UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket Nos. 030-12688 and 030-09761
RADIOLOGY-ULTRASOUND-NUCLEAR CONSULTANTS, PA.	)	License Nos. 29-06760-07 and 29-06760-08
Freehold, New Jersey	)	
	)	EA 90-061

ORDER IMPOSING A CIVIL MONETARY PENALTY

I

Radiology-Ultrasound-Nuclear Consultants, PA. (Licensee) is the holder of byproduct material License Nos. 29-06760-07 and 29-06760-08 issued by the Nuclear Regulatory Commission (Commission or NRC) which authorizes the Licensee to possess and use byproduct material for both diagnostic and therapeutic procedures in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on March 14, 1990. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated June 13, 1990. The Notice stated the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations. The Licensee responded to the Notice in a letter dated "June 21 - July 10, 1990." In its response, the Licensee: (1) admitted Violation D (but asserted Violation D is irrelevant); (2) denied Violation A; (3) denied Violation C, in that the Licensee contended that it had recorded daily wipe tests; and (4) neither admitted nor denied Violations B, E.1, E.2, F, G, and H. The Licensee also requested cancellation of the civil penalty.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated in the Notice, with the exception of Violation E.2, which needed clarification. The NRC staff, as set forth in the Appendix to this Order, has determined that: (1) the Licensee violated the NRC requirements associated with Violation E.2 as stated in the Notice; (2) Violation E.2 should be amended for clarification of the violation; and (3) the amendment of Violation E.2 should have no effect on the civil penalty. In addition, as set forth in the Appendix to this Order, the NRC staff has determined that cancellation of the civil penalty is not warranted and that the penalty proposed for the violations designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay a civil penalty in the amount of $1,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing shall be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address, and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

(a) whether the Licensee was in violation of the Commission's requirements as described in Violations A, B, C, E.1, F, G, and H set forth in the Notice referenced in Section II above and Violation E.2, as amended and as set forth in the Appendix to this Order referenced in Section III above, which the Licensee either denied, or did not admit or deny, and

(b) whether, on the basis of the violations referred to in Section V.(a) above, and Violation D set forth in the Notice, which the Licensee admitted, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 22nd day of February 1991

APPENDIX

EVALUATION AND CONCLUSION

On June 13, 1990, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection. Radiology-Ultrasound-Nuclear Consultants, PA (G. Anthony Doener, M.D.) (Licensee) responded to the Notice by letter dated June 21 - July 10, 1990. In its response, the Licensee: (1) admitted Violation D (but asserted Violation D is irrelevant); (2) denied Violations A and C; and (3) neither admitted nor denied Violations B, E.1, E.2, F, G, and H. The Licensee also requested cancellation of the civil penalty. The NRC's evaluation and conclusion regarding the Licensee's requests are as follows:

Restatement of the Violations

A. 10 CFR 35.615(d)(3) requires that the permanent radiation monitor installed in each teletherapy room be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

Contrary to the above, on those days prior to March 14, 1990 that the teletherapy unit was used for treatment of patients, the permanent radiation monitor in the teletherapy room was not checked with a dedicated check source for proper operation before the teletherapy unit was used for treatment.

B. 10 CFR 35.634(f) requires, in part, that a licensee's retained record of each spot-check required by 10 CFR 35.634(a) and (d) must include, among others things, the difference between the anticipated output and the measured output of the teletherapy unit.

Contrary to the above, as of March 14, 1990, the licensee's retained spot check records did not include the difference between the anticipated output and the measured output of the teletherapy unit.

C. 10 CFR 35.70(h) requires, in part, that a licensee retain for three years a record of each survey. 10 CFR 35.70(a) requires, in part, that a licensee survey at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, as of March 14, 1990, the licensee did not retain records of daily surveys of areas where radiopharmaceuticals were routinely prepared for use or administered.

D. 10 CFR 35.632(a)(2)(i) requires that a licensee perform full calibration measurements on each teletherapy unit whenever the spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration, corrected mathematically for radioactive decay.

Contrary to the above, the licensee did not perform full calibration measurements when spot check measurements performed by the licensee in

November 1986, in January, February, March, May and June 1987, and in March 1988, indicated that the teletherapy unit output differed by more than 5 percent from the output obtained at the last full calibration.

E. 10 CFR 35.21(a) requires that the Licensee appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, is required to ensure that radiation safety acti ities are performed in accordance with approved procedures. 10 CFR 35.21(b)(2) requires, in part, that the Radiation Safety Officer (RSO) establish and implement written policy and procedures for using byproduct material safely and performing checks of survey instruments and other safety equipment.

For using byproduct materials safely and performing checks of survey instruments and other safety equipment, the Licensee's Radiation Safety Officer established the procedures in NRC Regulatory Guide 10.8, Revision 2, Appendix C and D, which are required by Condition 13 of License No. 29-06760-08 to be met.

Appendix C requires, in part, that the measurements obtained during the dose calibrator linearity test be plotted and that the percent deviation be determined. Appendix D requires, in part, that all individuals who are occupationally exposed to ionizing photon radiation on a regular basis be issued a film or TLD whole body monitor and that individuals who, on a regular basis handle radioactive material hat emits ionizing photon radiation, be issued a film or TLD finger monitor to be processed on a monthly basis.

Contrary to the above:

1. between January 1987 and February 1988, the dose calibrator linearity test results did not include either a plot of the measurements or a determination of the percent deviation.

2. as of March 14, 1990, the RSO neither wore the issued whole body monitor while working with radioactive material on a regular basis, nor was he issued a finger monitor for use when handling radioactive material.

F. 10 CFR 35.50(b)(3) requires, in part, that the Licensee test the dose calibrator for linearity at least quarterly.

Contrary to the above, the Licensee did not test the dose calibrator for linearity during the last three quarters of 1988, nor at any time during 1989.

This is a repeat violation.

G. 10 CFR 35.51(a)(3) and (c) require that a licensee conspicuously note on each survey instrument the apparent exposure rate from a dedicated check source as determined at the time and date of the calibration and check each survey instrument for proper operation with the dedicated check source each day of use.

Contrary to the above, as of March 14, 1990, the licensee did not conspicuously note on the survey instrument the apparent exposure rate from a dedicated check source as determined at the time and date of the calibration, and did not check each survey instrument for proper operation with a dedicated check source each day of use.

H. 10 CFR 35.92(b) requires that a licensee retain a record of each disposal of byproduct material held for decay-in-storage as permitted under 10 CFR 35.92(a) for three years. The record must include, among other things, the date on which the byproduct material was placed in storage, the radionuclides disposed, and the background dose rate.

Contrary to the above, as of March 14, 1990, the licensee's retained records of disposal of byproduct material held for decay-in-storage did not include the date on which the byproduct material was placed in storage; the radionuclides disposed; or the background dose rate.

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

Civil Penalty - $1,000 - (assessed equally among the 9 violations)

Summary of Licensee's Response

Violation A

The licensee denies Violation A. The Licensee asserts that the permanent radiation monitor in the teletherapy room is checked each day as required, and is also checked before each radiation treatment using the cobalt unit as a dedicated check source. The Licensee states that a special dedicated check source is not used because this would result in unnecessary exposure to the radiation worker. The Licensee also states that no written records of the daily routine checks are kept because the checks are considered a "normal routine."

NRC Evaluation of Licensee's Response

Violation A

The Licensee is required to check the permanent radiation monitor in the teletherapy room with the cobalt unit each day before the teletherapy unit is used for treatment of patients. However, on the day of the inspection, the NRC inspector observed the Licensee treat the day's first patient with the teletherapy unit without checking the radiation monitor with the cobalt unit or any other dedicated check source. Further, when questioned by the inspector, the Radiation Safety Officer stated that he does not check the monitor until he begins the treatment. The regulation clearly requires that

the monitor be checked before the teletherapy unit is used for treatment of a patient. Therefore, the NRC concludes that the violation occurred as stated.

Summary of Licensee's Response

Violation B

The Licensee asserts that the anticipated output and the measured output of the teletherapy unit are recorded, and that the difference between the two measurements is self-explanatory.

NRC Evaluation of Licensee's Response

Violation B

The NRC agrees that the Licensee's records specified the measured output and the anticipated output of the teletherapy unit. However, these records did not include the difference between the two output values expressed as a percentage of the anticipated output as required by 10 CFR 35.634(a)(6). Therefore, the NRC concludes that the violation occurred as stated.

As a separate matter, the NRC acknowledges that, as indicated in 10 CFR 35.634, "Periodic spot-checks," item (a)(6) contains a typographical error. This item references the measured output required by paragraph (a)(5), not paragraph (b)(5) as stated in the regulation. A correction of this typographical error will be incorporated into the NRC's next revision of Part 35.

Summary of Licensee's Response

Violation C

The Licensee denies Violation C. The Licensee states that areas where radiopharmaceuticals are routinely prepared for use and administration are continuously surveyed by a Geiger instrument equipped with an acoustic alarm. The Licensee asserts that the acoustic alarm is better "perceived" than a visual reading of a monitoring instrument which might go unnoticed. Therefore, the Licensee maintains that any excess radioactivity is readily monitored. The Licensee also states that the daily wipe tests of areas where radiopharmaceuticals are used is recorded.

NRC Evaluation of Licensee's Response

Violation C

Continual acoustical monitoring may be superior to a visual reading from a survey instrument for a given purpose. Monitoring with a Geiger instrument, however, does not by itself satisfy the requirements of 10 CFR Part 30.70(h) to retain records of the results of certain surveys. While the NRC agrees that the Licensee performed and documented wipe tests beyond those required by 10 CFR 35.70(e), those tests detect removable surface contamination, and do not measure the ambient radiation exposure rates that 10 CFR Part 35.70(h) requires to be recorded. The Licensee did not retain records of surveys required by 10 CFR Part 35.70(a).

The Licensee did not document these surveys. Therefore, the NRC concludes the violation occurred as stated.

Summary of Licensee's Response

Violation D

The Licensee admits that spot check measurements of the teletherapy unit indicated that the teletherapy unit output differed by more than 5% from the output obtained at the last full calibration. However, the Licensee asserts this fact is irrelevant because: (1) the measuring instruments have an inaccuracy of more than 5%; and (2) Cobalt-60 decay is at a constant rate. Therefore, the Licensee asserts the required tests do not represent a test of the cobalt unit, but only represent a test of the measuring instrument which has no significance concerning the output of the cobalt unit. For these reasons, the Licensee concludes that spot check measurements exceeding +/-5% do not justify the expense it would incur to perform a full calibration of the cobalt unit and suggests that the NRC rescind the requirement for recalibration of the teletherapy unit under these circumstances since it constitutes an unnecessary burden on the workers and patients.

NRC Evaluation of Licensee's Response

Violation D

The Licensee admits the violation. As for the Licensee's contention that the violation is irrelevant to safety, the difference between the measured output and the anticipated output may indicate problems with the teletherapy unit such as malfunction of the timer, the collimator, or the source drive mechanism. The measured dose and doses administered to patients are not solely dependent on the decay of the source. In addition, the formula used to calculate the output dose from a spot check measurement contains a correction factor to compensate for any measuring instrument inaccuracy. Accordingly, the NRC staff concludes that Violation D is a significant violation.

Summary of Licensee's Response

Violation E

The Licensee did not admit or deny Violation E.1 in its response.

With respect to Violation E.2, the Licensee neither admits nor denies the violation. The Licensee asserts that the RSO did in fact wear a whole body monitor while working with radioactive material and that he exhibited the monitor to the inspector at the time of the inspection. The Licensee did acknowledge that the RSO had lost his finger monitor. The Licensee also points out that the RSO always wore a pocket dosimeter which is checked with a cesium source.

NRC Evaluation of Licensee's Response

Violation E

The Licensee did not admit or deny Violation E.1. The Licensee enclosed a letter concerning a linearity test of the cobalt unit timer, but the violation involves linearity test results for the dose calibrator, which is used for administering radiopharmaceuticals to patients. Therefore, based on the inspector's review during the inspection, the NRC concludes that the violation occurred as stated.

With respect to Violation E.2, the NRC has clarified the citation, upon reconsideration of the matter based on the Licensee's response. The NRC acknowledges that the RSO wore a whole body badge while working with radioactive material. However, the particular badge worn by the RSO is assigned from a local hospital and is not a whole body badge assigned to monitor exposure received exclusively while working at the Licensee's private practice facility. Under these circumstances, if an exposure were to occur, the Licensee would not be able to immediately ascertain from which facility, and under what conditions, the exposure occurred. In addition, the RSO admitted that he had lost his finger monitor and had not been wearing it. Under such conditions (the loss of the finger monitor) activities should not have continued without the finger monitor having been replaced. Therefore, it is clear from the Licensee's response that the RSO did not use a whole body badge issued by the Licensee nor did he use a finger badge issued by the Licensee. Accordingly, the Licensee was in violation of 10 CFR 35.21(a) and (b) as set forth in the amended Violation E.2 and restated below.

Restatement of Violation E.2, as Amended

E.2 10 CFR 35.21(a) requires that the licensee appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, is required to ensure that radiation safety activities are performed in accordance with approved procedures. 10 CFR 35.21(b)(2) requires, in part, that the Radiation Safety Officer (RSO) establish and implement written policy and procedures for using byproduct material safely and performing checks of survey instruments and other safety equipment.

For using byproduct materials safely and performing checks of survey instruments and other safety equipment, the licensee's Radiation Safety Officer established procedures in accordance with NRC Regulatory Guide 10.8, Revision 2, (Reg Guide 10.8) Appendix D, which is required by Condition 13 of License No. 29-06760-08 to be met.

Appendix D of Reg Guide 10.8 requires, in part, that all individuals who are occupationally exposed to ionizing photon radiation on a regular basis be issued a film or TLD whole body monitor and that individuals who, on a regular basis handle radioactive material that emits ionizing photon radiation, be issued a film or TLD finger monitor to be processed on a monthly basis.

Contrary to the above as of March 14, 1990, the RSO neither wore a whole body monitor issued by the Licensee while working with radioactive material on a regular basis, nor did he wear a finger monitor issued by the Licensee for use when handling radioactive material.

Summary of Licensee's Response

Violation F

The Licensee did not admit or deny Violation F, but argued that, because of its practices for administering radiopharmaceuticals, it has a wide margin for error in measuring dose activity before any error would cause the Licensee to give any excessive dose to its patients.

NRC Evaluation of Licensee's Response

Violation F

The Licensee did not admit or deny Violation F. The staff finds no validity in the Licensee's argument that, because of its practices for administering radiopharmaceuticals, it has a wide margin for error in measuring dose activity before the error would cause the Licensee to give any excessive dose to its patients. The Licensee had not performed a linearity test of its dose calibrator in over one year. This test is of safety significance because it is one of the quality assurance tests that assures that the dose given is within the parameters set by the regulations of the NRC. Dose calibrator quality assurance testing is also supported by national equipment standards of the American National Standards Institute, safety recommendations of the National Council on Radiation Protection and Measurements, and accepted practice of the American College of Nuclear Physicians. Without such testing, the Licensee cannot assure its dose calibrator response is within the appropriate range over the activity ranges it uses. Without such quality assurance testing, a failure of the dose calibrator would not be detected and could contribute to a misadministration. Therefore, based on the inspector's observation during the inspection, the NRC concludes that the violation occurred as stated and is safety significant.

Summary of Licensee's Response

Violation G

The Licensee did not specifically admit or deny Violation G. The Licensee states that it now has labeled its radiation survey meter and has indicated the apparent exposure rate from a dedicated source of cesium-137. The Licensee also states that it has used dedicated check sources, either Cesium-137 or Redium 227 regularly.

NRC Evaluation of Licensee's Response

Violation G

The Licensee did not admit or deny Violation G. The Licensee stated it now has indicated the apparent exposure rate from a dedicated cesium-137 source

on the label on the radiation survey instrument. The Licensee also states that it has regularly used its dedicated check sources. The NRC acknowledges that during the inspection the Licensee stated it performed a check of its survey instrument for proper operation with a dedicated check source each day of use. However, according to the Licensee's consultant, the Licensee did not supply a dedicated check source to the consultant at the time that the consultant performed the calibration of the Licensee's survey instruments. An apparent exposure rate from a dedicated check source was not determined. Since the exposure rate from a dedicated check source was not determined at the time of instrument calibration, the daily checks by the Licensee did not fulfill the requirements of 10 CFR 35.51(a)(3) and (c) as stated in Violation G. Therefore, the NRC concludes that the violation occurred as stated.

Summary of Licensee's Response

Violation H

The Licensee did not specifically admit or deny Violation H. The Licensee states it "checks" its waste (consisting of alcohol pads) with a crystal probe after every injection before it is put into storage and that it has never encountered any activity in the waste.

NRC Evaluation of Licensee's Response

Violation H

Although the Licensee asserts that its surveys of all waste after use indicated that the waste material was non-radioactive, the Licensee treated the material as byproduct material held for decay-in-storage (radioactive waste). In addition, contrary to the Licensee's assertion, it has been the NRC's experience that alcohol pads (held over injection sites) are radioactively contaminated and should be treated as radioactive waste. Because the Licensee treats its waste material (alcohol pads) as radioactive waste, it is required to maintain waste disposal records which reflect the information required by 10 CFR 35.92(b). Specifically, the Licensee's waste disposal records did not contain: (1) the date on which the byproduct material was placed in storage; (2) the radionuclides disposed; and (3) the background dose rates. Therefore, the NRC concludes that violation occurred as stated.

Summary of Licensee's Request for Mitigation

The Licensee requested cancellation of the civil penalty; however, no basis for this request was provided.

NRC Conclusion

The licensee provided information which the NRC considered in amending Violation E.2 to clarify the citation. However, it is clear from the Licensee's response that it was in violation of Violation E.2, as amended and restated in this Appendix. Therefore, for the reasons set forth above, the NRC has concluded that the violations occurred as stated in the Notice of Violation and as amended and restated in this Appendix. No basis for mitigation of the civil penalty was provided. As a result, the NRC finds that mitigation of the civil penalty is not warranted. Accordingly, the NRC concludes that a civil penalty in the amount of $1,000 should be imposed for the violations set forth in the Notice.

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