

Appendix A

NOTICE OF VIOLATION

Evanston and Glenbrook Hospitals

License No. 12-00437-01

As a result of the inspection conducted on December 9 through 22, 1982, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violations were identified:

1. 10 CFR 20.103(b)(2) states whenever the intake of radioactive material by any individual exceeds the 40-hour control measure, the licensee shall make such evaluation and take such actions as are necessary to assure against recurrence.

Contrary to this requirement, the NRC inspectors determined through statements by licensee representatives and the NRC inspectors' review of bioassay records that this condition is not being met. Specifically, on September 9, 1980, a thyroid bioassay on an individual indicated an intake of 1 microcurie (400 MPC-hours) of iodine-131 and no evaluation of this exposure was made. In addition, on October 24, 1980, thyroid bioassays on two individuals indicated intake of iodine-131 in excess of the 40 hour limit (156 and 56.3 MCP-hours) and no evaluations of these exposures were made and no action was taken to assure against recurrence.

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

2. License Condition No. 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in application dated September 28, 1978, and letter dated December 11, 1978. Item No. 5 in your letter dated December 11, 1978, states that the bioassay program includes monthly thyroid monitoring of personnel who handle iodine-131 or iodine-125.

Contrary to the above requirement, the NRC inspectors determined through statements by licensee representatives and review of bioassay records that this condition is not being met. Specifically, bioassays were not performed on individuals performing iodine-131 thyroid therapeutic treatments. For example, millicurie amounts of liquid iodine-131 were handled on April 21, 1980, July 15, 1980, July 23, 1980, July 24, 1980, August 18, 1980, and multiple dates during 1982 and monthly thyroid counts were not performed.

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

3. 10 CFR 20.401(c)(1) requires that records of bioassays, including results of whole body counting, be preserved until the Commission authorizes disposition.

Contrary to this requirement, the NRC inspectors determined through statements by licensee representatives and review of bioassay records that this condition is not being met. Specifically, records of bioassays performed were not kept between July 16, 1979, to February 7, 1980, February 28, 1980 to September 9, 1980, and multiple other periods.

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

4. License Condition No. 18 states that licensed material may be transported or delivered in accordance with 10 CFR 71.5, "Transportation of Licensed Material." 10 CFR 71.5 states that no licensee shall transport any licensed material outside of his facility unless the licensee complies with 49 CFR Parts 170-189.

- a. 49 CFR 173.393(n) states that prior to each shipment of any package, the shipper shall ensure by examination or appropriate test that external radiation and contamination levels are within the allowable limits.

Contrary to this requirement, wipe tests were not performed on packages transported between the Evanston and Glenbrook facilities since the date of the last inspection on June 24, 1980. In addition, wipe tests are not performed on packages containing spent generators being returned to Mallinckrodt.

- b. 49 CFR 173.395(a)(1) states that each shipper of a Specification 7A packaging must maintain on file for at least one year after the latest shipment, and be prepared to provide the Department, a complete certification and supporting safety analysis demonstrating that the construction methods, packaging design, and materials of construction are in compliance with the specification.

Contrary to this requirement, you failed to maintain on file the Specification 7A packaging certification for the packages used to ship generators to and from Glenbrook Hospital and generators returned to Mallinckrodt. The ammunition boxes also used to transport doses to and from Glenbrook Hospital do not have the required certification.

- c. 49 CFR 177.834(a) requires that any package containing radioactive material must be blocked and braced or secured against movement within the vehicle in which it is being transported.

Contrary to this requirement, a licensee representative stated packages containing generators transported to Glenbrook Hospital are placed on the back seat of a van and transported without securing against movement.

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

5. License Condition No. 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in application dated September 28, 1978, and letter dated September 8, 1980.

Your letter dated September 8, 1980, states that the incineration limit for soluble iodine-131 shall not exceed 8.8 microcuries per year.

Contrary to the above requirement, the NRC inspectors determined through statements by licensee representatives and review of incineration records that this condition is not being met. Specifically, on August 13, 1982, between 10 and 20 microcuries of soluble iodine-131 was incinerated. Furthermore, on September 22, 1982, an unspecified amount of iodine-131 was incinerated.

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

6. License Condition No. 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in application dated September 28, 1978 and letter dated September 8, 1980.

Item 6 in your letter dated September 8, 1980, states that when ash is removed from the incinerator, a G-M survey will be performed to ensure that the radiation levels in the incinerator do not exceed background levels. License Condition No. 23 states that ash residues may be disposed of as normal waste provided that surveys are performed to ensure the ash residues do not exceed the allowable limits.

Contrary to these requirements, The NRC inspectors determined through statements of licensee representatives that surveys of the incinerator have not been performed. Ash residues have not been surveyed before disposal as normal waste.

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

7. License Condition No. 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in application dated September 28, 1978. The referenced application states that the procedures described in Appendix F of the draft guide "Guide for Preparation of Applications for Medical Programs" will be followed. Appendix F requires that wipe tests be performed on the external surface of the final source container after opening packages containing radioactive material.

Contrary to this requirement, the NRC inspectors determined through statements by licensee representatives that this condition is not being met. Specifically, wipe tests of the final source containers are not being performed on packages containing radioactive material received at the Glenbrook facility.

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

8. License Condition No. 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in application dated September 28, 1978. Item No. 13 of the referenced application states that Section III of the Procedures Manual will be followed for ordering and receipt of radioactive material. Section III states that when a shipment arrives, Nuclear Medicine will monitor the parcel and its contents, as well as document in the records the amount of the isotope, the mass number, and the date the parcel arrived. The department which ordered the isotope is then notified that the parcel has arrived and will arrange to have it picked up at Nuclear Medicine.

Contrary to this requirement, the NRC inspectors determined through statements by licensee representatives that these conditions were not being met. Specifically, when parcels containing radioactive material arrive at the Evanston facility, they are normally taken to the laboratory which ordered the material. On multiple occasions, Nuclear Medicine has not monitored or recorded the receipt of packages containing radioactive material.

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

9. License Condition No. 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in application dated September 28, 1978. Item 19 of the referenced application states that urine and vomitus from iodine-131 therapy patients will be stored for decay in the radioactive waste storage area. When it has reached background levels as measured with a low-level survey meter, it will be released to the sanitary sewer system.

Contrary to the above requirement, the NRC inspectors determined through statements by licensee representatives that this condition is not being met. Specifically, urine from iodine-131 therapy patients was not held for decay on December 1, 1982, September 27, 1982, September 7, 1982, and other dates.

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

10. License Condition No. 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in application dated September 28, 1978, and letter dated February 8, 1979.

Your letter dated February 8, 1979, states that the generator and dose preparation areas will be surveyed for contamination on a daily basis and the results will be recorded.

Contrary to the above requirement, the NRC inspectors determined through statements by licensee representatives that this condition is not being met. Specifically, daily surveys have not been performed at the Glenbrook facility since the date of the last inspection on June 24, 1980, and records of daily surveys performed at the Evanston facility have not been maintained.

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

11. License Condition No. 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in application dated September 28, 1978. Item No. 10 of the referenced application states that the procedures described in Appendix D of the draft "Guide for Preparation of Applications for Medical Programs" will be followed. Appendix D requires that a quarterly linearity test be performed on the dose calibrator.

Contrary to the above requirement, the NRC inspectors determined through review of dose calibrator records that this condition is not being met. Specifically, the dose calibrator at the Glenbrook facility was not tested for linearity during the first and third quarter of 1981.

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

12. 10 CFR 35.14(5)(ii) requires for Group VI sealed sources that records of leak test results be kept in units of microcuries.

Contrary to this requirement, the NRC inspectors determined through review of leak test records that this condition is not being met. Specifically, the results of leak tests performed on the strontium-90 source have not been maintained in units of microcuries.

This is a repeat item of noncompliance.

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

13. 10 CFR 35.14(e)(1)(i) requires each licensee who possesses sealed sources as calibration or reference sources to perform tests for leakage and/or contamination at intervals not to exceed six months.

Contrary to this requirement, the NRC inspectors determined through statements by licensee representatives that this condition is not being met. Specifically, your 240 microcurie barium-133 and 216 microcurie cesium-137 sources have not been tested for leakage since the date of the last inspection on June 24, 1980.

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

14. License Condition No. 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in application dated September 28, 1978.

Item No. 24 of the referenced application states personnel monitoring devices will include TLD finger badges. Item No. 20 of the referenced application states TLD ring badges will be issued to personnel handling cesium-137 brachytherapy sources to determine exposure to the extremities.

Contrary to these requirements, the NRC inspectors determined through statements by licensee representatives and review of exposure records that these conditions are not being met. Specifically, a nuclear medicine technologist at the Glenbrook facility was not issued a TLD ring badge. Also, individuals at the Evanston facility who handle cesium-137 brachytherapy sources have not been issued TLD ring badges.

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

15. License Condition No. 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in application dated September 28, 1978.

Item No. 10 of the referenced application states that survey meters will be calibrated once every twelve months.

Contrary to this requirement, the NRC inspectors determined through statements by licensee representatives and review of records that this condition is not being met. Specifically, several survey meters located at the Evanston facility were found to be out of calibration. Many of these survey meters are currently being used for area surveys, package surveys, and disposal surveys. For example, the Eberline survey meter Serial No. 124 was last calibrated on August 25, 1981, and was used for package surveys on September 7 and 8, 1982, and other multiple dates.

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

16. License Condition No. 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in application dated September 28, 1978.

Item No. 7 of the referenced application refers to Section I of the Procedures Manual titled "Isotopes Committee". Section I states a minimum of four meetings a year will be held.

Contrary to the above requirement, the NRC inspectors determined through statements by licensee representatives and review of meeting records that this condition is not being met. Specifically, during 1981 the isotopes committee met on February 23, May 20, and August 27.

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

17. 10 CFR 20.207(a) requires licensed materials stored in an unrestricted area shall be secured from unauthorized removal from the place of storage.

Contrary to the above requirement, the NRC inspectors determined through observations that this requirement is not being met. Specifically, on December 21, 1982, a nominal 83 millicuries of tritium stored in an unlocked refrigerator in an unrestricted hallway across from Laboratory Room B510 was not secured against unauthorized removal from the place of storage.

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

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

Dated

J. A. Hind, Director
Division of Radiological and
Material Safety Programs

Appendix B

MANAGEMENT CONTROL

In order to provide you with some guidance in assessing the adequacy of your management control program, the NRC Region III office provides the following as the acceptance criteria for adequate management control for materials licensees. "Management Control" is a system instituted by management to assure that licensed activities are performed safely and in accordance with regulatory requirements (license conditions and applicable regulations).

This will include:

- a. Delineation of duties and responsibilities of all persons involved in licensed activities.
- b. Providing for indoctrination and training of all personnel performing licensed activities, specifically in those areas directly affecting compliance with NRC regulations and license conditions.
- c. Verification, as by checking, auditing and inspecting, that activities affecting safety related functions have been correctly performed. The verifying process should be performed by individuals or groups other than those performing the safety related procedures.
- d. Insuring continued compliance of licensed activities throughout periods during which routine activities may be interrupted, such as changes in equipment, personnel or facilities.

Because of the many variables involved, such as the number of personnel, type of activity being performed and the location or locations where activities are performed, the organizational structure for executing the management control program may take various forms; however, irrespective of the organizational structure, the individual or group responsible for this control should have the flexibility and authority to institute changes or corrections as required to maintain compliance with NRC regulations and license conditions.