Washington
WASHINGTON·UNIVERSITY·IN·ST·LOUIS
School of Medicine

Division of Radiation Safety

May 5, 1994

Roy J. Caniano, Chief
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: Response to Violation Notice
dated April 8, 1994

Dear Mr. Caniano:

The purpose of this correspondence is to reply to the Notice of Violation dated April 8, 1994 that resulted from an inspection of our institution during the period November 15 through November 18, 1993 (copy enclosed). As you are aware, we disputed the findings of the Commission in certain instances. However, your letter dated April 8, 1994 dismissed our arguments as without merit. Accordingly, we have accepted the opinions of the Commission and implemented actions and changes that we believe are satisfactory.

I. Materials License 24-00167-11

Violation 1. We understand that the Commission considers the assay of a unit dosage of a radiopharmaceutical intended for administration at another location, e.g., the patient's room, as "preparation of a radiopharmaceutical." A survey with a radiation survey instrument is conducted after assay each day that a radiopharmaceutical is handled, including the pure beta emitters phosphorus-32 and strontium-89. Since 10CFR 35.70(h) requires the recording of the detected dose rate in millirem per hour, the measurements will be conducted so as to measure only the bremsstrahlung components for 32P and 89Sr. The practice recommended by the USNRC inspector at the time of the November, 1993 visit is to measure and record the ambient dose rate (mrem/hr) before and after handling the radiopharmaceutical each day that a radiopharmaceutical is handled. This practice was instituted immediately after the November, 1993 inspection; hence, the licensee is in compliance with the request of the Commission.

[Note: it may be appropriate for the Commission to define "radiopharmaceutical preparation" for its licensees; perhaps, in the revised Regulatory Guide 10.8]

Washington University School of Medicine
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(314) 362-2988 FAX: (314) 362-3333
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Violation 2. We have modified our procedure for surveying the closet where short-lived dry waste is held for decay. A survey of both dose rate with a survey instrument and of removable contamination is performed each week **inside** the small enclosure. This practice was also begun immediately after the November, 1993 inspection, specifically on November 26, 1993; hence, we are in compliance with 10CFR Part 35.70(b) and (e).

Violation 3. All individuals who handle sealed sources of the licensee have been retrained to never attempt any repair or modification of the sources. The persons involved with the ytterbium-169 wire source have been counseled multiple times by multiple persons. A similar incident should never again occur. The licensee is currently in compliance with license condition 19.

Violation 4A. Jeff Williamson, Ph.D., the Chief Physicist for Brachytherapy, based on a telephone conference with John Jones of the Region III Office, understands that we should request a 30 day extension for the response to this violation and that the response will be accompanied by an application to amend the broad scope medical license regarding the closed circuit TV viewing of remote afterloaded brachytherapy patients. The licensee is aware of the importance of this issue and has instituted several actions — (i) an ad hoc task force was created November 26, 1993 to establish policy and standards for observation and management of brachytherapy patients, (ii) other institutions who utilize remote afterloading devices have been contacted to ascertain their license commitments regarding patient viewing, (iii) an additional CCTV monitor has been placed at the front nursing desk which is nominally staffed continuously, (iv) the importance of frequent viewing of implant patients has been added to our nursing and clerical staff inservice training, (v) bed alarms that sense patient motion have been tested and (vi) trials of required documentation of patient viewing have been instituted to see if documentation of viewing is a realistic commitment.

A 30 day extension is requested for the formal response to this violation.

Violation 4B. The unit clerks and patient care technologists, who normally provide no direct care to brachytherapy patients, are included in the Clinical Brachytherapy/Radiation Safety inservice training program. These anciliary personnel have been trained regarding access of individuals to brachytherapy treatment areas. The licensee has been in compliance with our license condition (letter dated July 18, 1991) since the incident that occurred July 24, 1992.

II. Materials License 24-00063-10

Violation 1. The licensee promptly modified the monthly spot check form to clearly indicate that the "Treatment door operability with treatment unit power off" test is performed with "Satisfactory" or "Unsatisfactory" results after the November, 1993 inspection. The inspection revealed that although the test was performed as part of the monthly spot checks the documentation did not state that the test was done with the unit power turned off. The licensee has been in compliance with 10CFR 35.634(d)(6) since the November, 1993 inspection.

In addition to responding to the Notice of Violation your letter requested a reply to two concerns. The responses are as follows:

Concern 1. We have adopted the recommendation stated on page 5 of the April 8, 1994 letter in which it is advised "A better technique would be to walk around the scanning room and record the highest reading" for the ambient dose rate surveys that are performed in scanning rooms each day that they have been used for one or more patient administrations. The procedure and the record form have been revised to incorporate the guidance effective April 26, 1994.

Concern 2. The judgement that the licensee has ineffectual training regarding radiation emergencies is not just. The RSO again discussed the matter of the hypothetical accident involving a therapy dosage of 131I with Ali Meigooni, Ph.D., a radiation oncology physicist. According to Dr. Meigooni, he was asked by the inspector what he would do if a bottle of 131I were accidentally broken. He said that he responded that it was not possible since the only operation was to remove the container from the package to conduct a dose calibrator assay with the procedure being conducted behind a shield in the brachytherapy storage room. The inspector persisted, asking what he would do if the source were dropped and accidentally broken. According to Dr. Meigooni, he replied that he would immediately call Radiation Safety for help using the telephone inside the brachytherapy source room. He told me that he both knew the number to call from memory and from the posted emergency instructions in the room. He said the inspector inquired what he would do if some of the contents had contaminated his shoes. Dr. Meigooni says that he replied that he would call Radiation Safety for help, remove his shoes, leave them in the room and wait immediately outside the door until help arrived. If his response is truthful (his response to the inspector can be discussed with him @ (314) 362-2633), it generally practices the guidance used by Radiation Safety — immediately call for assistance and secure the area.

However, the licensee has made special efforts during refresher and ALARA training and during internal audits and inspections to emphasize the importance of the proper response to a radiation emergency. The proper response to an emergency involving radioactive materials is regularly demonstrated by the licensee's personnel.

Regarding one other matter, it is requested that future correspondence regarding inspections be directed to Walter W. Davis, Jr., Assistant Dean for Facilities and Chief Facilities for the School of Medicine, who has replaced the retired Robert Hickok as a management representative to the Radiation Safety Committee. The mailing address for Mr. Davis is Box 8010, 660 S. Euclid Avenue, St. Louis, MO 63110-1093. Also, a copy of the correspondence to John Eichling, the RSO, would facilitate timely replies. Although the correspondence from the Region III Office ften shows that a copy to Eichling is intended it generally is not received.

Sincerely,

John Eichling

JE:fi

John Eichling, Ph.D.
Radiation Safety Officer

cc: Michael Cannon, Vice Chancellor and
General Counsel for Washington University
Walter Davis, Director of Facilities Management for
Washington University School of Medicine
Harry Leahey, Director of Industrial Contracts and Licensing
for Washington University
Carlos Perez, M.D., RSC Chairman
Barry Siegel, M.D., RSC Vice-chairman

NOTICE OF VIOLATION

Washington University
St. Louis, MO 63110

License No. 24-00167-11
Docket No. 030-0227[illegible]
License No. 24-000[illegible]3-11
Docket No. 030-151[illegible]1

During an NRC inspection conducted from November 15, 1993 to November 18, 1993, 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, the violations are listed below:

1. 10 CFR 35.70(a) requires a 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, as of November 18, 1993, the licensee failed to conduct a survey with a radiation survey instrument at the end of each day of use, in the cesium room at Barnes Hospital, where iodine-131, phosphorus-32, and strontium-89 are routinely prepared for use.

   This is a Severity Level IV violation (Supplement VI).

2. 10 CFR 35.70(b) requires that the licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored. 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, as of November 18, 1993 the 9th floor Pavilion of Barnes Hospital Radiopharmaceutical waste storage room and the cesium room at Barnes Hospital have not been surveyed weekly with a survey instrument as required by 35.70(b) nor have they been surveyed for removable contamination once each week as required by 35.70(e).

   This is a Severity Level IV violation (Supplement VI).

3. Condition 19. of License No. 24-00167-11 prohibits the opening of sealed sources containing licensed material.

   Contrary to the above, on May 5, 1993, a sealed source containing 2.8 millicuries of ytterbium-169 was inadvertently opened while attempting to straighten the source.

   This is a Severity Level IV violation (Supplement VI).

4. Condition 25. of the License No. 24-00167-11 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated April 27, 1988, and letters (among others) dated September 9, 1987, and July 18, 1991.

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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. Where good cause is shown, consideration will be given to extending the response time.

JAN 12 1994
Dated

Roy J. Caniano, Chief
Nuclear Materials Safety Branch