

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Syncor International
Blue Ash, Ohio

Docket No. 030-14827
License No. 34-18309-01MD
EA 90-053

During an NRC inspection conducted on July 6-8 and September 12-15, 1988, and an NRC investigation conducted between August 19, 1988 and January 18, 1990, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1988) the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

Violations Assessed Civil Penalties

- I. A. License Condition No. 19 requires, in part, that the licensee process radioactive material with reagent kits in accordance with the instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the reagent kit.

The brochure furnished by the manufacturer of the Tc-99m Medronate Reagent Kit used by the licensee on April 28, 1988 for compounding Tc-99m methylene diphosphonate (MDP) for bone imaging requires that sodium pertechnetate Tc-99m be slowly injected into the reaction vial.

Contrary to the above, on April 28, 1988, the licensee processed sodium pertechnetate Tc-99m with Tc-99m Medronate reagent kits in the preparation of Tc-99m MDP by injecting saline into the reaction vials supplied by the manufacturer, withdrawing the contents, adding the contents to a larger evacuated vial, and then adding sodium pertechnetate Tc-99m to the contents.

- B. License Condition No. 23 of NRC Byproduct Material License No. 34-18309-01MD requires that licensed materials be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983.

The application dated November 20, 1983 states in Attachment 2, Item K.2, that sodium pertechnetate elutions will be checked routinely for alumina breakthrough and that no eluate will be used if it exceeds 15 micrograms of alumina per milliliter of eluate.

Contrary to the above, sodium pertechnetate elutions were not routinely checked for alumina breakthrough and the resulting eluate, with an unknown alumina content, was used for preparation and dispensing of technetium-99m (Tc-99m) radiopharmaceuticals in at least the following examples,

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1. On August 8, 1988, six elutions of sodium pertechnetate from the molybdenum-99/technetium-99m generator were made but five of the six elutions were not checked for alumina breakthrough and the resulting eluate, with an unknown alumina content, was used for the preparation and dispensing of radiopharmaceuticals.
2. On August 9, 1988, eight elutions of sodium pertechnetate from the molybdenum-99/technetium-99m generator were made but seven of the eight elutions were not checked for alumina breakthrough and the resulting eluate, with an unknown alumina content, was used for the preparation and dispensing of radiopharmaceuticals.

These violations have been categorized in the aggregate as a Severity Level III problem (Supplement VI).

Cumulative Civil Penalty - \$15,000 (assessed equally between the two violations).

- II. 10 CFR 30.9(a) requires information provided to the Commission by a licensee or information required by the Commission's regulations or license conditions be complete and accurate in all material respects.

License Condition No. 23 of NRC Byproduct Material License No. 34-18309-01MD requires that licensed material be used in accordance with statements, representations and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983.

The application dated November 20, 1983 provides in Item 17, Appendix I that records will be kept of daily surveys of elution and preparation areas.

Contrary to the above, on at least one occasion in May or June 1988, the record kept of the daily survey of the licensee's elution and preparation areas was not accurate in that the survey readings were falsified by a licensee employee at the direction of a licensee management official.

This is a Severity Level III violation (Supplement VII).

Civil Penalty - \$5,000.

Violations Not Assessed a Civil Penalty

- III License Condition No. 23 of NRC Byproduct Material License No. 34-18309-01MD requires licensed material to be used in accordance with statements, representations, and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983.

The application dated November 20, 1983 states in Attachment 2, Item (1) that all radiopharmaceuticals dispensed from the nuclear pharmacy shall bear a prescription number and the proper label.

Attachment 2, Item (J) of the referenced application requires that each dose container be labeled to include, among other information, the pharmaceutical form.

Attachment 2, Item H.1.a. of the referenced application requires that a prepared Radiopharmaceutical Data Sheet be completed for each radiopharmaceutical prepared in-house and include the chemical form of the radionuclide.

A. Contrary to the above:

1. On April 28, 1988, 17 radiopharmaceutical doses which the licensee distributed from the nuclear pharmacy did not have proper labels in that the incorrect pharmaceutical form was listed on the dose container label. The dose containers listed the pharmaceutical form as Tc-99m methylene diphosphate (MDP) when the actual pharmaceutical form was Tc-99m sodium pertechnetate.
2. On April 28, 1988, a Radiopharmaceutical Data Sheet prepared by the licensee did not include the correct chemical form of the radionuclide in that it incorrectly listed the chemical form of a radiopharmaceutical prepared in-house as methylene diphosphate when the actual chemical form of the radionuclide was Tc-99m sodium pertechnetate.

B. Contrary to the above, on June 9, 1988, three radiopharmaceuticals which the licensee distributed from the nuclear pharmacy did not have proper labels in that the incorrect pharmaceutical form was listed on the dose container label. The dose containers listed the pharmaceutical form as Tc-99m MAA (Technetium Tc-99m Albumin Aggregated) when the actual pharmaceutical form was Tc-99m DTPA (Technetium Tc-99m pentetate).

C. Contrary to the above, on October 8, 1987, one radiopharmaceutical which the licensee dispensed from the nuclear pharmacy did not have a proper label in that the incorrect pharmaceutical form was listed on the dose container label. The dose container listed the pharmaceutical form as Tc-99m MAA (Technetium Tc-99m albumin aggregated) when the actual pharmaceutical form was Tc-99m sodium pertechnetate.

These violations have been classified in the aggregate as a Severity Level III problem (Supplement VI).

IV. License Condition No. 23 of NRC Byproduct Material License No. 34-18309-01MD requires licensed material to be used in accordance with statements, representations, and procedures contained in certain referenced applications and letters, including the application dated November 20, 1983.

A. The referenced application, dated November 20, 1983, states in Item 10 that cobalt-57, barium-133 and cesium-137 reference standards will be used to determine the accuracy of the licensee's dose calibrators.

Contrary to the above, from March 4, 1987, to May 21, 1988, a barium-133 reference source was not used to determine the accuracy of the licensee's dose calibrators.

This is a Severity Level IV violation (Supplement VI).

- B. The referenced application, dated November 20, 1983, states in Item 21.(B).(3) that the fume hood will be checked every six months with a volumeter to determine if the fume hood is operating according to specifications.

Contrary to the above, during the period October 21, 1987 through July 6, 1988, a period exceeding six months, the fume hood was not checked with a volumeter to determine if the fume hood was operating according to specifications.

This is a Severity Level IV violation (Supplement VI).

- C. License Condition No. 14.A(1) requires each sealed source containing licensed material, other than Hydrogen-3, with a half-life greater than 30 days and in any form other than gas to be tested for leakage and/or contamination at intervals not to exceed six months.

Contrary to the above, as of July 6, 1988, the date of the inspection, a sealed source containing a nominal 148 microcuries of Barium-133, which has a half-life of greater than 30 days and is in solid form, had not been tested for leakage since at least March 1986, a period in excess of six months.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Syncor International (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

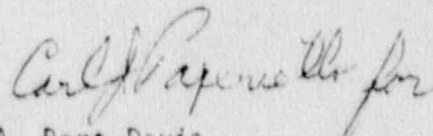
Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, with a

check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalties proposed above, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties, in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1988) should be addressed. Any written answer in accordance with 10 CFR 2.205 should set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure from imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U. S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.



A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 24 day of August 1990