NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Department of Veterans Affairs
VA Medical Center
Houston, Texas

Docket No. 30-03255
License No. 42-00084-06
EA 91-096

During an NRC inspection conducted June 10-12, June 18-20 and June 28, 1991, 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 (1991), 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. License Condition 20 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in the application dated May 22, 1985, and letter dated August 20, 1986.

1. Item 23.D.3(d) of the application dated May 22, 1985, specifies that a bioassay will be performed within 2 weeks of the last possible exposure to (volatile) I-125 or I-131 when operations (in research areas) are being discontinued or when the worker is terminating activities with potential exposure to radioiodine.

   Contrary to the above, the licensee failed to perform a bioassay for an individual within 2 weeks of the individual's last exposure to (volatile) I-125 and I-131, at which time the worker had terminated activities involving the use of radioiodine. Specifically, the individual had last worked with millicurie quantities of liquid radioiodine at the licensee's facility in August 1990, and a bioassay was not performed until March 31, 1991.

2. Item 8 of the letter dated August 20, 1986, specifies, in part, that for bioassays, the radiation safety officer (RSO) will perform the counting and calculations necessary to determine the amount of activity present in the person.

   Contrary to the above, as of June 20, 1991, the RSO had failed to perform the calculations necessary to determine the activity present in individuals for whom bioassays were performed. Specifically, the bioassays performed during the period from January 1990 to June 1991 for individuals working in nuclear medicine

consisted of a thyroid count using a scintillation detection system, but did not include the calculations necessary to determine and evaluate the activity present in the individuals' thyroid glands.

3. Item 21.B.1 of the application dated May 22, 1985, specifies that xenon-133 will be stored in a RADX Corp "Xenon-Kow 1I" located in the fume hood in Room 747A of Building 1A.

   Contrary to the above, the licensee did not limit the storage of xenon-133 to the RADX Corp. "Xenon-Kow II" within the designated fume hood in Room 747A of Building 1A, but also stored xenon-133 in Room B-11 of Building 26D on numerous occasions from January 1990 to June 1991.

   This is a repeat violation.

4. Item 7.B(.3) of the application dated May 22, 1985, specifies that the radiation safety committee (RSC) will review the training and experience of users of radioactive material and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with Nuclear Regulatory Commission regulations and the conditions of the license.

   Contrary to the above, the RSC had not reviewed a physician user's training and experience prior to the individual's use of gold-198 brachytherapy sources for patient treatments during December 1989 and February 1990.

5. Item 3 of the letter dated August 20, 1986, specifies, in part, that all radioactive material ordered by the V. A. Medical Center is ordered through the RSO who insures that the individual ordering the material is approved for the activity being ordered and that the activity ordered does not exceed the individual's possession limit.

   Contrary to the above, as of June 20, 1991, the RSO had failed to insure that an individual who ordered xenon-133 in curie quantities was approved for the activity ordered and that the activity ordered did not exceed the individual's possession limit. Specifically, the individual ordered and received 3-4 vials of xenon-133 containing 1 curie each per month over several years, although the individual was only approved by the RSC for a maximum possession limit of 400 millicuries.

6. Item 1 of the letter dated August 20, 1986, describes the conditions required for radionuclide use requests and approval by the RSC. Item 1.B. specifies, in part, that the procurement of all radioactive material must be approved by the Radionuclide Use Subcommittee (RUS) of the RSC.

   Contrary to the above, from January 10, 1990 to June 20, 1991, the RUS and RSC failed to approve an individual's procurement of radioactive material. Specifically, the individual had procured microcurie quantities of hydrogen-3, a material that the individual had not been approved to use or procure.

7. Items 22.B.3 and 22.B.4 of the application dated May 22, 1985, specify, in part, that contaminated [animal] carcasses will be placed in labeled plastic bags and stored in labeled radioactive waste drums specifically [designed] for biological waste, and the drums will be turned over to the appropriate commercial firm for disposal.

   Contrary to the above, during the week of May 27, 1991, the licensee failed to place four contaminated animal carcasses, containing approximately 1 millicurie total of cerium-141, strontium-85, scandium-46, and chromium-51, in a waste drum specified for radioactive biologic waste and to transfer the carcasses to a commercial firm for disposal. The carcasses were instead incinerated at the licensee's facility on May 30, 1991.

8. Item 15.H of the application dated May 22, 1985, specifies, in part that the immediate areas, e.g., hoods, benches, etc., in which radioactive materials are used will be checked at least daily for contamination; that a log record will be maintained of these survey results which are entirely negative; and that any contamination observed will be clearly marked and the RSO notified.

   Contrary to the above, from January 10, 1990 to June 20, 1991, the licensee failed to check at least daily for contamination in all laboratory areas where radioactive material was used, and failed to maintain a record of survey results for laboratory areas which were surveyed daily. Specifically, surveys were not conducted in Rooms 212 and 212A on each day of use, and records were not maintained for surveys conducted in Rooms 116, 118, and 119.

9. Item 15.M of the application dated May 22, 1985,

specifies, in part, that users will perform decontamination procedures when necessary. Item 15.R specifies, in part, that if contamination exceeds a level of 200 disintegrations per minute (dpm) per 100 square centimeters, decontamination will be done.

Contrary to the above, from January 10, 1990 to June 20, 1991, users of radioactive material had failed to routinely perform decontamination procedures when levels of contamination from phosphorus-32 exceeded 200 dpm per 100 square centimeters in Room 207A, a research area.

10. Item 15.R of the application dated May 22, 1985, specifies, in part, that periodic surveys will be conducted monthly in areas where less than 200 microcuries of radioactive material are used and weekly in all other lab areas. Weekly and monthly surveys will consist of a measurement of radiation levels with a survey meter and a series of smear tests to measure contamination levels.

    Contrary to the above, from December 1990 to June 1991, the licensee failed to conduct monthly surveys in laboratory areas where less than 200 microcuries of radioactive material were used, and failed to conduct weekly surveys in other laboratory areas where greater than 200 microcuries of radioactive material were used. Specifically, Room 225, where less than 200 microcuries of phosphorus-32 were used, was not surveyed monthly between December 1990 and June 1991. Additionally, Rooms 116, 118, and 119, where quantities in excess of 200 microcuries of phosphorus-32 were used, were not surveyed weekly between January and June 1991.

    This is a repeat violation.

B. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

    10 CFR 20.202(a)(1) requires that each licensee supply appropriate personnel monitoring equipment to, and require the use of such equipment by, each individual who enters a restricted area under such circumstance that he receives, or

is likely to receive, a dose in any calendar quarter in excess of 25 percent of the applicable value specified in 10 CFR 20.101(a).

10 CFR 20.101(a) requires that the licensee limit the whole body and extremity radiation dose of an individual in a restricted area to 1.25 and 18.75 rems per calendar quarter, respectively.

Contrary to the above, as of June 20, 1991, the licensee did not make surveys to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the whole body and extremities, and did not provide personnel monitoring equipment to each individual who entered a restricted area under circumstances such that they were likely to receive a dose in any calendar quarter in excess of 25 percent of the applicable values specified in 10 CFR 20.101(a). Specifically, the licensee failed to evaluate exposures for, or issue monitoring equipment to: (1) two physicians who had physically implanted brachytherapy sources during patient treatments completed in December 1989 and February 1990, and (2) nuclear medicine technology students who physically withdrew and administered radiopharmaceutical doses during 1990. The licensee also failed to evaluate an exposure received by an individual during the fourth quarter of 1990, a period when the individual's monitoring badge was determined to have been overexposed while not in use.

This is a repeat violation.

C. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within 3 days after the administration of the dosage.

Contrary to the above, on September 12 and October 18, 1990, the licensee administered to two patients approximately 100 millicuries each of iodine-131 (in liquid form), dosages which required hospitalization for compliance with 10 CFR 35.75, and the licensee did not measure the thyroid burden of the nuclear medicine technologists and physicians who helped prepare and administer the dosages until September 17 and October 23, 1990, respectively, periods in excess of 3 days.

D. 10 CFR 20.401(c)(1) requires, in part, that records of bioassays made pursuant to 10 CFR 20.108 be preserved until the Commission authorizes disposition. 10 CFR 20.108 states

that where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the Commission may incorporate appropriate provisions in any license directing the licensee to make available to the individual appropriate bioassay services. Item 23 of the license application dated May 22, 1985 describes the licensee's bioassay procedures.

Contrary to the above, as of June 20, 1991, records of bioassays made pursuant to the conditions of the license for bioassays performed during the third quarter of 1990 were not preserved. Specifically, records regarding routine bioassays for certain individuals in the research staff were not kept, although the NRC had not authorized their disposition.

E. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, (1) from January 1990 to June 1991, the licensee failed to survey with a radiation detection instrument at the end of each day of use imaging rooms within the nuclear medicine department where radiopharmaceuticals were routinely administered; and (2) from April to June 1991, the licensee failed to survey with a radiation detection instrument at the end of each day of use the nuclear medicine hot lab where radiopharmaceuticals were routinely prepared.

F. 10 CFR 35.70(h) requires, in part, that a licensee retain a record of each survey required by 10 CFR 35.70(e). The record must include, among other items, the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, from April 1991 to June 1991, the licensee did not include in records of removable contamination surveys conducted in areas where radiopharmaceuticals were routinely prepared for use and administered, the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

This is a repeat violation.

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Contrary to the above, from April 1991 to June 1991, the licensee did not include in records of removable contamination surveys conducted in areas where radiopharmaceuticals were routinely prepared for use and administered, the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters.

This is a repeat violation.

G. 10 CFR 35.50(c) requires a licensee to perform appropriate checks for constancy and tests for accuracy, linearity, and geometry dependence required by 10 CFR 35.50(b) following adjustments or repair of the dose calibrator.

Contrary to the above, following the repair of the RADX Assayer I dose calibrator in March and April 1991, the licensee did not perform a test for geometry dependence, and such test was appropriate due to the nature of the repair. The licensee had used the dose calibrator to measure patient radiopharmaceutical doses from April to June 1991.

H. 10 CFR 35.51(a)(3) requires that a licensee conspicuously note the apparent exposure rate from a dedicated check source, as determined at the time of calibration, and the date of calibration on any survey instrument used to show compliance with 10 CFR Part 35.

10 CFR 35.51(c) requires, in part, that a licensee check each survey instrument for proper operation with the dedicated check source each day of use.

Contrary to the above, from February to June 20, 1991, the licensee did not conspicuously note on a Ludlum Model 14C survey instrument (Serial No. 81934) used to show compliance with 10 CFR Part 35, the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration; and from February to June 20, 1991, the licensee routinely did not check its survey instrument with a dedicated check source on days when the instrument was used. Specifically, the licensee had used the survey instrument for routine surveys in the nuclear medicine department from February to June 1991.

This is a repeat violation.

I. 10 CFR 35.205(e) requires, in part, that a licensee check each month the operation of reusable collection systems for radioactive gases.

Contrary to the above, the licensee used two reusable collection systems for radioactive xenon-133 gas and did not check the operation of the collection systems from January 1990 to June 1991.

J. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, the licensee did not conduct a

physical inventory of three sealed sources containing cesium-137, iodine-125, and iodine-129 (Serial Nos. 052, 524927, and 222032179A, respectively) from January 10, 1990 to June 20, 1991, a period in excess of a calendar quarter.

This is a repeat violation.

K. 10 CFR 30.51(a) requires that each licensee keep records showing the receipt, transfer, and disposal of byproduct material.

Contrary to the above, as of June 20, 1991, the licensee did not keep records of the disposal of byproduct material. Specifically, no records were kept for the disposal of hydrogen-3 and iodine-125 via the sanitary sewerage system within the nuclear medicine RIA lab.

L. 10 CFR 35.92(b) requires that a licensee retain for 3 years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a), and that the record include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Contrary to the above, from January 1990 to June 1991, the licensee's records of disposal of byproduct material permitted under 10 CFR 35.92(a) did not include the date on which the byproduct material was placed in storage.

M. 10 CFR 20.403(b) requires, in part, that each licensee shall within 24 hours of discovery of the event, report any event involving licensed material possessed by the licensee that may have caused or threatens to cause (1) a loss of one day or more of the operation of any facilities affected or (2) damage to property in excess of $2,000.

Contrary to the above, the licensee failed to report within 24 hours of discovery an event of May 30, 1991, involving licensed material which resulted in the loss of more than 10 days of operation of an incinerator at the licensee's facility, and damage which required decontamination of the incinerator assessed at $6,000.00. Specifically, the licensee incinerated animal carcasses containing licensed material on May 30, 1991, and the incinerator was not decontaminated and returned to operation until June 13, 1991.

This is a Severity Level III problem (Supplements IV & VI). Cumulative Civil Penalty - $25,000 (assessed equally among the 22 violations).

Pursuant to the provisions of 10 CFR 2.201, the Department of Veterans Affairs (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 Penalty (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 or demand for information may be issued as to 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 penalty 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 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 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 in whole or in part, 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 (1991), 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 Act, 42 U.S.C. 2282c.

The response noted above (Reply to 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 IV, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011.

Dated at Rockville, Maryland
this 15th day of November 1991