NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

The Ohio State University

Columbus, Ohio

Dockets No. 030-02640;
030-31605; and 030-32479
Licenses No. 34-00293-02;
34-00293-14; and 34-00293-15
EA 94-032

During an NRC inspection conducted from September 27 to November 4, 1993, violations of NRC requirements were identified. In accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose civil penalties 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 penalties are set forth below:

I. Violations Associated with a Breakdown in Control of Licensed Activities

A. License Condition No. 34 of License No. 34-00293-02 requires that the licensee submit a Decommissioning Funding Plan on or before January 1, 1993.

Contrary to the above, as of October 1, 1993, the licensee failed to submit a Decommissioning Funding Plan. (01012)

B. License Condition No. 36, Amendment No. 71 dated June 29, 1992, requires that the licensee perform stack effluent sampling when the estimated aggregate release of all radionuclides through a fume hood exceeds 50 percent maximum permissible concentration (MPC), averaged over one month. License Condition No. 37 requires that the sampling program be implemented within 90 days of the date of this license (i.e. by October 1, 1992).

Licensee calculations estimate that the 50 percent MPC threshold is met if greater than 40 millicuries of iodine-125 is processed (iodinated) in an unfiltered fume hood per month, assuming a release fraction of .001.

Contrary to the above, the licensee failed to perform stack effluent sampling in the months of October - December 1992, January - March 1993, May and June 1993 and August 1993. These were all months in which greater than 40 millicuries of volatile iodine-125 was processed in the unfiltered fume hood located in Doan Hall, room 204A. (01022)

C. 10 CFR 35.32(f)(2) requires each licensee submit to the NRC Region III Office by January 27, 1992, a written certification that the licensee's quality management program has been implemented along with a copy of the program.
Contrary to the above, as of June 10, 1993, the licensee had not submitted to the NRC a copy of its quality management program and a written certification that the program had been implemented.

(01032)

D. 10 CFR 20.105(b) requires that, except as authorized by the Commission in 10 CFR 20.105(a), no licensee allow the creation of radiation levels in unrestricted areas which, if an individual were continuously present in the area, could result in his receiving a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days.

Contrary to the above, on September 28, 1993, during a 25 minute duration high dose rate remote afterloading treatment, the licensee allowed the creation of radiation levels outside the patient entrance door to the Interoperative Radiation Therapy room, an unrestricted area, such that if an individual were continuously present in the area, he could have received a dose in excess of 2 millirems in any one hour. Specifically, radiation levels of 5 millirem per hour were found approximately one foot from the door at waist level. (01042)

E. License Condition No. 39, Amendment No. 71 dated June 29, 1992, requires that the licensee conduct its program in accordance with the statements, representations and procedures contained in an application dated July 29, 1986, and a letter dated February 24, 1989.

1. Item 17.3 of the application dated July 29, 1986, entitled "Area Survey Procedures" requires that all laboratory area surveys include:

(1) A measurement of radiation levels with a survey instrument appropriate for the possible contamination, and sufficient sensitivity to detect 0.1 millirad per hour;

(2) A series of wipe tests to measure removable contamination levels; and

(3) Measured exposure rates and contamination levels keyed to relevant features such as active storage and waste areas

Contrary to the above, in 1993 through October 1,1993, research laboratory surveys did not always include measurements of radiation and contamination levels as required. Specifically, surveys performed in the following laboratories which use P-32 did not include radiation level measurements in any lab areas or contamination level measurements in active storage and waste areas:

Building	Laboratory No

Bio-Sciences	622 E
Bio-Sciences	616
Bio-Sciences	812, 814, 820 and 822

(01052)

2. Item 15.3.18 of the application dated July 29, 1986, entitled "General Rules For Safe Use of Radioactive Material "requires, in part, that laboratories dispose of radioactive solid waste in labelled waste cans provided by the Office of Radiation Safety.

   Contrary to the above, on September 30, 1993, solid radioactive waste contaminated with phosphorus-32 was disposed of in unlabelled cardboard boxes in Bio-Sciences Laboratories No.616 and 919. (01062)

3. The referenced letter dated February 24, 1989, "Addition of Remote Afterloading Brachytherapy Unit" states in item (V)(C) that rooms used for treatment will be posted "Caution - Radiation Area".

   Contrary to the above, during a high dose rate remote afterloader treatment on September 28, 1993, the interoperative radiation therapy room was not posted "Caution Radiation Area." (01072)

F. 10 CFR 35.59(g) requires a licensee in possession of a sealed source conduct a quarterly physical inventory of all such sources in its possession.

   Contrary to the above, a quarterly physical inventory of several sealed sources located in the radiopharmacy laboratory was not performed in 1991 through September 27, 1993. Specifically, sources in storage and not used and those with activities less than 100 microcuries were not normally inventoried. Also, sources with activities in excess of 100 microcuries and in use were inventoried every six months rather than quarterly. (01082)

G. 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, as of October 1, 1993, the licensee did not make surveys to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the whole body and extremities. Specifically, the licensee failed to complete an evaluation of whole body and extremity (hand/fingers) radiation doses received by a radiation safety office staff member in September 1991, when 57,770 millirem and 260,000 millirem were recorded by the whole body film and TLD finger dosimetry devices, respectively, used by the individual. (01092)

H. 10 CFR 35.404(a) and (b) require that after removing the last temporary implant from a patient, the licensee shall make a radiation survey of the patient and retain a record of the patient survey for three years. Each record must include in part the dose rate from the patient expressed as millirem per hour and measured at one meter from the patient.

Contrary to the above, on August 23, 1992, and multiple other dates in 1992 and 1993, records of temporary brachytherapy source explant patient surveys did not include the dose rate from the patient expressed as millirem per hour. Furthermore, no record was retained of patient surveys performed on May 19, 1993, or March 8, 1993, after brachytherapy sources were removed from patients. (01102)

I. 10 CFR 35.32(a)(1) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

The licensee's quality management program dated June 11, 1993, states in Item No. 1 that prior to administration, an authorized user shall sign and date (signature, not initialize) a written directive for any therapeutic dosage of a radiopharmaceutical and any dosage of NaI-131 greater than 30 microcuries.

Contrary to the above, on September 2[illegible], 1993, and on multiple other dates in 1993, written directives for administration of greater that 30 microcuries of NaI-131 were not dated by the authorized user. Furthermore, on September 17, 1993, a written directive to administer 5 millicuries of NaI-131 was initialed by the authorized user and also was not dated. (01112)

J. 10 CFR 20.401(b) requires, in part, that each licensee maintain records in the same units used in this part, showing the results of surveys required by 10 CFR 20.205(b). The radiation units for removable package contamination used in 10 CFR 20.205 are microcuries and/or disintegrations per minute.

Contrary to the above, results of surveys performed in accordance with 10 CFR 20.205(b) were not maintained in the required units. Specifically, on September 3, 1993, and on multiple other dates in

1992 and 1993, results of package wipe tests were recorded as "ok" rather than in the required units of microcuries or disintegrations per minute. (01122)

K. 10 CFR 35.92(b) requires that a licensee retain for three years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a), and the record include the date on which the byproduct material was placed in storage, the radionuclides disposed, and the name of the individual who performed the disposal.

Contrary to the above, the licensee's records of disposals of previously contaminated syringes and other items used in the Nuclear Medicine Department and made under 10 CFR 35.92(a), did not always contain the required information. For example disposal records for May 7, June 15 and October 15, 1993 did not contain any of the required information. (01132)

L. 10 CFR 35.59(d) requires, in part, that a licensee retain for five years records showing the results of leak tests conducted on sealed sources and include the signature of the Radiation Safety Officer.

Contrary to the above, results of leak tests on sealed sources used in the nuclear medicine department and conducted on August 3, 1993 and multiple other dates in 1993, did not contain the signature of the Radiation Safety Officer. (01142)

M. 10 CFR 36.23(a) requires, in part, that the personnel entrance door or barrier to a radiation room at a panoramic irradiator have a lock that is operated by the same key used to move the sources.

Contrary to the above, as of September 27, 1993, the lock to the entrance door of the irradiator room could not be operated by the same key that was used to move the irradiator source. Specifically, one key was used to operate the source and another independent key was used to lock the door to the irradiator room. (01152)

N. 10 CFR 36.23(b) requires, in part, that each entrance to a radiation room at a panoramic irradiator have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry must cause the sources to return to the fully shielded position and also activate a visible and audible alarm to make the individual entering the room aware of the hazard.

Contrary to the above, as of September 27, 1993, the entrance to the radiation room at the panoramic irradiator did not have an independent backup access control to detect personnel entry while the source was exposed. (01162)

O. 10 CFR 36.23(c) requires, in part, that a radiation monitor be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high.

Contrary to the above, as of September 27, 1993, the radiation monitor to detect the presence of high radiation levels in the radiation room of the panoramic irradiator was not integrated with personnel access door locks to prevent room access when radiation levels were high. (01172)

P. 10 CFR 36.23(d) requires, in part, that before the source moves from its shielded position in a panoramic irradiator, a source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the source would be moved from its shielded position.

Contrary to the above, as of September 27, 1993, the source control did not automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the source will be moved from its shielded position. (01182)

Q. 10 CFR 36.27(a) requires, in part, that the radiation room at the panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm and the source must automatically become fully shielded if a fire is detected.

Contrary to the above, as of September 27, 1993, the radiation room at the panoramic irradiation did not have a smoke detector and the heat detector in the room did not activate an audible alarm causing the source to become fully shielded if a fire were detected. (01192)

R. 10 CFR 36.31(a) requires, in part, that the mechanism that moves the source of a panoramic irradiator require a key to actuate. The key must be attached to a portable radiation survey meter by a chain or cable.

Contrary to the above, as of September 27, 1993, the key that actuated the mechanism that moved the source of the panoramic irradiator was not attached to a portable radiation survey meter. (01202)

S. 10 CFR 36.67(a) requires, in part, that upon first entering the radiation room of panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position.

Contrary to the above, during the inspection on September 27, 1993, the irradiator operator did not use a survey meter upon first entering the radiation room of the panoramic irradiator

after an irradiation, to determine that the source returned to its fully shielded position. (01212)

T. 10 CFR 36.67(b)(2) requires, in part, that before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall activate a control in the radiation room that permits the source to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

Contrary to the above, as of September 27, 1993, there was no control in the radiation room of the panoramic irradiator that permitted the source to be moved from the shielded position only if the door to the radiation room was locked within a preset time after setting the control. (01222)

U. License Condition No. 26 of License No. 34-00293-15 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

The referenced application dated August 14, 1991, states in Item No. 8, that irradiator operators will receive total training that includes approximately 40 hours of reading assignments and discussions, followed by a comprehensive examination with a minimum passing score of 75 percent.

Contrary to the above, as of September 27, 1993, an individual operating the irradiator since February 1993 had not taken the required examination. (01232)

V. 10 CFR 36.33(f) requires, in part, that pool irradiators have a physical barrier, such as a railing or cover, which must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool.

Contrary to the above, as of November 4, 1993, during normal operation the pool irradiator did not have an adequate physical barrier to prevent personnel from accidently falling into the pool. Specifically, an approximate 3 by 5 foot section over the irradiator pool did not have a railing or a cover to prevent personnel from accidentally falling into the pool. (01242)

W. 10 CFR 35.75(a) requires that a licensee not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either the measured dose rate from the patient is less than 5 millirems per hour at a distance of one meter or the activity in the patient is less than 30 millicuries.

Contrary to the above, on May 8, 1993, the licensee released a patient who had received 197 millicuries of iodine-131 on May 6,

1993, and at the time of release, the dose rate from the patient was not determined and the patient was released 6 hours before the activity in the patient was calculated to be less than 30 millicuries. (01252)

X. 10 CFR 35.25 (a)(1) requires that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user shall instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material.

Contrary to the above, a resident physician who was under the supervision of an authorized user was not instructed in the principles of radiation safety appropriate to that individual's use of byproduct material. Specifically, on November 13, 1991, the authorized user failed to instruct the supervised individual in the proper handling of "Syed" catheters designed to house cesium-137 brachytherapy sources (byproduct material). As a result, the resident physician unknowingly implanted a portion of the catheter that did not contain any cesium-137 brachytherapy sources, necessary to achieve treatment as prescribed by the authorized user. (01262)

Y. 10 CFR 35.310(a) requires that the licensee provide radiation safety instruction for all personnel caring for the patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75. The instruction must describe the licensee's procedures for patient control, visitor control, contamination control, waste control and notification of the Radiation Safety Officer in case of the patient's death or medical emergency.

Contrary to the above, on May 8, 1993, a nurse cared for a patient who received radiopharmaceutical therapy consisting of 197 millicuries of iodine-131 for a radiopharmaceutical therapy treatment and was hospitalized for compliance with 10 CFR 75, and the nurse had not received any of the required radiation safety instructions. In addition, an intern caring for the same patient did not receive proper radiation safety instruction in the licensee's procedures for patient control. (01272)

Z. 10 CFR 35.315(a)(5) requires for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, the licensee shall either monitor material and items removed from the patient's room to determine that their radioactivity cannot be distinguished from the natural background radiation level or handle them as radioactive waste.

Contrary to the above, between April 14 and April 19, 1993, trash and linen were removed from a room housing a patient treated with 74 millicuries of iodine-131 and who was hospitalized for compliance with 10 CFR 35.75, and the materials and items (e.g.,

linens, trash) removed from the patient's room were not monitored to determine that their radioactivity could not be distinguished from the natural background radiation level or handled as radioactive waste. Specifically, the linens were handled as soiled (non-radioactive) materials and laundered with other hospital linens. (01282)

AA. 10 CFR 20.405(a) requires, in part, that within 30 days a licensee make a report in writing to the Commission concerning each exposure to radiation in excess of any applicable limit in 10 CFR 20.101. The report must include the cause of the exposure and the corrective steps taken or planned to prevent a recurrence. 10 CFR 20.405(b) requires that the report include for each individual exposed, the name, social security number, and date of birth.

Contrary to the above, the licensee did not submit a written report concerning an exposure in excess of 10 CFR 20.101 limits which occurred in September 1991, until November 27, 1991, and did not include in the report the cause of the exposure, the corrective steps taken or planned to prevent recurrence, or the exposed individual's name, social security number and date of birth. (01292)

BB. License Condition No. 27, Amendment No. 64, dated April 24, 1986, requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated December 4, 1979.

Item 8 of the December 4, 1979, application specifies that the criteria for acceptable training and experience for physicians requesting authorization for clinical use of radioactive material contained in Appendix A of Regulatory Guide 10.8, dated January 1979, will be required as a minimum for the requestee to be approved. Appendix A of Regulatory Guide 10.8 required that individuals who use or directly supervise the use of byproduct material for diagnostic studies be a physician that has:
200 hours of training in basic radioisotope handling techniques, and 500 hours of experience with the types and quantities of byproduct material for which application is being made, and 500 hours of supervised clinical training in an institutional nuclear medicine program covering all appropriate types of diagnostic procedures, including patient examination, followup and other specified criteria, or Certification by the American Board of Nuclear Medicine or American Board of Radiology in one of several specified disciplines.

Contrary to the above, a physician was approved by the licensee's Medical Radionuclide Committee for use of byproduct material in humans, and the physician had not satisfied the applicable training and experience criteria of Appendix A, Regulatory Guide 10.8. Specifically, on April 1, 1992, the committee approved a physician to use carbon-14 in humans for a bile excretion research

study and the physician did not meet any of the Appendix A, Regulatory Guide training and experience criteria, and was not otherwise certified by an appropriate Board. (01302)

These violations represent a Severity Level II Problem (Supplements IV and VI).
Civil Penalty - $14,000.

II. Violations Associated With Loss or Potential for Loss of Control of Material

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

Contrary to the above, a survey performed after implanting sources in a patient did not include all areas of use. Specifically, on November 13, 1991, cesium-137 brachytherapy sources remained in a transport cart after it was thought they were implanted in a patient and the radiation survey performed after implant did not include the transport cart to confirm that sources were not misplaced. (02013)

B. 10 CFR 20.207(a) requires that licensed material stored in an unrestricted area be secured against removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under the constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

1. Contrary to the above, between November 18 and 23, 1992, licensed material consisting of a nominal 0.95 millicurie iridium-192 source used for brachytherapy was located in patient room no. 832, an unrestricted area, was not in storage, was not secured against unauthorized removal, and was not under constant and immediate control of the licensee. (02023)

2. Contrary to the above, on April 17, 1991, licensed material consisting of iodine-125 seeds (sealed sources) used for brachytherapy were left overnight in an autoclave located in the surgical area, an unrestricted area, were not in storage, were not secured against unauthorized removal, and were not under constant and immediate control of the licensee. (02033)

C. 10 CFR 35.406(a) requires that promptly after removing them from a patient, a licensee return brachytherapy sources to the storage

area and count the number of sources to ensure that all sources taken from the storage area have been returned.

Contrary to the above, on November 18, 1992, after removing iridium-192 brachytherapy sources from a patient and returning them to the storage area, the licensee did not count the number returned to assure that all sources taken from the storage area had been returned. (02043)

D. 10 CFR 20.201(b) requires each licensee make such surveys as may be necessary to comply with the requirements of 10 CFR 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 adequate surveys to assure compliance with that part of 10 CFR 20.105(b) which limits radiation levels in unrestricted areas. Specifically, a survey on November 18, 1992, performed after a brachytherapy source explant, failed to locate a nominal 0.95 millicurie iridium-192 seed that was located on the floor near a patient's bed which resulted in radiation levels that exceeded the limits specified in CFR 20.105(b). (02053)

These violations represent a Severity Level III problem (Supplements IV and VI).
Civil Penalty - $3,750

Pursuant to the provisions of 10 CFR 2.201, The Ohio State University (Licensee) is 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 Penalties (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 as to 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 under 10 CFR 2.201, the Licensee may pay the civil penalties 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 penalties proposed above, or may protest imposition of the civil penalties 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 penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, 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 penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section V.B 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 penalties.

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

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalties, 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 60532-4351.

Dated at Lisle, Illinois
this 10 day of June 1994