

APPENDIX A

NOTICE OF VIOLATION

The Childrens Hospital Corporation
Boston, Massachusetts 02115

Docket No. 030-08021
License No. 20-09568-17

As a result of the inspection conducted on November 19 and 20, 1985, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

- A. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20. 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 November 20, 1985, inadequate surveys were made to assure compliance with 10 CFR 20.101(a). Specifically, no evaluation was made of the dose to the extremities of three Nuclear Medicine Technologists whose hands were contaminated with technetium-99m on October 31, 1984. In addition, no evaluation was made of the skin dose to an individual involved in a radioiodination procedure on March 20, 1984 which may have caused skin contamination leading to a thyroid uptake of approximately 150 nanocuries of iodine-125.

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

- B. 10 CFR 20.203(e) requires that each area or room in which licensed material is used or stored and which contains any radioactive material in an amount exceeding 10 times the quantity of such material specified in Appendix C of this part shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

CAUTION
RADIOACTIVE MATERIAL

Contrary to the above, on November 19, 1985, research laboratories where millicurie amounts of phosphorous-32 were used and stored were not posted.

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

- C. Condition 26 of License No. 20-09568-17 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated January 13, 1984 and letter with enclosure dated May 11, 1984.

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1. Item 23 of this application requires that all persons performing radioiodinations involving more than 1 millicurie of iodine-125 or iodine-131 must have their thyroids scanned within one month of each iodination.

Contrary to the above, an investigator performed two 12 millicurie and one 2 millicurie iodinations on February 6, 13 and 28, of 1984, respectively, and did not receive a thyroid scan until April 10, 1984, a period greater than one month. In addition, two other investigators performed iodinations of 10 millicuries and 2 millicuries of iodine-125 on March 5 and 6 of 1984 and August of 1985 and did not receive thyroid scans until April 26 of 1984 and October 3, 1985, respectively, periods greater than one month.

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

2. Item 13 of this application refers to Section 5 of the Radiation Safety Manual.

Subitem 5.1.1 of the Radiation Safety Manual requires that the Radiation Control Unit compare radionuclide purchase requests against the (authorization) permit to insure that the purchaser is authorized for the amount and type of radionuclide requested.

Contrary to the above, the Radiation Control Unit approved radionuclide purchase requests in excess of the amount of activity authorized under the purchaser's permit and for radionuclides not authorized under the purchaser's permit. Specifically a permit holder was allowed to purchase 10 millicuries of sulfur-35 on November 4, 1985, and was authorized for 2 millicuries of sulfur-35. The same permit holder was allowed to purchase 10 millicuries of chromium-51 on March 6 and October 29, 1985, and was not authorized to work with chromium-51.

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

3. Subitem 3.2 of the Radiation Safety Manual requires that no person use any radionuclide in any amount without authorization from the Radiation Safety Committee.

Contrary to the above, during 1985 an investigator used 250 microcuries of hydrogen-3 and was not authorized to use any radionuclide. In addition, another investigator used 20 millicuries of chromium-51, a radionuclide for which the investigator is not authorized.

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

Pursuant to the provisions of 10 CFR 2.201, The Childrens Hospital Corporation is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.