Rockville, Maryland, between 7:15 a.m. and 4:30 p.m. on Federal workdays. Comments may also be submitted through the Internet by addressing electronic mail to DLM1@NRC.GOV.

Those considering public comment may request a free single copy of draft NUREG-1556, Volume 2, by writing to the U.S. Nuclear Regulatory Commission, ATTN: J. Bruce Carrico, Mail Stop TWFN 8F5, Washington, DC 20555-0001. Alternatively, submit requests through the Internet by addressing electronic mail to JBC@NRC.GOV. A copy of draft NUREG-1556, Volume 2, is also available for inspection and/or copying for a fee in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC 20555-0001.

FOR FURTHER INFORMATION CONTACT: J. Bruce Carrico, Mail Stop TWFN 8-F5, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-7826; electronic mail address: JBC@NRC.GOV.

Electronic Access

NUREG-1556, Volume 2, is also available electronically by visiting NRC's Home Page (<http://www.nrc.gov>) and choosing "Nuclear Materials," then "Business Process Redesign project," then "Library," and then "draft NUREG-1556, Volume 2."

Dated at Rockville, Maryland, this 28th day of August, 1997.

For the Nuclear Regulatory Commission.

Larry W. Camper,

Chief, Medical, Academic, and Commercial Use Safety Branch, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 97-24677 Filed 9-16-97; 8:45 am]

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OFFICE OF MANAGEMENT AND BUDGET

Budget Analysis Branch; Sequestration Update Report

AGENCY: Office of Management and Budget—Budget Analysis Branch.

ACTION: Notice of transmittal of sequestration update report to the President and Congress.

SUMMARY: Pursuant to Section 254(b) of the Balanced Budget and Emergency Control Act of 1985, as amended, the Office of Management and Budget hereby reports that it has submitted its Sequestration Update Report to the President, the Speaker of the House of Representatives, and the President of the Senate.

FOR FURTHER INFORMATION CONTACT: Ellen Balis, Budget Analysis Branch—202/395-4574.

Dated: September 10, 1997.

Clarence C. Crawford,

Associate Director for Administration.

[FR Doc. 97-24640 Filed 9-16-97; 8:45 am]

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OFFICE OF MANAGEMENT AND BUDGET

Cumulative Report on Rescissions and Deferrals

September 1, 1997.

This report is submitted in fulfillment of the requirement of Section 1014(e) of the Congressional Budget and Impoundment Control Act of 1974 (Public Law 93-344). Section 1014(e) requires a monthly report listing all budget authority for the current fiscal year for which, as of the first day of the month, a special message had been transmitted to Congress.

This report gives the status, as of September 1, 1997, of ten rescission proposals and seven deferrals contained in three special messages for FY 1997. These messages were transmitted to Congress on December 4, 1996, and on February 10 and March 19, 1997.

Rescissions (Attachments A and C)

As of September 1, 1997, ten rescission proposals totaling \$407 million had been transmitted to the Congress. Congress approved six of the Administration's rescission proposals, totaling \$285 million, in P.L. 105-18. Attachment C shows the status of the FY 1997 rescission proposals.

Deferrals (Attachments B and D)

As of August 1, 1997, \$882 million in budget authority was being deferred from obligation. Attachment D shows the status of each deferral reported during FY 1997.

Information From Special Messages

The special messages containing information on the rescission proposals and deferrals that are covered by this