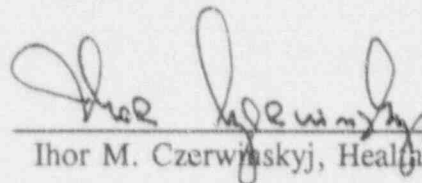


U. S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-14950/92-002
Docket No. 030-14950
License No. 29-18376-01 Priority 4 Category G
Licensee: Rhoda H. Cobin, M.D.
44 Godwin Avenue
Midland Park, New Jersey 07432
Facility Name: Rhoda H. Cobin, M.D.

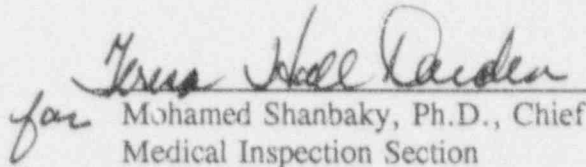
Enforcement Conference Conducted At: Region I, King of Prussia, Pennsylvania

Prepared By:


Ihor M. Czerwinskyj, Health Physicist

1/15/93
Date

Approved By:


for Mohamed Shanbaky, Ph.D., Chief
Medical Inspection Section

1-15-93
Date

Conference Summary: An Enforcement Conference was held at NRC Region I Office in King of Prussia, Pennsylvania on December 17, 1992 to discuss the violations identified during the routine inspection conducted on February 7, 1992. The corrective actions taken and planned by the licensee since the inspection were also discussed. Enforcement options available to the Commission were explained. This conference was closed to the general public. The conference was transcribed for the record by a court stenographer.

DETAILS

1.0 Attendees:

Licensee - Rhoda H. Cobin, M.D., Authorized User
Michael Caprio, Consultant

NRC:

R. Cooper, Director, Division of Radiation Safety and Safeguards(DRSS)
R. Bellamy, Chief, Nuclear Material Safety Branch, DRSS
I. Czerwinskyj, Health Physicist, NMSS
K. Smith, Regional Counsel
D. Holody, Regional Enforcement Officer
B. Letts, Regional Director OI
J. DelMedico, Senior Enforcement Specialist, OE
J. Schluter, Radiological Specialist, NMSS (by telephone)

2.0 Summary

The licensee and consultant physicist met with NRC representatives on December 17, 1992 in the Region I Office at King of Prussia, Pennsylvania. In the opening remarks, the Director of the Division of Radiation Safety and Safeguards explained the format and purpose of the conference. The Enforcement Policy was explained by the Enforcement Officer.

The Director of the Division of Radiation Safety and Safeguards asked the licensee to provide some general information about her medical practice and use of radioactive materials. The licensee stated that she is an endocrinologist in private practice, and a small user of radioactive material confined exclusively to radioiodine for diagnosis and thyroid therapy. She employs a health physics consultant on whom she relies for expertise in the requirements of the Nuclear Regulatory Commission Codes, Rules and Regulations, and who performs most of the required surveys, tests and calibrations.

The Director of DRSS asked the inspector who conducted the February 7, 1992 inspection of the licensee's facility to verbalize the apparent violations identified during the inspection to provide the licensee an opportunity to respond to these items. The Licensee:

- 1) Denied the first apparent violation, which states that the licensee failed to provide the Commission with complete and accurate information in the license application dated July 7, 1989. The licensee explained that she had two

survey meters in her possession, just as she stated in her letter to the Commission dated May 22, 1990, in support of her license renewal application dated July 7, 1989. The licensee stated that the second high range measuring survey instrument was obtained from her consultant whenever therapy doses of iodine-131 were administered;

2) Denied the second apparent violation, which states that the licensee failed to calibrate the survey instrument annually. The licensee's consultant stated that the Dosimeter Corporation of America, Model 3700 survey instrument was calibrated by his consulting company in May 1991, but that the records of the calibration, inadvertently, were not provided to the licensee. The Director of the DRSS asked the licensee to provide the calibration records by FAX to Region I (this record was not provided to Region I.);

3) Denied the third apparent violation, which states that the licensee failed to check each dose calibrator for accuracy, linearity, and geometry. The licensee's consultant questioned the need to perform the geometry test for the calibrator, since the licensee uses only capsules, and the capsules are of one size only. In addition, the licensee's consultant stated that the performance of the geometry test in a crowded office will subject the workers in the office to unnecessary radiation exposure. The consultant stated that he did not perform the linearity test for the same reason -- doing the test would subject the non-radiation workers in the office to unnecessary radiation exposure. The consultant further questioned the Commission's requirement of performing the dose calibrator accuracy test using two different energy calibration sources. Since the licensee uses only one radioisotope, iodine-131, the licensee's consultant's professional opinion as a Certified Health Physicist, is that doing the accuracy test with one source is sufficient. The Director of DRSS pointed out to the licensee that she agreed to perform the above tests in her application for license renewal dated July 7, 1989 and in her letter to the Commission dated May 22, 1990 and that she can not unilaterally decide which codes, rules or regulations of the Commission she will or will not comply with;

4) Denied the fourth apparent violation, which states that the licensee failed to check the dose calibrator for constancy at the beginning of each day of use. The licensee stated that she always checks her dose calibrator for constancy. On the days indicated by the inspector when the constancy check was not performed, she is certain that the test was done, but it may have been recorded in a different record book. The Director of DRSS asked the licensee to provide to the Region I Office by FAX, appropriate missing records (Some of the constancy records were received in the Region I Office by fax.);

5) Denied in part, the fifth apparent violation which states that the licensee failed to ensure that doses determined by a check in the dose calibrator to be off by more than 10% from the prescribed dose, not be administered to the patient. The licensee acknowledged administering doses to patients that she

determined by assaying in her dose calibrator to be off by more than ten percent, but she disregarded her dose determination and relied solely on the dose assay by the radiopharmaceutical supplier. She stated that even if the dose was off by more than ten percent, it would not produce any ill effects on the patient. The Director of DRSS asked the licensee if she is familiar with the requirements to hospitalize patients who are administered greater than 30 millicuries (mCi) of iodine-131, and with the possession limit of the license of 30 mCi of iodine-131. The licensee replied that she is familiar with both of the requirements;

6) Admitted, with an explanation, to the sixth apparent violation which states that the licensee failed to repair or replace the dose calibrator if accuracy or constancy error exceeded ten percent. She admits noticing her constancy checks of the dose calibrator to be off over ten percent and the consultants accuracy test to be off over ten percent. But she attributed the readings to the erratic behavior of her dose calibrator. The licensee stated that she was planning to send her calibrator for repair right after the unannounced inspection by the NRC; and

7) Denied the seventh apparent violation which states that the licensee failed to survey for removable contamination, once each week, all areas where radiopharmaceuticals are routinely prepared for use, administered or stored. The licensee's consultant stated that the licensee used only iodine-131 capsules, that there is no possibility of any contamination of any areas of the facility and that on his advice, the licensee did not conduct any surveys for removable contamination. The consultant physicist asked the NRC's advice of areas to be wiped in this particular case. The Director of DRSS pointed out to the licensee that she agreed to do tests for removable contamination in the license application and that a gelatin capsule of iodine-131 is not considered to be a sealed source, that contamination from the capsule is possible and that the required surveys must be performed.

The Enforcement Officer discussed the enforcement options available to the NRC. The Director of DRSS thanked the licensee and consultant for participating in the enforcement conference. The meeting was adjourned.