NRC Form 374
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 16

MATERIALS LICENSE

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. Veterans Administration Medical Center	In accordance with letter dated September 7, 1984
2. 4101 Woolworth Avenue Omaha, Nebraska 68105	3. License number 26-00138-10 is amended in its entirety to read as follows:
	4. Expiration date July 31, 1990
	5. Docket or Reference No. 030-02409

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 with Atomic Numbers 1 through 83	A. Any	A. Not to exceed 50 millicuries per radionuclide except: Hydrogen-3 300 millicuries Carbon-14 100 millicuries Phosphorus-32 500 millicuries Chromium-51 100 millicuries Cobalt-60 60 millicuries Molybdenum-99 3 curies Technetium-99m 3 curies Iodine-125 100 millicuries Iodine-131 500 millicuries Xenon-133 3 curies Cesium-137 150 millicuries Gold-198 300 millicuries
B. Cesium-137	B. Sealed source (J. L. Shepherd Model No. 6810)	B. 1500 curies
C. Cesium-137	C. Sealed sources	C. 1.2 curies total

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
26-00138-10

Docket or Reference number
030-02409

Amendment No. 16

9. Authorized use:

A. Medical research, diagnosis, and therapy. Research and development as defined in Section 30.4(q), 10 CFR Part 30. Studies in laboratory animals.

B. For use in J. L. Shepherd Mark I (Model 22) irradiator for the irradiation of biological samples, chemicals, and small animals.

C. For use in J. L. Shepherd Model 28-6A calibrator for calibration of instruments.

CONDITIONS

10. Licensed material shall be used only at the Veterans Administration Medical Center, Omaha, Nebraska.

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. Licensed material shall be used by, or under the supervision of, individuals designated by the Omaha VAMC Isotope Committee, J. J. Matoole, M.D., Chairman.

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

14. A. (1) Each sealed source, except Items B. and C., acquired from another person and containing licensed material, other than hydrogen-3, with a half-life greater than 30 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 6 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.

14. (continued)

(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 6 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 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 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 IV, 611 Ryan Plaza Dr., Suite 1000, Arlington, Texas 76011, describing the equipment involved, the test results, and the corrective action taken.

15. A. Each sealed source, Items B. and C., containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed 6 months. In the absence of a certificate from a transferor indicating that a test has been made within 6 months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

15. (continued)

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 Region IV, U. S. Nuclear Regulatory Commission, 611 Ryan Plaza Dr., Suite 1000, Arlington, Texas 76011, describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

16. Sealed sources, Items B. and C., containing licensed material shall not be opened or removed from their respective source holders by the licensee.

17. 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.

18. 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.

19. Detector cells containing licensed material shall not be opened or the foil sources removed from the detector cell by the licensee.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
26-00138-10

Docket or Reference number
030-02409

Amendment No. 16

20. Experimental animals administered licensed materials or their products shall not be used for human consumption.

21. Needles or standard medical applicator cells containing cobalt-60 as wire shall not be opened by the licensee unless specifically authorized by a condition in this license.

22. Patients containing cobalt-60, cesium-137, or iridium-192 implants shall remain hospitalized until a source count and surveys made with an appropriate radiation detection instrument indicate that all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the Commission for 5 years from the time the implants are removed.

23. Patients containing iodine-131 for the treatment of thyroid carcinoma (or patients containing therapeutic quantities of gold-198) shall remain hospitalized until the residual activity is 30 millicuries or less.

24. 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 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.

25. Written instructions provided by J. L. Shepherd for the Mark I irradiator shall be followed, and a copy of these instructions shall be made available to each individual using or having responsibility for use of licensed material. Any changes in these instructions shall have the prior approval of the U.S. Nuclear Regulatory Commission, Region IV, Nuclear Material Safety Section, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
26-00138-10

Docket or Reference number
030-02409

Amendment No. 16

26. 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 by the manufacturer or by other persons specifically authorized by the Commission or an Agreement State to perform such activities.

27. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

28. A. Technetium-99m separated from molybdenum-99 either by elution of a molybdenum-99/technetium-99m generator or by an extraction process shall be tested to detect and quantify molybdenum-99 activity prior to administration to patients.

B. The licensee shall not administer technetium-99m to patients if the technetium-99m contains more than one (1) microcurie of molybdenum-99 per millicurie of technetium-99m or if it contains more than 5 microcuries of molybdenum-99 per dose of technetium-99m at time of administration. The limits for molybdenum-99 contamination represent maximum values and molybdenum-99 contamination should be kept as low as reasonably achievable below these limits.

C. The licensee shall establish written procedures for personnel performing tests to detect and quantify molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of molybdenum-99, in excess of the limits specified in Subitem B., above are detected.

D. Personnel performing tests to detect and quantify molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.

E. (1) The licensee shall maintain for inspection by the Nuclear Regulatory Commission records of the results of each test performed to detect and quantify molybdenum-99 contamination and records of training given to personnel performing these tests.

(2) Records described in Subitem E.1 above shall be maintained for 3 years following the performance of the tests and the training of personnel.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
26-00138-10

Docket or Reference number
030-02409

Amendment No. 16

29. 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:

A. Application dated November 11, 1978
B. Letter dated September 6, 1979
C. Letter dated September 24, 1980
D. Letter with attachments dated September 8, 1982
E. Letter dated February 11, 1983
F. Letter dated September 7, 1984

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

Original Signed By
C. L. Cain

Date JUL 24 1985

By _____
Nuclear Materials Safety Section
Region IV
Arlington, Texas 76011

Official Record Copy

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