NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

The Curators of the University of Missouri
Columbia, Missouri

License No. 21-01103-04
Docket No. 030-02278
EA 94-031

During an NRC inspection conducted from January 24 through 28, 1994, 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 Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

1. 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.

   Contrary to the above, the licensee did not make surveys to assure compliance with 10 CFR 20.105(b) which limits radiation levels in unrestricted areas. Specifically, on December 18, 1993, the licensee did not survey the hallway and entrances of M609 Health Science Center to assure that phosphorus-32 from a spill that occurred that day did not leave the laboratory. Further, as of December 31, 1993, the licensee did not survey hands, feet, and personal items prior to leaving the area following a spill of phosphorus-32 to assure that 10 CFR 20.101 radiation exposure limits were not exceeded. (01013)

2. Condition 30 of License No. 24-00513-32 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated February 28, 1992, and letters dated June 5, 1992 and June 30, 1992.

   A. Item 7.B. of the application states, in part, that the Radiation Safety Committee will empower the Radiation Safety Officer to issue interim amendments or changes to authorizations of a non-significant nature, e.g., minor increases in quantities. All interim authorizations issued by the Radiation Safety Officer must be reviewed and approved at the next Committee meeting.

      Contrary to the above, on October 11, 1993, the Radiation Safety Officer through a staff member, authorized an increase in the possession limit from 0.05 to 0.1 millicurie (mCi) of iodine-125 for a researcher. The Radiation Safety Committee next met to conduct business on December 3, 1993, and did not review and approve the interim authorization. Additionally, on August 13,

1993, the Radiation Safety Officer authorized a new isotope (phosphorus-33) with a possession limit of 1 mCi for a researcher. This was reviewed, in a general way, by the Radiation Safety Committee at the next meeting as they discussed the possibility of issuing all phosphorus-32 and sulfur-35 users a blanket authorization for phosphorus-33. However, as of January 24, 1994, no action was taken with respect to this researcher and no blanket authorization was adopted at any subsequent Radiation Safety Committee meeting. (02013)

B. Item 10.3.A. of the application states, in part, that specific procedures involving the acquisition and receipt of radioactive materials are found in the Radiation Safety Manual.

Item A.6. of Chapter 5 of the Radiation Safety Manual, states, in part, that upon receipt of radioactive materials, authorization and receipt records are checked to insure that delivered materials are within the authorized levels.

Contrary to the above, on numerous occasions authorization and receipt records were not checked to insure that delivered materials were within the authorized levels. For example, on November 19, 1993, the Environmental Health and Safety staff authorized a delivery of 10 millicuries of sulfur-35 for a researcher approved for 5 millicuries. On April 21, 1993, a delivery of 5 millicuries of hydrogen-3 was authorized for a researcher approved for 2 millicuries. On August 13, 1993, a delivery of 2 millicuries of phosphorus-32 was authorized for a researcher approved for 1 millicurie. On October 14, 1993, a delivery of 5 millicuries of phosphorus-32 was authorized for a researcher approved for 1 millicurie. (02023)

C. Item 8.B. of the application states, in part, that basic instruction and general information on radiation safety and responsibilities are presented by the authorized users or by their senior staff as an introductory session before a radiation worker is involved with radioactive materials or radiation procedures.

Contrary to the above, a radiation worker assigned to 107 Dalton Hall, worked with radioactive materials, including carbon-14 and iodine-125, for at least two years before basic instruction and general information on radiation safety and responsibilities was given. Further, a radiation worker in M609 Health Science Center, worked with radioactive material since September, 1993, but had not attended formal training as of January 28, 1994. (02033)

D. Item 10.4.E. of the application states, in part, that the University shall maintain and make available for inspection a current record of accumulated inventory.

Contrary to the above, as of January 28, 1994, the licensee did not maintain a current record of accumulated inventory. (02043)

E. Item 10.5.B. of the application states, in part, that typical rules for safe laboratory practice are to be followed and are set forth in the Radiation Safety Manual.

Item B.1. of Chapter 7 of the Radiation Safety Manual states, in part, that eating and drinking are prohibited in all radioactive work areas. Moreover, food and drink for human use are not to be stored or prepared in radioisotope use or storage areas.

Contrary to the above, on January 25, 1994, an NRC inspector observed a laboratory employee in M506 Health Science Center, a radioactive work area, eating popcorn prepared in the microwave oven located in the same room. Further, food and drink were observed in many of the laboratories where radioisotopes were used and/or stored. (02053)

F. Item 10.6.B. of the application states, in part, that all fume hoods are tested for air flow measurements on a semi-annual basis.

Contrary to the above, as of January 24, 1994, a fume hood used to store iodine-131, located in the University Hospital nuclear medicine hot lab, was last tested for air flow on December 31, 1992. (02063)

3. 10 CFR 35.21(a) requires that a licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures.

A. 10 CFR 35.59(d) requires that a licensee retain records of leak test results for five years, and that the records include the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries, and the signature of the Radiation Safety Officer.

Contrary to the above, as of January 24, 1994, the licensee's retained records of leak test results did not contain the measured activity of each test sample expressed in microcuries, the estimated activity of each source, or the signature of the Radiation Safety Officer. (03013)

B. 10 CFR 35.59(g) requires, in part, that a licensee retain records of quarterly physical inventories of sealed and brachytherapy sources for five years, and that the records contain, among other things, the signature of the Radiation Safety Officer.

Contrary to the above, as of January 24, 1994, the licensee's retained records of physical inventories of sealed and

brachytherapy sources did not contain the signature of the Radiation Safety Officer. (03023)

C. 10 CFR 35.59(i) requires, in part, that a licensee retain a record of each quarterly ambient dose rate survey in all areas where brachytherapy sources are stored. The record must include the signature of the Radiation Safety Officer.

Contrary to the above, as of January 24, 1994, the record of the quarterly ambient dose rate survey of areas where brachytherapy sources are stored did not contain the signature of the Radiation Safety Officer. (03033)

D. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

Contrary to the above, as of January 24, 1994, the licensee did not survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored. Specifically, the licensee surveyed a storage area located on the 7th floor of University Hospital, an area where contaminated items are kept for decay-in-storage following I-131 radiopharmaceutical therapy, monthly. (03043)

E. 10 CFR 35.70(h) requires that a licensee record the removable contamination in each area in disintegrations per minute per 100 square centimeters.

Contrary to the above, as of January 24, 1994, records of contamination survey results were being recorded in picocurie/100 cm^2 (pCi/100 cm^2). (03053)

F. 10 CFR 35.406(c) requires that immediately after implanting sources in a patient, a licensee shall make a radiation survey of the patient and the area of use to confirm than no sources have been misplaced. Further, a licensee shall make a record of each survey.

Contrary to the above, as of January 24, 1994, the licensee failed to make a record of each survey of the patient and the area of use immediately after implanting the sources. (03063)

4. 10 CFR 35.21(a) requires that a licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures are described in the application dated February 28, 1992, and letters dated June 5, 1992, and June 30, 1992.

Item 10.6.D. of the letter dated June 5, 1992, states that the licensee commits to compliance with 10 CFR 35 and to applicable portions of Regulatory Guide 10.8 (Revision 2, August 1987).

A. Item 3. of Appendix I, Regulatory Guide 10.8, requires that either after each procedure or before leaving the area, a radiation worker monitor his/her hands for contamination in a low-background area with a crystal probe or camera.

Contrary to the above, as of January 24, 1994, the technologist at Ellis Fischel Treatment Center did not his monitor hands for contamination in a low-background area with a crystal probe or camera either after each procedure or before leaving the area. (04013)

B. Item 2. of Appendix N of Regulatory Guide 10.8 regarding Records, requires, in part, that the Radiation Safety Officer review and initial records of survey results at least monthly and also promptly in those cases in which action levels were exceeded.

Contrary to the above, as of January 24, 1994, the Radiation Safety Officer did not review and initial records of survey results at least monthly and also promptly in those cases in which action levels were exceeded. (04023)

C. Item 1.d. of Appendix N of Regulatory Guide 10.8 regarding Records, requires, in part, that a licensee record measured dose rates.

Contrary to the above, survey records at Ellis Fischel Cancer Center did not include the measured dose rates. (04033)

D. Item 1.e. of Appendix N of Regulatory Guide 10.8 regarding Records, requires, in part, that a licensee record actions taken in the case of excessive dose rates or contamination and follow up survey information. The licensee established a 100 pCi/100 cm^2 contamination trigger level.

Contrary to the above, on September 17, 1993, a contamination survey indicated an activity of 4E+3 pCi/100 cm^2 and no documentation of actions taken or follow up survey information was recorded. (04043)

This is a Severity Level III problem (Supplement VI).
Civil Penalty - $ 5,000.

Pursuant to the provisions of 10 CFR 2.201, The Curators of the University of Missouri (Licensee) are hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and

Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information 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. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to:

Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532.

Dated at Lisle, Illinois
this 9th day of March 1994