

NOTICE OF VIOLATION

University of Wisconsin
Madison, Wisconsin

Docket No. 030-03465
License No. 48-09843-18
Docket No. 030-15202
License No. 48-09843-32
Docket No. 030-31201
License No. 48-09843-34
Docket No. 030-14141
License No. 48-00361-17

During an NRC inspection conducted on June 17-21, 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 violations are listed below:

License No. 48-09843-18:

- A. 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, radiopharmaceuticals were used on May 25, 1991, and on June 1, 8 and 9, 1991, and surveys of the elution, preparation and injection areas were not performed.

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

- 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 20.103 limits the airborne concentration of radioactive material in restricted and unrestricted areas.

Contrary to the above, the licensee failed to perform an adequate evaluation of the airborne concentration of iodine-131 in a restricted area where an individual handled a therapeutic quantity of iodine-131 on February 19, 1991. Specifically, a thyroid bioassay performed on February 26, 1991, indicated the presence of 0.145 microcuries of iodine-131 in the individual's thyroid; however, no evaluation was made to determine the amount of iodine-131 that may have been present in the thyroid on February 19, 1991, to show compliance with 10 CFR 20.103.

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

License No. 48-09843-32:

- C. 10 CFR 20.203 (c) (6) (iv) requires each area in which there may exist radiation levels in excess of 500 rems in one hour at one meter from a sealed radioactive source that is used to irradiate materials, to be equipped with devices that will automatically generate visible and audible alarms to alert personnel in the area before the source can be put into operation and in sufficient time for any individual in the area to operate a clearly identified control device which shall be installed in the area to prevent the source from being put into operation.

Contrary to the above, as of June 21, 1991, the required devices have not been installed in room B-460 Medical Sciences Building which houses two cobalt-60 sources capable of delivering radiation levels in excess of 500 rems per hour at a meter.

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

- D. License Condition No. 17 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in referenced letters and applications. Referenced letter dated November 22, 1989 states that a radiation monitor with a backup power supply will be provided in room B-460, Medical Sciences Building, to indicate the status of the cobalt-60 beam.

Contrary to the above, as of June 21, 1991, the radiation monitor in room B-460 does not have a backup power supply.

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

License No. 48-09843-34:

- E. License Condition No. 19 requires the licensee to equip the teletherapy room monitor with a backup power supply separate from the power supply to the teletherapy unit.

Contrary to the above, as of June 21, 1991, the AECL Eldorado 78 cobalt-60 teletherapy room monitor did not have a backup power supply separate from the power supply for the teletherapy unit.

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

License No. 40-00361-17:

- F. License Condition No. 17 requires the licensee to conduct its program in accordance with statements, representations and procedures contained in referenced applications and letters. Referenced application dated November 2, 1979 states in Item 13 (F) that each access door to the irradiator room is electronically interlocked.

Contrary to the above, as of June 21, 1991, the microswitch on the control room access door was disengaged from the interlock system.

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

Pursuant to the provisions of 10 CFR 2.201, University of Wisconsin-Madison is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137, 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.

Dated at Glen Ellyn, Illinois
this 1st day of October, 1991

Charles E. Norelius

Charles E. Norelius, Director
Division of Radiation Safety
and Safeguards

SUMMARY OF CONCERNS

As a result of the inspection conducted on June 17-21, 1991, the following concerns/recommendations were identified as indicators of performance which, if unchecked, may lead to health and safety problems.

License No. 48-09843-18:

- a. The licensee should consider providing lab personnel with hands-on training in instrumentation use, wipe test techniques, record keeping, and decontamination procedures to assure that these tasks are being performed and evaluated adequately. [Section 5 (A)(2)]
- b. The licensee should consider evaluating the design of the radiopharmacy fume hood to determine if the air flow rate in the radiopharmacy fume hood should be powerful enough to allow venting of all iodine-131 received at the University of Wisconsin Hospitals and Clinics facility. [Section 5 (A)(5)]
- c. The licensee should consider using radioactive check sources to ensure operability of survey instruments prior to use. [Section 5 (A)(5)]
- e. The licensee should consider reviewing the nuclear medicine departmental procedure manual with the staff to assure that rooms used for patients treated with iodine-131 are not released for unrestricted use until the radiation/contamination levels are at or below 200 dpm/100 cm². [Section 5 (A)(6)]
- f. The licensee should consider modifying the documentation of safety system checks for the irradiators located in room B-480 to reflect the specific system being tested and the name of the person conducting the test. [Section 5 (C)]
- g. The licensee should consider reminding all laboratory personnel to secure all areas where radioactive material is used and stored to the extent that a safety hazard may exist. [Section 5 (A)(7)]

License No. 48-09843-28:

- h. The licensee should consider periodically reviewing the irradiator users list to assure that it is current and accurate. [Section V (B)]
- i. The licensee should consider providing refresher training for individuals who have not used irradiators during a specified period of time. In addition, the licensee should consider whether documentation of user training should include the type of training received, dates of training and the instructor's name. [Section 5 (B)]

License No. 48-09843-32:

- j. The licensee should consider reviewing training documentation to assure completeness of records. The licensee should consider whether the time frames for grading course examinations are appropriate. [Section 5 (C)]

License No. 48-09843-33:

- k. The licensee should consider periodically reviewing training records to assure that they are current and accurate. [Section 5 (D)]

License No. 48-09843-34:

No concerns were identified.

License No. 48-00361-17:

- l. The GTNS facility license authorizes two different frequencies for interlock system tests. To simplify testing requirements the licensee should consider requesting a license amendment to clarify the frequency and scope of the tests to be performed. [Section 5 (F)]
- m. If increased use of the GTNS facility is contemplated, the licensee should consider the implementation of engineering controls to assure that the facility is devoid of persons prior to operation of the cobalt-60 beam. [Section 5 (F)]

License No. SNM-116:

No concerns were identified.