

MATERIALS LICENSE

Amendment No. 31

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); and to import such byproduct and source material. 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.

<p>Licensee</p> <p>1. Yale-New Haven Hospital</p> <p>2. 20 York Street New Haven, Connecticut 06504</p>	<p>In accordance with application dated December 13, 1984</p> <p>3. License number 06-00819-03 is amended in its entirety to read as follows:</p> <p>4. Expiration date August 31, 1990</p> <p>5. Docket or Reference No. 030-01244</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35</p> <p>B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35</p> <p>C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35</p> <p>D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35</p> <p>E. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35</p> <p>F. Any byproduct material listed in Section 31.11(a) of 10 CFR 31</p>	<p>7. Chemical and/or physical form</p> <p>A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35</p> <p>B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35</p> <p>C. Any radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35</p> <p>D. Any radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35</p> <p>E. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35</p> <p>F. Prepackaged kits</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As necessary for uses authorized in Subitem 9.A.</p> <p>B. 5 curies of each byproduct material authorized in Subitem 6.B.</p> <p>C. As necessary for uses authorized in Subitem 9.C.</p> <p>D. As necessary for uses authorized in Subitem 9.D.</p> <p>E. 2.5 curies total for sources authorized in Subitem 6.E.</p> <p>F. 10 millicuries of each byproduct material authorized in Subitem 6.F.</p>

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| G. Xenon 133 | G. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA | G. 2 curies |
| H. Uranium (depleted in the isotope Uranium 235) | H. Cadmium plated metal | H. 300 kilograms |
| I. Any byproduct material with Atomic Nos. 3 through 83, inclusive | I. Any | I. 100 millicuries of each byproduct material with Atomic Nos. 3 through 83, inclusive |
| J. Americium 241 | J. Sealed source (Amersham AMC-25) | J. 45 millicuries |
| K. Hydrogen 3 | K. Any | K. 500 millicuries |
| L. Americium 241 | L. Any sealed source | L. 40 curies; no source to exceed 10 curies |
| M. Gadolinium 153 | M. Sealed sources (Gulf Nuclear, Inc., Model GD-1) | M. 2 sources, not to exceed 1.5 curies per source |
| N. Iridium-192 | N. Sealed source manufactured by ByK-Mallinckrodt CIL. B.V. | N. 50 curies. Not to exceed 15 curies per source |
| O. Cesium 137 | O. Sealed Source (AECL Model ORNL-RAMCO-50 or ISO-1000) | O. 2400 curies |

9. Authorized use

- A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100, Title 10, Code of Federal Regulations.
- B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- C. Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- D. Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- E. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

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- F. In vitro studies.
- G. Blood flow and pulmonary function studies.
- H. For use as shielding in a linear accelerator.
- I. through K. Medical research and diagnosis.
- L. Measurement of distributions in a tissue equivalent phantom, medical research and therapy.
- M. For use in a NOVO Model BMC-Lab 22a Bone Densitometer for measurement of bone mineral content.
- N. For use in Model Gamma Med II-i automated remote afterloading medical irradiator manufactured by Isotopen Technik Dr. Sauerwein GmbH, for use in medical research, diagnosis and therapy including use on humans and animals.
- O. For use in a AECL Model Gamma Cell 1000 C irradiator for irradiation of blood samples.

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities, Yale-New Haven Hospital, 20 York Street, New Haven, Connecticut.
- 11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions, and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."
- 12.
 - A. Licensed material shall be used by, or under the supervision of, individuals designated by the the Radioisotopes Committee, Eugene A. Cornelius, M.D., Ph.D., Chairman.
 - B. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.3(b).
 - C. Physicians designated to use licensed material in or on humans shall meet the training and experience criteria established in Appendix A of Regulatory Guide 10.8 (Revision 1), dated October 1980.
- 13.
 - A.
 - (1) Each sealed source acquired from another person and containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for contamination and/or leakage prior to use. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.
 - (2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

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CONDITIONS

(3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.

C. Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months.

D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with the U.S. Nuclear Regulatory Commission, Region I, 631 Park Avenue, King of Prussia, Pennsylvania 19406, describing the equipment involved, the test results, and the corrective action taken.

14. Sealed sources containing licensed material listed in Items 6.E., J., L., M., N., and O. shall not be opened.

15. A. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.

B. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Centigrade.

16. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), Title 10, Code of Federal Regulations, Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.

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17. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
18. Licensed material in Items 6.A. through 6.E. shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.
19. Patients containing Iodine 131 for the treatment of thyroid carcinoma shall remain hospitalized until the residual activity is 30 millicuries or less.
20. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
 - A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of ten (10) half-lives.
 - B. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.
 - C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
21. The irradiator facility in item 9.N. above shall be provided with a system permitting continuous observation of the patient from outside the treatment room during patient irradiation.
22. A set of written emergency instructions shall be posted at the machine control of the irradiator in item 9.N. above. These instructions shall inform the machine operator of the procedure to be followed should he be unable to turn the machine's primary beam of radiation "off" with the controls outside the treatment room.
23.
 - A. Access to the room in which the irradiator in item 9.N. above is located shall be controlled by a door at each entrance. Such doors shall be normally closed.
 - B. Each entrance to the irradiator room shall be equipped with an electrical interlock system that will turn the irradiator machine's primary beam of radiation "off" immediately upon opening of any entrance door. The interlock system shall be connected in such a manner that the irradiator machine's primary beam of radiation cannot be turned "on" until all treatment room entrance doors are closed and the beam "on-off" control is reset at the control panel.
 - C. Electrical interlocks on entrance doors to the irradiator room shall be tested for proper operation each day the irradiator is used. Records of test results shall be maintained for inspection by the Commission.
 - D. In the event of malfunction of any door interlock, the irradiator machine control shall be locked in the "off" condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

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24. Prior to initiation of a treatment program, and subsequent to each installation of an irradiator source, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

- (1) The source housing of the irradiator in item 9.N. with the irradiator source in the "off" position. The maximum and average radiation levels at one meter from the teletherapy source in the "off" position shall not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively.
- (2) All areas adjacent to the treatment room with the irradiator source in the "on" position. The survey shall clearly establish:
 - (a) That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 20.101, Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation" (10 CFR 20).
 - (b) That quantities of radiation in unrestricted areas do not exceed the limits specified in Section 20.105(b), 10 CFR 20.
 - (c) The intensity of the primary beam of radiation at a specified distance from the teletherapy source.

B. Tests shall be made to determine proper operation of:

- (1) Electrical interlocks on entrance doors to the irradiator treatment room.
- (2) The irradiator source "on-off" indicators, both at the source housing and on the irradiator machine control panel.
- (3) The irradiator treatment timing device.

C. A report of the results of the above surveys and tests shall be sent to the U. S. Nuclear Regulatory Commission, Region I, Nuclear Materials Safety Section, 631 Park Avenue, King of Prussia, Pennsylvania 19406, not later than thirty (30) days following each installation of a irradiator source.

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25. A. Each sealed source containing licensed material in the AECL Gamma Cell 1000 C shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.
- B. The test shall be capable of detecting the presence of 0.05 microcurie of contamination on the test sample. The test samples shall be taken from appropriate accessible surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.
- C. If the test reveals the presence of 0.05 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the test with the U.S. Nuclear Regulatory Commission, Region I, 631 Park Avenue, King of Prussia, Pennsylvania 19406, describing the equipment involved, the test results, and the corrective action taken.
- D. Tests for leakage and/or contamination shall be performed by licensee or by other persons specifically authorized by the Commission or an Agreement State to perform such services.
26. The procedures contained in AECL's instruction manual for the "Gammacell 1000 C" 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.
27. This license does not authorize repairs or alterations of the irradiator involving removal of shielding or access to the licensed material except as provided otherwise by specific condition of this license. Removal replacement and disposal of sealed sources shall be performed only by A.E.C.L. or by other persons specifically authorized by the Commission or an Agreement State to perform such activities.
28. After installation of the irradiator and Cesium 137 or Cobalt 60 source and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine radiation levels around, above, and below the irradiator with the source in the irradiate position and with the source in the shielded position. A detailed report in duplicate of the results of the surveys shall be sent to the U. S. Nuclear Regulatory Commission, Region I, Nuclear Materials Section, 631 Park Avenue, King of Prussia, Pennsylvania 19406, not later than thirty (30) days following installation of the source.
29. The licensee may use the Calicheck device for performing linearity tests of the dose calibrator in accordance with the procedures in the Calcorp, Inc. Manual dated March 2, 1982.

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CONDITIONS

30. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated December 13, 1984 including ALAKA Program; letters dated August 31, 1984, November 5, 1984, November 16, 1984 and January 29, 1985; two letters dated February 25, 1985 and letter dated July 1, 1985. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

AUG 13 1985

Date _____

Original Signed By:

By Jenny M. Johansen

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