Washington
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School of Medicine

Division of Radiation Safety

February 10, 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

Dear Mr. Caniano:

Enclosed is our institution's response to your letter dated January 12, 1994 that reported the results of an inspection that was conducted by John P. Jones, Evelyn R. Matson and Robert Hays of your office during the period of November 15 through November 18, 1993. The inspection reviewed activities associated with NRC Byproduct Material Licenses No. 24-00167-11, 24-00063-13, 24-00063-10 and 24-00167-13.

Although we dispute the findings of the Commission in certain instances, we feel that we benefit from the inspections, each time making changes that improve the overall strength of our radiation safety program. I particularly appreciate the several conversations that I had with one of the inspectors, Mr. John Jones.

Sincerely,

John Eichling

John Eichling, Ph.D.
Radiation Safety Officer

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enclosures

cc: Michael Cannon, Vice Chancellor and
General Counsel for Washington University
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I. Materials License 24-00167-11

Violation 1 Failure to conduct a survey with a radiation detection 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.

Response

We believe the interpretation by the Commission that we are in violation of 10CFR 35.70(a) is incorrect. The rule requires a survey of ambient radiation exposure with a survey instrument at the end of each day of use in all areas where radiopharmaceuticals are **routinely prepared or administered.**

Packages containing unit dosages of I-131, 89-Sr or 32-P that are intended for patient administration at other locations, e.g., in patient rooms, are temporarily stored in the "cesium" room. Prior to being transported offsite for patient administration, the activity of each dosage is verified with a dose calibrator as required by the Commission. The vials are never opened in the cesium room. We do not believe that the Commission intends to interpret the dose calibrator measurement of activity as "preparation for use." We believe that the preparation for use phrase applies to the preparation of radiopharmaceuticals that require operations with unsealed reagents, e.g., the kit preparation of labeled radiopharmaceuticals used in nuclear medicine.

However, since the inspection, a survey instrument dose rate measurement is obtained and recorded each time a unit dosage is checked in the dose calibrator. In addition, Radiation Safety personnel conduct the surveys that are required in 10CFR 35.70(b) and 35.70(e) because the room is used to store radiopharmaceuticals or radiopharmaceutical waste. We will continue to conduct the multiple-point weekly surveys of ambient dose rate and removable activity. However, we request Commission authorization to cease performing the daily ambient dose rate survey by concurring that dose calibrator verification of the activity in an unopened vial does not constitute radiopharmaceutical preparation.

Violation 2 Failure to conduct weekly radiation surveys in a Nuclear Medicine radiopharmaceutical waste room.

Response

The licensee uses a small **lead shielded** closet located in the Barnes Hospital Nuclear Medicine facility for the storage of radiopharmaceutical waste. The practice prior to the inspection was to measure ambient exposure rates **outside** the room since personnel only briefly occupy the room when either placing waste material in the room or when removing parcels from the room **and** to conduct a wipe test on every parcel prior to being placed in storage.

Since the inspection we have changed the survey practice. We now conduct a weekly survey **inside** the storage closet consisting of measurements of both ambient dose rate and removable activity and are in compliance with the requirement.

Violation 3 Accidental damage of sealed source

Response

A Radiation Safety technician, while conducting a test for removable activity, inappropriately attempted to straighten the encapsulated rod source at the request of the user. The thin fragile encapsulation was damaged. The technician, who had

been grasping the source with forceps in both hands put the source back into the source's container. This manipulation was conducted behind a lead and lead glass protective barrier intended for the handling of sealed sources. The technician, who had already conducted a wipe test of the source prior to the incident, then performed wipe tests of the damaged source, the outside of the storage vial and of the forceps used to hold the source. He immediately assayed the wipes. Although the removable activity on all the wipes was less than the 0.005 μCi reporting criterion, we reported the incident to the Region III Office of the NRC and properly disposed of the source. The technician has been retrained to only conduct the required wipe test, never to handle any sealed source for any purpose except to conduct the wipe test. The user has also been reminded that sealed sources cannot be altered by the licensee in any way. The licensee has been in compliance with condition 25 of the broad scope medical license since the incident occurred.

Comment by the RSO: Since this response is placed in the NRC Public Document Room it is important to explain the ease with which the source was damaged. Most medical sealed sources contain materials in a form, e.g., a powder, that may be dispersed if the source is broken. Accordingly, such sources are securely encapsulated, often with double layers of welded stainless steel. The activity of this source (2.8 millicuries of ytterbium-169) was in the form of a yttrium rod that had been activated with neutron bombardment. Since the activity was contained in the rod, the manufacturer used thin encapsulation to seal the wire. Hence, I believe it is important to note that the ease with which the source was damaged is an indication of the attendant hazard of the contents, not to the encapulation integrity of sealed sources in general.

A related concern of the Commission involving this incident was that once the source was damaged inappropriate emergency action was taken to ensure that spread of activity had not occurred. The user knew at the time of the incident that the activity of the source was in the form of an activated rod of yttrium and that spread of radioactivity was not likely. But to verify that assumption, the technician obtained wipe samples from the exterior of the source's storage vial as well as from the forceps used to grasp the source (the damaged source was immediately placed in the storage vial — the source never touched any surface other than the forceps). The user and the technician then locked the cesium room. The technician immediately went to the Radiation Safety Office while the user returned to his office to await the results of the wipe tests. The technician informed the user that the wipes of the storage vial and of the forceps were at background level and that the wipe of the damaged source showed removable activity (0.002 μCi). The user made the decision to dispose of the damaged source.

We believe that the knowledge of the nature of the source combined with the results of the negative wipe tests of the storage vial and of the forceps used to hold the source demonstrated that no dispersion of activity had occurred and that no emergency existed.

We are aware that the user did not respond well when queried by the inspector about what he would do in the case of an accident, e.g., spilling a vial of iodine-131. The licensee has made a considerable effort to train and to inform individuals of the actions to take in the case of an accident involving radioactive materials. Emergency instructions are conspicuously posted in all use areas, approximately a thousand sites. The instructions provide guidance of the proper actions to take and specify the names of Radiation Safety personnel to call for assistance. The proper response to an emergency involving radioactive materials is emphasized in the annual refresher training that is provided for all individuals working with radioactive materials. We will continue to stress the importance of emergency response.

Violation 4A: Failure to comply with commitments made to the Commission regarding patient viewing.

Response

The NRC alleges that Condition 25 of our Broadscope License has been violated because of failure to post an employee at the Team II nursing desk of Station 4400, where the CCTV video monitor was located, during an LDR remotely-afterloaded brachytherapy treatment. NRC alleges this violates a written commitment expressed in a letter of 18 April 1988, that "patient viewing [be] available via video camera and monitoring systems" and that "if patient viewing is not available then treatment will be halted." Moreover, NRC expresses concern that "use of the monitors was not required at any particular interval" and that we had "[failed] to impress on the nursing staff.. [the necessity of] regular use of video monitors to ensure that the sources and catheter guide tubes are not disturbed during treatment and to provide for prompt detection of any operational problem with the remote afterloading device".

We share NRC's concern over the lapse of nursing care standards that occurred in one of the incidents involving a patient receiving remotely-afterloaded brachytherapy. It is medically unacceptable to leave **any** GYN inpatient unobserved and untended for a 5 hour period of time. **However, we disagree that this constitutes a violation of our license or any of its associated commitments. As much as we share NRC's concern, we view this ruling as an intrusion into standards of medical practice, a domain that falls outside NRC's lawfully-defined sphere of jurisdiction.** In support of this position, we advance the following considerations:

(a) The letter of 18 April 1988 makes no mention of video monitoring. This provision is, in fact, discussed in the letter of 9 September 1987.

(b) Patient viewing, as described in our license amendment, occurs under the heading of "Facilities," and clearly outlines only a commitment to have a viewing apparatus or "facility" available for elective use of the nursing staff. Clearly, no commitment to staff this viewing system is implied. Although the nursing staff desk in which the CCTV monitor was placed was not continuously staffed, the facility was freely available to the night staff.

(c) The original intent of the viewing system was not to confirm the patient's condition or state of the remote afterloading system at required intervals but to provide an alternative to opening the door and interrupting the treatment (thereby increasing elapsed treatment time) for visualizing the patient. This intent is clearly spelled out in the vendor-supplied Pre-Installation Manual (1985 edition) upon which our license amendment was patterned.

(d) In contrast to HDR brachytherapy patients, continuous viewing (by a posted staff member) of manually- or remotely-loaded **LDR** patients is not standard of practice in the U.S. In our efforts to find a solution to the problems of transitory and unpredictable patient compliance, a number of major institutions were contacted. We could find no nursing standards that addressed the monitoring issue nor any institution using LDR afterloading devices that had a required monitoring procedure.

(e) We have investigated use of bed alarms and found them unacceptable as a means of detecting excessive patient motion. We have found they can not distinguish between normal exercise motions that bed-bound patients must practice to avoid serious side effects of bed-boundedness, and those motions indicative of forcible applicator removal. In addition, they respond inconsistently to patients of different weights. We are investigating other technologies, e.g., telemetry-monitored pressure sensors, as a means of solving this problem.

(f) In general the CCTV monitoring system can not detect afterloader malfunctions. We have to rely on the machine fault detection and alarm systems to detect such states. In addition, CCTV monitors can not detect slippage of the applicator system. This requires detailed examination of the patient's pelvic area, including removal of the bedclothes and packing material surrounding the proximal aspects of the applicator handles. At best remote viewing can detect acute patient distress and excessive, uncompliant motion that might displace the applicator system or even physically traumatize the patient. Clearly, remote viewing is not infallible even for this purpose. We note that in the 23 October 1993 incident, the **patient had been visually observed less than 5 minutes before forcibly removing her applicators.**

Having argued that the surveillance issue falls outside of NRC's regulatory domain, we wish to impress upon NRC that we are very concerned over the issues of protecting patients from trauma induced by non-compliant behavior and are prepared to take medical and potentially expensive steps in our patients' interest **as a matter of institutional policy.** We have taken, or are considering taking the following steps although we maintain none of them are required by our Broadscope License.

(a) We have placed an additional CCTV monitor at the front (Team I) nursing desk which is nominally staffed continuously. Unit clerks are now expected to view the monitor periodically while carrying out their assigned tasks. This procedure was in place during the 23 October 1993 incident. The importance of frequent visualization of implant patients is now included in our nursing and clerical staff inservices.

(b) We are developing a formal set of Nursing Standards of Practice for Brachytherapy Patients. This document will address the issues of frequency of viewing patients and how to document compliance with our policy. Other relevant issues addressed include use of restraints and improved patient education and assessment to reduce the incidence of non-compliant behavior. This document, to our knowledge, will be the first and only attempt to deal with these questions.

(c) As noted above, we are investigating the use of remote sensing technology to more rapidly and specifically detect dangerous non-compliant behavior. We emphasize that no off-the-shelf product exists which specifically addresses our problem including bed alarms.

Violation 4B: Failure to restrict access of visitors to brachytherapy treatment area.

The NRC alleges we violated a commitment expressed in a letter dated 18 July 1991 that only visitors and workers authorized by trained nursing staff are allowed to enter the brachytherapy area. On 24 July 1992, an untrained unit clerk admitted visitors to a restricted area. Although our policies explicitly forbid this practice, NRC expresses concern that our response to this incident was inadequate.

Response: We agree that this incident constitutes a violation of our commitment to area security of the Pulsed Dose-Rate remote afterloader expressed in the above referenced document. To reduce the likelihood of such incidents, we are including unit clerks and patient care technologist, who nominally provide no care directly to implant patients, in our Clinical Brachytherapy/Radiation Safety inservicing program.

Additional Concern

An inspector identified an additional concern that has not been addressed in this response. The inspector observed that the surveys of ambient radiation exposure rates that are required at the end of each day of use in all areas where radiopharmaceuticals are routinely prepared for use or administered are only being performed at the center of certain rooms. The Commission adds that the routine weekly contamination swipe tests often identify areas of low level contamination and that the daily instrument "surveys should be performed adequately enough to detect radioactive material contamination."

The licensee believes that the requirements and intentions of 10CFR 35.70 are not correctly interpreted by the inspector in this situation. It is our belief that the daily instrument survey is intended to identify the presence of any unintended significant source of radiation exposure, e.g., a source inadvertently left in an imaging room or a source not properly shielded in the radiopharmacy. Then, with an interval of a week, another survey consisting of multiple point tests for removable activity as required by 10CFR 35.70(e) is conducted to identify low levels of removable contamination. The survey conducted with the instrument cannot identify areas of low-level contamination unless you are very lucky in choosing the site(s) of measurement or unless you perform many, many (perhaps, hundreds or more) measurements in a given room. The following illustrates the point:

> Assume that the survey instrument can be used to successfully identify an exposure that is only 10% above the minimum capability of 0.1 millirem per hour that is required by 10CFR 35.220, i.e., assume that one can identify an increase in the measured value of 0.01 millirem/hr. The recommended action level in Regulatory Guide 10.8 (Revision 2, 1987) for surface contamination is 20,000 DPM/100cm^2 for radionuclides such as 51Cr, 99mTc, 201Tl, etc., in restricted areas. Consider a area of 100 cm^2 contaminated with 99mTc at the action level of 20,000 DPM. The exposure rate due to the small amount of contamination is 0.005 mR/hr at one centimeter! [20,000 DPM ÷ $2.2X10^9$ DPM/mCi = $9X10^{-6}$ mCi; exposure rate = $9X10^{-6}$ mCi X0.6 R-cm^2/mCi-hr = 0.005 mR/hr @ 1 cm]. At a distance of a foot from the contaminated area, the instrument's response will be about 1,000 times less. Thus, the ambient dose rate survey cannot be successfully used to identify areas of low level contamination but only to identify significant sources of exposure.

We believe that Regulatory Guide 10.8 recognizes that situation. Exhibit 16 of the Guide shows the model form for recording the daily surveys and indicates single instrument measurements in imaging rooms and multiple measurements in the hot lab, namely, 5 in the hot lab. We perform single instrument surveys in the center of each imaging room and 13 such measurements in the radiopharmacy to verify that no significant exposure source is present and not shielded. We believe this practice is consistent with the guidance provided by the Commission in Regulatory Guide 10.8.

II. Materials License 24-00063-10

Violation Failure to clearly document one component of the monthly safety spot-checks.

Response

It was not clearly indicated on our monthly teletherapy spot checks that we check the treatment door operability "with the treatment unit off". This check is performed but the documentation did not clearly state that the unit power is turned off. It was demonstrated during the inspection, during an emergency off demonstration (which terminates power to the unit), that the door operated independently and properly. We have modified our monthly spot check form to now clearly state, "Treatment door operability with treatment unit power off" "Satisfactory" _____ "Unsatisfactory" _____.

Additional Concerns

(1) It was apparent that the radiation oncology physicists and radiation oncologists, are not included in the annual Co-60 teletherapy drill, and did not receive specific instruction on the institution's policies and procedures regarding a stuck Co-60 teletherapy source. Since the inspection these professional, board certified individuals have been fully instructed on our policies and procedures' regarding Co-60 teletherapy units and are currently going through an emergency drill. In the future, all Staff radiation oncologists and radiation physicists will be included in the annual refresher for emergency procedures regarding Co-60 teletherapy and drill given to all personnel.

(2) During the inspection, there was difficulty opening the Cobalt door from the inside. The hydraulic mechanism has been improved to ease the tension, to where the treatment technologist can open the door from inside the room without difficulty. This improvement has not hampered any other aspect of the door closing mechanism.