

MATERIALS LICENSE

Amendment No. 05

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee

1. Children's Hospital

2. 300 Longwood Avenue
Boston, Massachusetts 02115

In accordance with application dated

August 28, 1986,

3. License number 20-09568-18 is amended in
its entirety to read as follows:

4. Expiration date February 28, 1992

5. Docket or
Reference No. 030-118646. Byproduct, source, and/or
special nuclear material7. Chemical and/or physical
form8. Maximum amount that licensee
may possess at any one time
under this license

A. Cesium 137

A. Sealed sources
(ORNL-Ramco-50)

A. 2,400 curies

B. Cesium 137

B. Sealed sources (AECL
Model C-161 Type 8)

B. 4,000 curies

9. Authorized use

- A. For use in an Isomedix Inc. Gammator M(38) irradiator for irradiating blood.
B. For use in an Atomic Energy of Canada, Ltd. Gammacell 40 Low Dose Rate Laboratory Irradiator for irradiating small animals, biologic samples and other materials except those of an explosive or hazardous nature.

CONDITIONS

10. Licensed material shall be used only at the licensee's facility, Children's Hospital's Blood Bank, 300 Longwood Avenue, Boston, Massachusetts or at Enders Pediatric Research Building, 20 Blackfan Street, Boston, Massachusetts.
11. Licensed material shall be used by, or under the supervision and in the physical presence of, Laurence Button, Sherwin V. Key, David Williams, M.D., or individuals trained in accordance with the procedures described in application dated March 5, 1986.
12. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from detector cells by the licensee.
13. A(1) Any sealed sources or detector cells specified in Items 7.A. and 7.B. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source or detector cell received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

20-09568-18

Docket or Reference number

030-11864

Amendment No. 05

(13. continued)

CONDITIONS

- (2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source or detector cell is exempt from such leak tests when the source or detector cell contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.
- B. Any sealed source or detector cell in storage and not being used need not be tested. When the source or detector cell is removed from storage for use or transfer to another person, it shall be tested before use or transfer.
- C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source or detector cell shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region 1, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch, 631 Park Avenue, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
- D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.
14. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.
15. The procedures contained in AECL's instruction manual for the "Gammator M" or "Gammacell 40" device shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of licensed material.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

20-09568-18

Docket or Reference number

030-11864

Amendment No. 05

(Continued)

CONDITIONS

16. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated February 27, 1981
- B. Application dated March 5, 1986
- C. Application dated August 28, 1986
- D. Letter dated August 28, 1986

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Date _____

For the U.S. Nuclear Regulatory Commission

Original Signed By

John E. Glenn

By _____

Nuclear Materials Safety and
Safeguards Branch, Region I
King of Prussia, Pennsylvania 19406

26 JAN 1987

Docket Nos. 30-08021
30-11864 ✓

License Nos. 20-09568-17
20-09568-18 ✓

The Childrens Hospital Corporation
ATTN: Albert L. Broseghini, Ph.D.
Director, Research Administration
300 Longwood Avenue
Boston, Massachusetts 02115

Gentlemen:

Subject: Inspection No. 30-08021/85-01 and 30-11864/85-01

This refers to your letter dated February 27, 1986, in response to our letter dated January 29, 1986.

Thank you for informing us of the corrective and preventive actions documented in your letter. However, your letter has been reviewed and additional information is found to be needed.

In response to Item A, you have failed to submit an evaluation of the exposure of the individuals contaminated with radioactive materials that estimates the skin exposures of these individuals resulting from low energy beta particles and electrons associated with the radionuclides involved in these contamination incidents.

We apologize for the delay of our reply to your response.

Please submit to this office within seven (7) days of receipt of this letter a written statement containing the requested information.

Sincerely,

Original Signed By
John E. Glenn

John E. Glenn, Ph.D. Chief
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts

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The Childrens Hosptial
Corporation

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bcc:
Region I Docket Room (w/concurrences)

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Glenn

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RL THE CHILDRENS HOSPITAL -

12/12/86



The Children's Hospital • Boston

300 Longwood Avenue, Boston, Massachusetts 02115 • Telephone (617) 735-7048

Office of Research Administration

February 27, 1986

John E. Glenn, Ph.D., Chief
Nuclear Materials Safety Section B,
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region 1
631 Park Avenue
King of Prussia, PA 19406

RE: Inspection No. 85-01
License Nos. 20-09568-17 &
18

Dear Dr. Glenn,

This is in response to your letter of January 29, 1986 concerning the Nuclear Regulatory Commission inspection conducted by Mr. Jensen and Mr. Miller on November 19 and 20, 1985.

We have reviewed the findings as detailed in Appendix A - Notice of Violation and answer as follows:

A. Survey reports indicate that two technologists had dose rates of 0.1 mR/hr at one inch and the third had an exposure rate of 0.25 mR/hr at one inch due to skin contamination. We evaluated the technologists' exposures by contaminating a water filled glove with Tc-99m and taking a ratio of dose rates at one inch and at contact. We estimate the dose rate at contact to be less than 0.8 mR/hr, and the exposure time to be less than 8 hours, for a dose of less than 6.5 mR or 0.00035 x MPD for the quarter for the first two cases. The third individual received about 16.5 mR, or 0.0009 x MPD.

The dose for the radioiodination is considerably more

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difficult to evaluate. On March 20, 1984 he performed an iodination, monitored his hands, clothing and work area and found them free of contamination. He then transferred his material to a different fume hood and injected it into an HPLC. After the HPLC work he left the lab and did not return for a thyroid scan until April 10. At that time his thyroid burden was measured as 150 nanocuries and his hands showed about 1200 cpm contamination at contact as measured with a Ludlum Model 3 survey meter with a Model 44-3 scintillation probe. A routine lab survey on April 6 indicates his lab coat was contaminated, with a dose rate of 0.1 mR/hr at contact as measured with an Eberline E-120 with a HP-190 thin-end window G.M. probe. We assume the iodinator's gloved hands were as contaminated as his lab coat, so imparted a dose of about 3 mR in this first day. We further assume that 50% was removed the first day by normal hygiene, and that the contamination remained constant until the measurement April 6. Days 2 through 21 each contributed 0.05 mR/hr, or another 24 mR. A survey on April 10 showed no detectable activity with the G.M. Therefore the total dose to the iodinator's hands is less than 27 mR, or less than .0014 x MPD.

B. The particular laboratories identified during the inspection were posted on November 21, 1985. In addition, a complete review of posting and labelling of rooms and areas was completed during the routine monthly surveys in December.

We are now in compliance.

C.1. We concede that the three cases cited for failure to have a thyroid scan within one month of each iodination are correct, but note that the first two individuals had been suspended from performing iodinations until the requirement was met. The third individual was scanned shortly after returning from a one month vacation.

We have taken two steps to prevent a recurrence. In 1984, thyroid scans were available only two mornings each month from the Harvard University Health Services. This considerable inconvenience was the principle reason for the first two incidents. In January 1985, a thyroid monitor was installed in the Radiation Control Unit and so thyroid scans are more convenient. As a result, compliance with the one month rule is improved. In addition, we have tightened our procedures for reviewing compliance. The iodination logs are now compared with the thyroid scan logs on a semi-monthly rather than a monthly basis.

We are now in compliance.

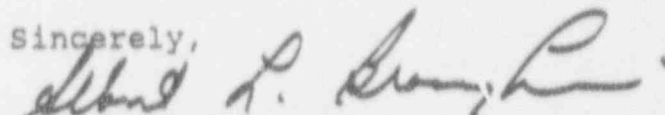
C.2. C.3. Purchase requisitions were reviewed and improperly approved because the check against the Permit was based on memory, not on a printed copy of the Permit. The

Radiation Control Unit now maintains a hard copy of possession limits for reference.

We are now in compliance.

We trust these answers are clear and satisfy the concerns raised in the inspection.

Sincerely,

A handwritten signature in dark ink, appearing to read "Albert L. Broseghini", written in a cursive style.

Albert L. Broseghini, Ph.D.
Director,
Research Administration

cc: T. Treves, M.D.