

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Allegheny General Hospital
Pittsburgh, Pennsylvania

Docket Nos. 030-02981
030-00462
030-30452
License Nos. 37-01317-01
37-01317-02
37-01317-03
EA 93-309

During an NRC inspection conducted on December 13 - 20, 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 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 of Quality Management Program Requirements

- A. 10 CFR 35.32(a) requires that a licensee establish and maintain a written Quality Management Program (QMP) to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

10 CFR 35.32(a)(1)(iv) requires, in part, that prior to administration, a written directive be prepared for administration of quantities greater than 30 microcuries of sodium iodide I-131.

As defined in 10 CFR 35.2, a written directive means an order in writing for a specific patient, dated, and signed by an authorized user prior to the administration of a radiopharmaceutical which includes the dosage and route of administration.

Contrary to the above, on 41 occasions between January 1992 and January 1993, and on 7 occasions in October 1993, the licensee administered doses of sodium iodide of between 30 microcuries and 2 millicuries without first preparing a written directive prior to administering the radiopharmaceutical to the patient. (IFS Code 01013)

- B. 10 CFR 35.32(a) requires that a licensee establish and maintain a written Quality Management Program (QMP) to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user.

10 CFR 35.25(a)(1) requires, in part, that the licensee instruct supervised individuals in the licensee's written QMP.

Contrary to the above, between January 1992 and October 1993, the licensee did not instruct all nuclear medicine technologists,

supervised individuals, in the licensee's written QMP.
(IFS Code 01023)

These violations represent a Severity Level III problem (Supplement VI).
Civil Penalty - \$3,750

II. Other violations of NRC Requirements

- A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized 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 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.

Contrary to the above, as of December 14, 1993, licensed material labeled as consisting of 140 microcuries (actual activity of 15 microcuries) of iodine-125 located in a hallway, an unrestricted area, was not secured against unauthorized removal, and was not under constant surveillance and immediate control of the licensee.
(IFS Code 02013)

This is a repetitive violation (second occurrence).

- B. Condition 13 of License No. 37-01317-01 requires, in part, that radioactive waste held for decay-in-storage be held for decay a minimum of 10 half-lives before disposal in ordinary trash.

Contrary to the above, from November 15, 1990 to December 14, 1993, a container of iodine-131 waste held for decay-in-storage was not held for 10 half-lives before disposal in ordinary trash.
(IFS Code 02023)

- C. Condition 22 of License No. 37-01317-01 requires, in part, that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated October 25, 1983.

1. Item No. 11 of this application requires that a survey with a calibrated survey meter be performed each time a new radioactive item is placed within the radioactive waste storage vault.

Contrary to the above, as of December 15, 1993, a survey of the radioactive waste storage vault was not performed each time a new radioactive item was placed within the vault.
(IFS Code 02033)

2. Item No. 20.15 of this application requires, in part, that prior to a brachytherapy implant, all available nursing staff be trained on the description of brachytherapy sources and applicator.

Contrary to the above, as of December 14, 1993, a nurse assigned to care for a brachytherapy patient had not been trained on the description of brachytherapy sources and applicator. (IFS Code 02043)

3. Item No. 20.A of this application requires, in part, that the brachytherapy source storage safe be installed in the east wall of the Mevatron 20 Room.

Contrary to the above, as of December 14, 1993, the brachytherapy source storage safe was not installed in the east wall of the Mevatron 20 room, but was located on the floor of the radiation therapy source storage room. (IFS Code 02053)

4. Item No. 20.E of this application requires, in part, that the brachytherapy source log book contain the number of sources taken out of the safe, the number of sources inserted into the patient, the number of sources returned to the safe that were not implanted, the number of sources returned to the safe after treatment, and the total source inventory.

Contrary to the above, as of December 14, 1993, the brachytherapy source log book did not contain the total source inventory of sources in the safe after treatment. (IFS Code 02063)

- D. 10 CFR 20.203(e) requires that rooms in which licensed material is used and which contain radioactive material (other than natural uranium or thorium) in an amount exceeding 10 times the quantity specified in Appendix C of Part 20 be conspicuously posted "Caution Radioactive Material."

Contrary to the above, on December 14, 1993, several research labs which contained greater than 10 times Appendix C quantities of licensed material other than natural uranium or thorium were not posted as required. (IFS Code 02073)

- E. 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 20.106, which limits the yearly average concentration of radioactive material in air discharged to unrestricted areas. Specifically, as of December 14, 1993, surveys to assure compliance with 10 CFR 20.106 were not made during procedures involving iodinating proteins with millicurie quantities of iodine-125. (IFS Code 02083)

- F. 10 CFR 20.105(b) requires, in part, 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.

Contrary to the above, on September 13, 1993, the licensee allowed the creation of radiation levels in a patient room adjoining an iodine-131 therapy patient's 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, the adjoining patient's room was measured by the licensee to read 3 millirem per hour and the patient room was not restricted from use. (IFS Code 02093)

- G. 10 CFR 35.315(a)(8) requires, in part, that a licensee retain records of thyroid burden measurements performed on individuals who help prepare or administer dosages of iodine-131 in amounts that require the patient to be hospitalized for compliance with 10 CFR 35.75, and that the records include the date of the measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

Contrary to the above, as of December 14, 1993, the licensee's records of thyroid burden measurements performed on individuals who had helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75 did not include the date of the bioassay. (IFS Code 02103)

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

Contrary to the above, as of December 13, 1993, the personnel entrance door to a radiation room at a panoramic irradiator did not have a lock that was operated by the same key used to move the source. (IFS Code 02113)

- I. 10 CFR 36.27 requires that the radiation room at a panoramic irradiator have heat and smoke detectors and be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room.

Contrary to the above, as of December 13, 1993, the radiation room of the panoramic irradiator did not have heat and smoke detectors and was not equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. (IFS Code 02123)

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

Contrary to the above, as of December 13, 1993, the key to the mechanism that moved the sources of a panoramic irradiator was not attached to a portable radiation survey meter. (IFS Code 02133)

- K. 10 CFR 36.31(b) requires that the console of a panoramic irradiator have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

Contrary to the above, as of December 13, 1993, the console of the panoramic irradiator did not have a source position indicator that indicated when the source was in transit. (IFS Code 02143)

- L. 10 CFR 36.51 requires, in part, that before an individual is permitted to operate an irradiator without a supervisor present, the individual be instructed on the requirements of 10 CFR Part 36 relevant to the irradiator.

Contrary to the above, as of December 13, 1993, none of the authorized users of the irradiator had been instructed on the relevant requirements of 10 CFR Part 36. (IFS Code 02153)

- M. 10 CFR 36.53 requires, in part, that the licensee have and follow emergency procedures which include actions in the event of a fire alarm or explosion in the radiation room and actions in the event of a natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility.

Contrary to the above, as of December 13, 1993, the licensee's emergency procedures did not include actions in the event of a fire alarm or explosion in the radiation room and actions in the event of a natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility. (IFS Code 02163)

- N. 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 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.

Contrary to the above, as of December 13, 1993, the radiation room of the panoramic irradiator was not equipped with a control 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. (IFS Code 02173)

- O. Condition 11A of License No. 37-01317-02 limits the use of licensed material to named individuals.

Contrary to the above, on December 13, 1993, a resident not authorized by this license condition used licensed material for calibration of instruments. (IFS Code 02183)

This is a repetitive violation (second occurrence).

These violations represent a Severity Level III problem (Supplements IV and VI).
Civil Penalty - \$5,000

Pursuant to the provisions of 10 CFR 2.201, Allegheny General Hospital (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 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 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 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 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 violation(s) 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 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 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 response 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 I.

Dated at Rockville, Maryland
this day of March 1994