NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 06-00819-03
Docket or Reference number: 030-01244

CORRECTED COPY

Amendment No. 28

Yale-New Haven Hospital
20 York Street
New Haven, Connecticut 06504

In accordance with letter dated November 5 1984, License Number 06-00819-03 is amended as follows:

Items 6., 7., 8., and 9. are amended to read:

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	a. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	A. As necessary for uses authorized in Subitem 9.A.
B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. 5 curies of each byproduct material authorized in Subitem 6.B.
C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. Any radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. As necessary for uses authorized in Subitem 9.C.
D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. Any radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. As necessary for uses authorized in Subitem 9.D.
E. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. 2.5 curies total for sources authorized in Subitem 6.E.
F. Xenon 133	F. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	F. 2 curies
G. Uranium (depleted in the Uranium 235)	G. Cadmium plated metal	G. 300 kilograms

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(6., 7. and 8. continued)

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
H. Any byproduct material with Atomic Nos. 3 through 83, inclusive	H. Any	H. 100 millicuries of each byproduct material with with Atomic Nos. 3 through 83, inclusive
I. Americium 241	I. Sealed source (Amersham AMC-25)	I. 45 millicuries
J. Hydrogen 3	J. Any	J. 500 millicuries
K. Americium 241	K. Sealed sources (Gamma Industries Model No. VD)	K. 10 curies
L. Gadolinium 153	L. Sealed sources	L. 2 sources, each source not to exceed 1 curie
M. Iridium-192	M. Sealed source manufactured by ByK-Mallinckrodt CIL. B.V.	M. 50 curies. Not to exceed 15 curies per source

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.
F. Blood flow and pulmonary function studies.
G. For use as shielding in a linear accelerator.
H. through J. Medical research and diagnosis.
K. Measurement of distributions in a tissue equivalent phantom.
L. For use in a NOVO Model BMC-Lab 22a Bone Densitometer for in vivo measurement of bone mineral content.
M. 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.

Conditions 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, and 21 are amended to read:

10. Licensed material shall be used only at the licensee's facilities, Yale-New Haven Hospital, 20 York Street, New Haven, Connecticut.

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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 Radioisotope Committee, Eugene A. Cornelius, M.D., Ph.D., Chairman.

B. Membership of the Radioisotope Committee includes the Resident, Diagnostic Radiology and the Resident, Therapeutic Radiology, each of whom rotates annually. The names of these two members need not appear on the membership roster provided the NRC.

C. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.3(b).

D. 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.

(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.

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(13. continued) CONDITIONS

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 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.

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.

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(20. continued) CONDITIONS

C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

21. 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 April 21, 1978; letter received November 30, 1978; letters dated May 12, 1978, October 9, 1979, November 27, 1979, February 27, 1981, August 24, 1981, January 18, 1982, January 28, 1982, March 22, 1982, April 8, 1982, April 27, 1982, April 28, 1982, July 22, 1982, September 15, 1982, December 8, 1982, and September 13, 1983, including the Users Handbook provided by the manufacturer; and ALARA Program dated March 11, 1982 letter dated November 5, 1984; letter with enclosure dated January 29, 1985 and letter dated February 25, 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.

Conditions 22, 23, 24, and 25 are added to read:

22. The irradiator facility in item M. above shall be provided with a system permitting continuous observation of the patient from outside the treatment room during patient irradiation.

23. A set of written emergency instructions shall be posted at the machine control of the irradiator in item M. 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.

24. A. Access to the room in which the irradiator in item 9.M. 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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(Continued) CONDITIONS

25. 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 M above, 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.

For the U.S. Nuclear Regulatory Commission

Date JUN 18 1985

By Original Signed By:
Jenny M. Johansen

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