

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Roche Professional Service Centers, Inc.
Philadelphia, Pennsylvania

Docket No. 030-29240
License No. 37-27830-01MD
EA 90-161

During an NRC inspection conducted on October 23 and 31, 1989, at the licensee's facility in Philadelphia, Pennsylvania, and a subsequent investigation by the NRC Office of Investigations, 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, (1989), the Nuclear Regulatory Commission proposes to impose a civil penalty 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.

I. Violations Assessed A Civil Penalty

- A. License Condition 11A of Facility License No. 37-27830-01MD requires that licensed material be used by or under the supervision of the individuals named in this License Condition. Condition 12 of this license requires that at least one individual named in Condition 11A of the license be physically present at the authorized place of use whenever licensed material is being used.

Contrary to the above, on September 17, 1989, a technician used licensed material (by drawing doses) when an authorized user listed in Condition 11A of the license was not physically present at the authorized place of use. Additionally, on October 23, 1989, technicians also utilized licensed material when an authorized user listed in Condition 11A of the license was not present at the authorized place of use.

- B. 10 CFR 30.9 requires, in part, that information provided to the Commission by an applicant for a license or by a licensee shall be complete and accurate in all material respects.

Contrary to the above, information provided by the licensee's then Facility Manager during an interview with an NRC inspector on October 23, 1989 was inaccurate in that the Facility Manager answered "No", in response to a question from the inspector regarding whether licensed material was ever used or handled without an authorized user being present. This statement was not accurate in all material respects in that the Facility Manager subsequently admitted to an NRC investigator on February 15, 1990, that she had authorized a technician to draw doses on September 17, 1989 without an authorized user being present in the facility. This statement was material because had NRC been

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aware that the technician had drawn doses on September 17, 1989 without an authorized user being present at the facility, NRC would have taken further regulatory action at that time.

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

Civil Penalty - \$7,500 (assessed equally between the two violations)

II. Violations Not Assessed A Civil Penalty

A. Condition 23 of License No. 37-27830-01MD requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in the license application dated April 30, 1986.

1. Item 8 of this application requires that the "Personnel Training Program" contained in Appendix C of Regulatory Guide FC 410-4 (dated August 1985) be followed.

Appendix C requires, in part, that training be provided before an employee assumes duties with or in the immediate vicinity of radioactive materials and that the training be sufficient to ensure that individuals who work in or frequent restricted areas are instructed in the items specified in Section 19.12 of 10 CFR Part 19, and that individuals who work in the immediate vicinity of radioactive materials be informed about radiation hazards and appropriate precautions.

Contrary to the above, as of October 23, 1989, licensee employees who worked in or frequented restricted areas or worked in the immediate vicinity of radioactive materials had not received all the required training to ensure that they were adequately instructed in the items specified in Section 19.12 of 10 CFR, as well as radiation hazards and appropriate precautions as evidenced by the following examples:

- (1) three employees did not receive initial training before they began work;
- (2) approximately nine licensee drivers did not receive training in radiological safety procedures for checking radiopharmaceutical shipment (ammo) boxes in and out; and
- (3) two drivers had not received training in the use of a survey meter.

This is a Severity Level IV violation.

2. Item 10.4 of this application requires that the Procedure for Calibration of Dose Calibrators in Appendix E of Regulatory Guide FC-410-4 be followed.

- a. Item 4.g of Appendix E requires, in part, that if the measured activity of the dose calibrator constancy test varies by greater than $\pm 5\%$ (from the predicted activity), the dose calibrator is to either be adjusted or an arithmetic correction factor is to be used to correct the dosage assays.

Contrary to the above, on nine occasions between April 5, 1989 and September 13, 1989 the measured activity of the constancy test, performed on the cobalt-57 setting for the CRC-12 dose calibrator, varied greater than $\pm 5\%$ from the predicted activity, and the dose calibrator was neither adjusted nor was an arithmetic correction factor used to correct the dosage assays.

This is a Severity Level IV violation.

- b. Item 1 of Appendix E requires that the dose calibrator linearity test be performed at installation and at 3 month intervals thereafter.

Contrary to the above, as of October 31, 1989, the licensee's dose calibrators had not been tested for linearity since June 10, 1989, an interval greater than 3 months.

This is a Severity Level IV violation.

3. Item 9.1 of this application requires, in part, that decayed waste, stored in the storage area above the first floor (non-restricted area), will not exceed background levels.

Contrary to the above, on October 31, 1989, a box of decayed waste located in the non-restricted storage area above the first floor measured 3 mR/hr at the surface, which exceeded the background level of 0.03 mR/hr for this area.

This is a Severity Level IV violation.

4. Item 10.7 of this application requires that the general rules for safe use of radioactive material contained in Appendix H of Regulatory Guide FC 410-4 be followed.

Item 3 of Appendix H requires that hands and clothing be monitored for contamination after each procedure or before leaving the area where radioactive materials are used.

Contrary to the above, on October 23, 1989, several licensee employees who prepared shipments of radiopharmaceuticals within the restricted area did not monitor their hands and clothing prior to leaving the area where radioactive materials were used.

This is a Severity Level IV violation.

Pursuant to the provisions of 10 CFR 2.201, Roche Professional Service Centers, Inc. (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 the Notice. The 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 Atomic Energy 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 penalty by letter 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 penalty 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 penalty, 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 penalty should not be imposed. In addition to protesting the civil penalty, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1989), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be 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 for 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 Atomic Energy Act, U.S.C. 2282(c).

The responses noted above (Reply to a Notice of Violation, letter with payment of civil penalty, 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, DC 20055 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

FOR THE NUCLEAR REGULATORY COMMISSION

Original Signed By:
Thomas T. Martin

Thomas T. Martin
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 16th day of November 1990