

**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, 36, 39, 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.

*RC 02/110*

*314047*

Licensee	In accordance with letter dated <b>December 22, 2004,</b>
1. Mayo Clinic Rochester	3. License number 22-00519-03 is amended in its entirety to read as follows:
2. 200 First Street SW Rochester, MN 55905	4. Expiration date May 31, 2012
	5. Pocket No. 030-02195 Reference No.

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 3-83, inclusive	A. Any	A. 1 curie per radionuclide. Total possession not to exceed 10 curies except as listed below: Hydrogen-3            5 curies Iodine-131            5 curies Molybdenum-99      40 curies Rhenium-188        3 curies Samarium-153       10 curies Technetium-99m    40 curies Tungsten-188       3 curies Xenon-133            2 curies
B. Americium-241	B. Sealed source (registered pursuant to Section 32.210 of 10 CFR Part 32 or an Agreement State equivalent)	B. 4 sources not to exceed 100 millicuries each
C. Hydrogen-3	C. Foil	C. 2 curies
D. Any byproduct material with Atomic Numbers between 3-83, inclusive	D. Sealed sources (registered pursuant to Section 32.210 of 10 CFR Part 32 or an Agreement State equivalent)	D. No single source to exceed 1.5 curies, except as listed below; total possession not to exceed 10 curies. Iodine-125            2.0 curies Palladium-103       2.0 curies Iridium-192           4.0 curies



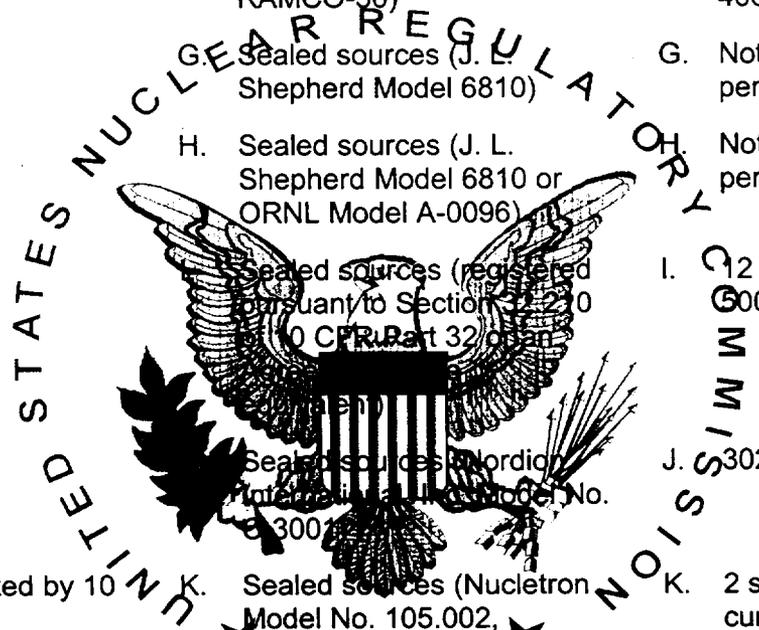
**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
22-00519-03

Docket or Reference Number  
030-02195

Amendment No. 64

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
E. Cesium-137	E. Sealed sources (J. L. Shepherd & Associates Model 78-10)	E. Two sources not to exceed 260 curies each
F. Cesium-137	F. Sealed sources (ORNL RAMCO-50)	F. One source not to exceed 400 curies
G. Cesium-137	G. Sealed sources (J. L. Shepherd Model 6810)	G. Not to exceed 4,000 curies per source set
H. Cesium-137	H. Sealed sources (J. L. Shepherd Model 6810 or ORNL Model A-0096)	H. Not to exceed 5,000 curies per source set
I. Gadolinium-153	I. Sealed sources (registered pursuant to Section 32.20 of 10 CFR Part 32 or an equivalent)	I. 12 sources not to exceed 600 millicuries each
J. Cesium-137	J. Sealed sources (Nordig International, Inc. Model No. 300)	J. 3027 curies total
K. Iridium-192, permitted by 10 CFR 35.600	K. Sealed sources (Nucletron Model No. 105.002, manufactured by Mallinckrodt Medical BV or AEA Technology, Inc.)	K. 2 sources not to exceed 12 curies each.



9. Authorized Use:

- A. through B. Medical diagnosis, therapy, and research in humans. Research and development as defined in Section 30.4 of 10 CFR Part 30, including animal studies; student instruction and instrument calibration.
- C. To be used in gas chromatographs.
- D. Medical use as defined in Section 35.2 of 10 CFR Part 35 (which includes diagnosis, therapy, and research in humans); animal studies and instrument calibration.
- E. For use in J. L. Shepherd & Associates Mark I-25 irradiator for medical and radiobiological research.
- F. For use in an Isomedix, Inc. Gammator 50B (AECL Gammacell 10) irradiator for biomedical research.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
22-00519-03

Docket or Reference Number  
030-02195

Amendment No. 64

- G. To be used in J. L. Shepherd Model Mark I-25 irradiator for the irradiation of medical and biological samples.
- H. To be used in J. L. Shepherd Model 143-68 irradiator for the irradiation of medical and biological samples.
- I. To be used for automatic attenuation correction on gamma cameras.
- J. To be used in a Nordion International, Inc. Model Gammacell 3000 Elan Type II irradiator for the irradiation of medical and biological samples.
- K. One source for medical use, as permitted by 10 CFR 35.600, in a Nucletron MicroSelectron-HDR Model 105.999 remote afterloading brachytherapy device. One source (not to exceed 12 curies while stored pending installation) in a shipping container for source replacement. The source may also be used for physics calibrations and intercomparison studies.

**CONDITIONS**

10. A. Licensed material shall be used only at the licensee's facilities located at the Mayo Clinic Rochester campus, Rochester, Minnesota.
- B. Licensed material in 10 CFR 35.600 (including Xenon-133 and generators), 35.500, and iodine-131 for treatment of hyperthyroidism and cardiac dysfunction may be used at temporary job sites of medical care facilities where in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulation of licensed material.
- C. Licensed material listed in Subitem K. may be used and stored at the Charlton or Eisenberg buildings located on the Mayo Foundation campus, Rochester, Minnesota.
11. The Radiation Safety Officer for the activities authorized by this license is Richard J. Vetter, Ph.D.
- 12.A. The use of licensed material in or on humans shall be by an authorized user as defined in 10 CFR 35.2.
- B. Individuals designated to work as authorized users, authorized nuclear pharmacists, or authorized medical physicists, as defined in 10 CFR 35.2, shall meet the training, experience and recentness of training criteria established in 10 CFR Part 35, and shall be designated, in writing, by the licensee's Radiation Safety Committee.
- C. Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee, **Robert J. Witte, M.D.**, Chairperson. The licensee shall maintain records of individuals designated as users for three years after the individual's last use of licensed material.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
22-00519-03

Docket or Reference Number  
030-02195

Amendment No. 64

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in 10 CFR 30.72 which require consideration of the need for an emergency plan for responding to a release of licensed material, and shall further restrict the possession of unsealed licensed material to less than  $10^5$  times the applicable limits in Appendix C of 10 CFR 20, as specified in 10 CFR 30.35(d).
14. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:
- A. Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into use until tested.
- D. Sealed sources need not be leak tested if:
- (i) they contain only hydrogen;
  - (ii) they contain only a radioisotope as:
  - (iii) the half-life of the isotope is 30 days or less;
  - (iv) they contain not more than 100 microcuries of beta and/or gamma emitting material or not more than 10 microcuries of alpha emitting material; or
  - (v) they are not designed to emit alpha particles, are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- E. **The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.**
- F. 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.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
22-00519-03

Docket or Reference Number  
030-02195

Amendment No. 64

15. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer and approved by U.S. Nuclear Regulatory Commission.
16. 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.
17. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.
18. Pursuant to 10 CFR Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import up to 999 kilograms of depleted uranium contained as shielding material.
19. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
20. The licensee is authorized to hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal as ordinary trash, provided:
- Radioactive waste to be disposed of in the ground shall be held for decay a minimum of 10 half-lives.
  - Before disposal as ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
  - Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.
  - A record of each disposal permitted under this License Condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
21. Pursuant to 10 CFR 20.1302 (c) and 10 CFR 20.2002, the licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
22-00519-03

Docket or Reference Number  
030-02195

Amendment No. 64

22. Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with Atomic Nos. 1 through 83, except as identified below, as ordinary waste in a landfill, provided that the concentration of radionuclides (in microcuries per gram of ash) at the time of disposal are no greater than the values of Table II, Column 2, 10 CFR Part 20, Appendix B. For hydrogen-3, carbon-14, aluminum-26, chlorine-36, silver-108m, niobium-94, iodine-129, technetium-99 and thallium-204, the concentration can be no greater than one-tenth of the value in Table II, Column 2, 10 CFR Part 20, Appendix B. If more than one radionuclide is present in the ash, then the sum of fractions rule applies.
23. Experimental animals administered licensed materials or their products shall not be used for human consumption.
24. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
25. This license does not authorize commercial distribution of licensed material.
26. 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.
27. For each J. L. Shepherd and Associates, Mark I Cesium-137 irradiator installed and used, the licensee shall:
- A. Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available; and
  - B. Permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and
  - C. Have room monitors installed that will:
    - (i) Operate at all times when the irradiator is in use; and
    - (ii) Activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and
    - (iii) Detect any radiation leaking from the irradiator door; and
    - (iv) Be visible to the irradiator user when he is next to the irradiator; or
  - D. If a room monitor is not installed, have available a calibrated and operable survey meter which will be used to:
    - (i) Determine the radiation level at the irradiation door when the door is closed; and
    - (ii) Check for any increase in radiation levels each time the irradiator door is opened.

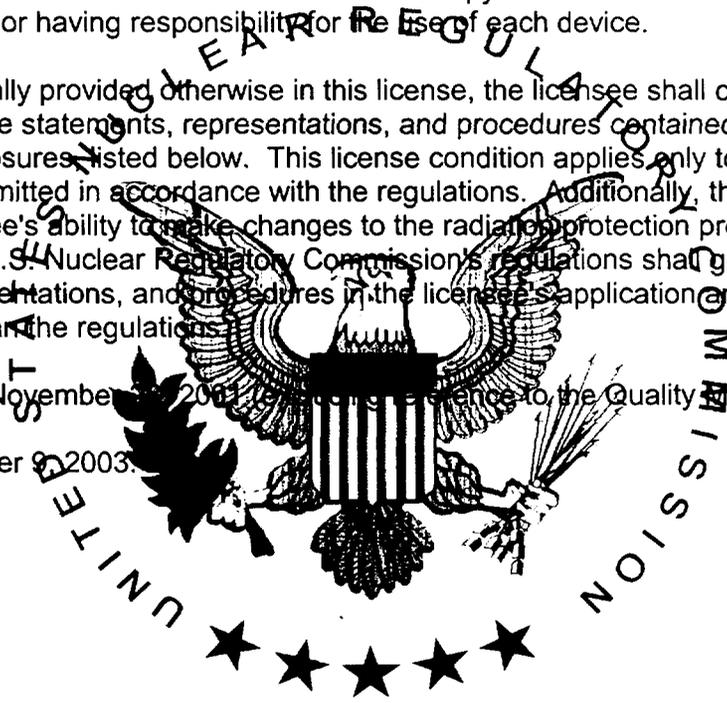
**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number  
22-00519-03

Docket or Reference Number  
030-02195

Amendment No. 64

- E. Immediately stop the use of the irradiator and notify the U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532-4352, ATTN: Chief, Nuclear Materials Safety Branch, by telephone if abnormal levels of radiation or any malfunction of the irradiator is detected; and
- F. Not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.
- 28. The procedures contained in J. L. Shepherd, ORNL instruction manual for the Models 7810, 6810, RAMCO-50, A-0096 devices shall be followed and a copy of these manual shall be made available to each person using or having responsibility for the use of each device.
- 29. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. 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 November 1, 2002 (with reference to the Quality Management Program); and
  - B. Letter dated October 9, 2003.



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

APR 01 2005

Date \_\_\_\_\_

By Colleen Carol Casey  
Colleen Carol Casey  
Materials Licensing Branch  
Region III