

NOTICE OF VIOLATION  
AND  
PROPOSED IMPOSITION OF CIVIL PENALTY

Pesara Pushpamala Reddy, M.D.  
Butler, Pennsylvania

Docket No. 030-15058  
License No. 37-18422-01  
EA 88-291

During an NRC inspection conducted between November 14, 1988, and February 10, 1989, 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, 53 Fed. Reg. 40019 (October 13, 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:

- A. 10 CFR Part 19.12 requires, in part, that all individuals working in a restricted area shall be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and function of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of November 14, 1988, technologists working in the nuclear medicine laboratory, a restricted area, had not been instructed in the proper procedures for using a radiation survey meter, in the procedures for safely opening radioactive material packages, in the procedures for performing adequate daily and weekly radiation surveys, or in the procedures for performing required dose calibrator performance tests (linearity and constancy).

- B. Condition No. 13 of License No. 37-18422-01 requires that licensed radioactive material be possessed and used in accordance with the representations, statements, and procedures contained in the license application dated March 25, 1984, and in the subsequent letters submitted in support of that application.

1. Item 14 of the application dated March 25, 1984, requires that radioactive material packages be opened in accordance with the procedures contained in Appendix F of Regulatory Guide 10.8. Appendix F requires that radioactive material package receipt surveys include direct radiation measurements at three feet and on contact with the package and measurements of removable radioactive contamination. The measurements must be sensitive enough to detect 22,000 disintegrations per minute per 100 square centimeters.

Contrary to the above, as of November 14, 1988, and for an indeterminate period prior thereto, radioactive material package receipt surveys and removable radioactive contamination

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measurements were not performed in accordance with the procedures described in Regulatory Guide 10.8. Specifically, the surveys failed to include direct radiation survey measurements at three feet and on contact with the surface of the package, and the method used to analyze removable radioactive contamination was not sufficiently sensitive to detect 22,000 disintegrations per minute per 100 square centimeters.

2. Item 10 of the application dated March 25, 1984, requires that dose calibrator constancy be evaluated in accordance with the procedures described in Appendix D of Regulatory Guide 10.8. Appendix D, Item A.1, Section 2, requires that dose calibrator constancy be evaluated each day that the instrument is used to assay patient doses.

Contrary to the above, on August 11 and 25, September 15 and 16, October 13 and 27, and November 7, 1988, the dose calibrator instrument was used to assay patient doses, and the dose calibrator constancy was not checked on those days.

3. Item 10 of the application dated March 25, 1984, requires that dose calibrator linearity be evaluated in accordance with the procedures described in Appendix D of Regulatory Guide 10.8. Appendix D, Item A.3, Section 2, requires that dose calibrator linearity be evaluated on a quarterly basis.

Contrary to the above, dose calibrator linearity was not evaluated during the first or second calendar quarters of 1988.

4. Item 17 of the application dated March 24, 1984, requires that area radiation surveys be performed in accordance with the procedures described in Appendix I of Regulatory Guide 10.8. Appendix I requires preparation and injection areas to be surveyed on a daily basis and requires that analysis of area radiation survey contamination wipe samples to be sufficiently sensitive to detect 200 disintegrations per minute.

Contrary to the above, as of November 14, 1988, and for an indeterminate period of time prior thereto, direct radiation survey measurements were not made of radiopharmaceutical preparation and injection areas on a daily basis, and the method used for the analysis of area radiation survey contamination wipe samples was not sufficiently sensitive to detect 200 disintegrations per minute.

- C. 10 CFR 35.14 requires that a licensee notify the Nuclear Regulatory Commission by letter within thirty days of any change in mailing address.

Contrary to the above, as of February 16, 1989, the licensee had not notified the NRC of several changes of mailing addresses which occurred in the later half of 1988.

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

Civil Penalty - \$1,500 (assessed equally among the six violations).

Pursuant to the provisions of 10 CFR 2.201, Pesara Pushpamala Reddy, M.D., (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. 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, (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, 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, or money order payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, 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 violation(s) 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, should be addressed. Any written answer in accordance with 10 CFR 2.201, 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 Act, 42 U.S.C. 2282c.

The responses to the Director, Office of Enforcement, 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, D.C. 20555 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 J. Martin*

*for*

William T. Russell  
Regional Administrator

Dated at King of Prussia, Pennsylvania  
this *12th* day of May 1989