NOTICE OF VIOLATION

Washington University
St. Louis, MO 63110

License No. 24-00167-11
Docket No. 030-02271
License No. 24-00063-11
Docket No. 030-15101

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.

A. Item V.C. of the letter dated September 9, 1987, entitled, "Amendment to the NRC Regarding Remote Afterloading Devices," states; "Patient viewing is available via video camera and monitoring systems. If patient viewing is not available, then treatment will be halted."

Contrary to the above, on June 27, 1993, between 01:36 am and 05:21 am, no persons were assigned to the nursing station where the video monitors were located and therefore patient viewing was not available and treatment was not halted.

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

B. The letter dated July 18, 1991, states, in Item V.C.3., that only visitors and hospital workers authorized by trained nursing staff are allowed to enter the brachytherapy treatment area.

Contrary to the above, on July 24, 1992, visitors not authorized by the trained nursing staff, were allowed to enter the brachytherapy treatment area.

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

5. 10 CFR 35.634(d)(6) requires that a licensee authorized to use a teletherapy unit for medical use perform safety spot-checks once in each calendar month that assure proper operation of electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

Contrary to the above, as of November 18, 1993, the licensee had failed to include in the monthly safety spot-checks, tests that assure the proper operation of electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

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

Pursuant to the provisions of 10 CFR 2.201, Washington University is hereby required to submit a written statement of explanation to the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois, 60532-4351, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is

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

ENCLOSURE 2

INFORMATION REQUIRED FOR LICENSING REMOTE AFTERLOADING DEVICES

NOTE: This document assumes that you have a medical license (group medical license or broad scope license) and you wish to amend your license to permit use of a remote afterloading device. Accordingly, it is not necessary to submit information about calibration of survey instruments, radiation safety committee, personnel monitoring program, leak testing and ALARA program, unless any of these change because of this amendment request. Address these changes in your amendment request.

I. Description of the Source(s) and Device(s)

A. Source description*

1. Radionuclide

2. Manufacturer's name and model number**

3. Maximum activity (in curies)

4. Number of sources***

B. Device description

1. Manufacturer's name**

2. Model name/number

*If you wish to possess and use more than one radionuclide in the device, provide the information in 1-4 for each radionuclide.

**The supplier can tell you if either the device or the source(s) you propose to use within the device has not had a health and safety review by either the NRC or an Agreement State (i.e., is not listed in the NRC's "Registry of Radioactive Sealed Sources and Devices"). If the review has not been conducted, you should request a copy of "Guidelines for Applications for Registration of Sealed Sources" or "Guidelines for Applications for Registration of Devices," as appropriate, from your regional NRC office and submit the information requested therein.

***You may wish to request two sources (or sets of sources); one (set) to be used in the device and one (set) to be stored in its shipping container in your possession as necessary for replacement of the source (set) in the irradiation device.

II. Intended Use

The typical response is "to be used for interstitial and intracavitary treatment of cancer." Any other intended uses, such as "non-human use," should be described.

III. Proposed Users

A. If your facility already has physician-users approved for use of 10 CFR 35.100 Group VI materials, you may simply state that the use of the device will be limited to those individuals.

B. If you are a broad scope medical licensee, you should state that your Radiation Safety Committee will approve users for this device who are physicians (ref. 10 CFR 35.3(b)) and who hold one of the medical specialty certifications listed below in C.3.

C. For each proposed (human-use) user* who does not satisfy III.A. or III.B., you should submit the following:

1. The physician's full name

2. Evidence of the physician's licensure to practice medicine (ref. 10 CFR 35.3(b))

3. Indicate certification

a. By the ABR in Radiology or Therapeutic Radiology

b. By the AOBR in Radiation Oncology

c. By the Canadian Royal College of Physicians and Surgeons (RCPS) in Therapeutic Radiology (include copy of certificate)

d. As a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR) (include copy of certificate and evidence of specialization in radiation therapy)

4. In lieu of 3. above, you may submit the name and license number of the NRC or Agreement State license on which the physician is authorized to use teletherapy for human use or 10 CFR 35.100 Group VI sources for therapy.

*If the physician is not board certified in one of the specialties listed in C.3 and has not been previously licensed by NRC or an Agreement State, NRC will transmit the proposed user's credentials to the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) for evaluation. Contact your NRC regional office for additional information.

IV. Training for Individuals (ref. 10 CFR 19.12)

A. Provide outline of training given to device operators

B. Describe additional training provided to individuals who will conduct source exchanges

C. Provide name and affiliation of instructor conducting training in A. and B. above

D. Confirm that individuals who are trained in the use of the device and have practiced the emergency procedures will be on-site while the device is in use

E. Outline topics covered in retraining and state the frequency of such retraining. Confirm that the retraining will include "dry-runs" of emergency procedures.

V. Facilities

A. Submit annotated drawing(s) (both plan and elevation) of each treatment room* indicating:

1. Scale

2. Direction of north

3. Identification of room (i.e., room number)

4. Type, density and thickness of all shielding materials-walls, floor, ceiling

5. Location of entrance, windows, conduits, etc.

6. Nature of and distance to adjacent areas

7. Use of adjacent areas (i.e., restricted or unrestricted-ref. 10 CFR 20.3(a)(14) and (17))

*Treatment is usually performed in rooms specially constructed or modified for radiation therapy.

B. Describe Continuous Viewing System For Each Treatment Room

1. Primary

2. Backup if primary system fails or commit to halting treatments

C. Describe Area Security For Each Treatment Room

1. Interlocks on entry, etc.

2. Restricted area(s) controls (e.g., signs, locks, alarms, lights, etc.)

3. If other radiation-producing devices are in the room, means of assuring only one device in operation at a time

4. Means of verifying source "safe" condition (e.g., permanently installed radiation monitor)

5. Confirm that, once tripped, the entry interlock must be reset before activation of device

D. Shielding Evaluations, Calculations, Safety Measures For Each Treatment Room

1. Estimate of maximum "on-time" per hour and per week

2. Calculation of exposure rate in <u>each</u> adjacent area with most adverse source orientation(s) and source combinations

3. For unrestricted areas, must meet either a or b below:

a. With "on-time" considered and "occupancy factor"*=1 (ref. 10 CFR 20.105(b)(1) and (2)):

(1) < 2 mR in any 1 hour, AND

(2) $\leq$ 100 mR in any 7 days

b. Request higher radiation levels (ref. 10 CFR 20.105(a)):

(1) < 500 mR/year

(2) Need information re: average radiation levels and anticipated occupancy times [Reminder to licensee: recordkeeping required]

*"Occupancy factor" is used as in NCRP Report No. 49: a factor used to correct for the degree of occupancy of the area in question while the source is in the exposed position.

4. For restricted areas, the following should be described:

   a. Physical/administrative control of access

   b. Signs: Location, number, wording

   c. Personnel monitoring

   d. Training (ref. 10 CFR 19.12)

   e. Surveys (ref. 10 CFR 20.201(b))

VI. Operating Procedures

A. You need not provide a copy of procedures but you need to supply the following minimum commitments:

1. Have implemented written operating procedures

2. Copies given to appropriate staff

3. Procedures:

   o Require securing unit, console, room when unattended

   o Require that only the patient be in room with device activated

4. Daily (or on each day of use) checks will be performed and will include checks of:

   o Interlocks

   o Reproducibility of source positioning within catheter within ±1 mm

   o Verification of source position indicators (e.g., lights, alarms, room monitor)

   o Inspection of guide tubes for kinks and other imperfections

5. Treatment time calculations will be independently verified before treatment is begun.

B. Calibration of Source in Device

1. Describe procedures, frequencies and equipment used to determine:

   o Dose accuracy to within 5 percent

   o Travel time error

   o Accuracy of timing device

2. Describe qualifications of individual(s) performing calibrations if they do not meet criteria in 10 CFR 35.24(a) or 35.24(b)

C. If the device with installed source(s) will be moved from one treatment room to another, describe checks that will be conducted after each move and before use to ensure proper operation of both the device and associated safety systems (e.g., interlocks, lights).

VII. Emergency Procedures

Submit a copy of emergency procedures and specify that these procedures will be posted near each place of use. As a minimum, your procedures should include:

o When the procedures are to be followed,

o Step-by-step actions and by whom these actions are to be taken,

o Giving first consideration to minimizing exposure to patient,

o Requiring securing area; posting warning notice, and

o Providing names and on-duty/off-duty telephone numbers of at least 2 people to be notified

VIII. Waste Disposal

Usually by return to an authorized recipient, such as the source/device manufacturer.