# MATERIALS LICENSE

Amendment No. 50

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. V. A. Medical Center<br>Radiation Safety Office (11R) | In accordance with application dated October 25, 1984 and letter dated February 4, 1985 |
| 2. 150 Muir Road<br>Martinez, California 94553 | 3. License number 04-02956-02 is amended in its entirety to read as follows: |
| | 4. Expiration date May 31, 1990 |
| | 5. Docket or Reference No. 030-01228 |

| 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. 2 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 Section 31.11(a) of 10 CFR 31 | E. Any | E. 3 millicuries of each byproduct material authorized in Subitem 6.E. |
| F. Americium 241 | F. Sealed source Amersham/Searle Model No. AMC.24 | F. 14 millicuries |

**MATERIALS LICENSE**
SUPPLEMENTARY SHEET

License number
04-02956-02

Docket or Reference number
030-01228

Amendment No. 50

| 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 |
|---|---|---|
| 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. 200 millicuries |
| H. Uranium (Depleted Uranium 235) | H. Cadmium plated metal | H. 140 kilograms |
| I. Strontium 90 | I. Sealed source (Tracerlab Inc. Model RA-1A) | I. 50 millicuries |
| J. Strontium 90 | J. Sealed source (Nuclear Enterprises Model 25-031) | J. 10 millicuries |
| K. Rubidium 86 | K. Any | K. 10 millicuries |
| L. Cesium 137 | L. Sealed source contained in J.L. Shepherd and Associates Model 28-5 single source beam calibrator | L. 100 millicuries |
| M. Hydrogen 3 | M. Prelabelled organic chemicals | M. 120 millicuries |
| N. Carbon 14 | N. Any | N. 60 millicuries |
| O. Iodine 125 | O. Any | O. 60 millicuries |
| P. Phosphorus 32 | P. Any | P. 40 millicuries |
| Q. Iodine 131 | Q. Any | Q. 20 millicuries |
| R. Chromium 51 | R. Any | R. 20 millicuries |
| S. Sulfur 35 | S. Any | S. 40 millicuries |

**MATERIALS LICENSE**
SUPPLEMENTARY SHEET

License number
04-02956-02

Docket or Reference number
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Amendment No. 50

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|---|---|---|
| T. Technetium 99m | T. Any | T. 50 millicuries |
| U. Calcium 45 | U. Any | U. 40 millicuries |
| V. Chlorine 36 | V. Any | V. 40 millicuries |

9. Authorized use

A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 of 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 Titel 10, Code of Federal Regulations.

E. In vitro studies.

F. To be used in Searle Analytic Model SS-10244 Anatomical Marker.

G. For blood flow and pulmonary function studies.

H. As shielding in a linear accelerator.

I. For treatment of superficial eye disease.

J. Standard for instrument calibration.

K. In vitro studies.

L. Standard for instrument calibration.

M. through V. In vitro studies; animal studies

CONDITIONS

10. Licensed material shall be used only at Veterans Administration Medical Center; 150 Muir Road; Martinez, California.

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".

**MATERIALS LICENSE**
SUPPLEMENTARY SHEET

License number
04-02956-02

Docket or Reference number
030-01228

Amendment No. 50

CONDITIONS

(continued)

12. A. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

| | |
|---|---|
| Albert Weinshelbaum, M.D. | Groups I, II, III, IV and V<br>Americium 241 Anatomical Marker<br>In vitro studies, animal studies<br>Xenon 133 |
| Ildiko Sandford, M.D. | Groups I, II and III<br>Americium 241 Anatomical Marker<br>In vitro studies<br>Xenon 133 |
| E.C. Larkin, M.D. | In vitro studies, animal studies |
| Emmanuel Samouhes, M.D. | Depleted uranium for shielding<br>Strontium 90 for treatment of superficial eye disease |
| Antolin Raventos, M.D. | Depleted uranium for shielding<br>Strontium 90 for treatment of superficial eye disease |
| C. Largman, Ph.D. | In vitro studies, animal studies |
| Charles A. Barnett, M.D. | Groups I, II, III, IV and V<br>In vitro studies, animal studies<br>Americium 241 Anatomical Marker<br>Xenon 133 |
| Marquerite T. Hays, M.D. | Groups I, II, III, IV and V<br>In vitro studies, animal studies<br>Americium 241 Anatomical marker<br>Xenon 133 |
| Robert Noth, M.D. | In vitro studies, animal studies |
| A. R. Bautigam, Ph.D., M.D. | In vitro studies, animal studies |
| Albert P. Wheatley, Jr. | Strontium 90 for instrument calibration<br>Cesium 137 for instrument calibration<br>Depleted uranium for shielding |
| George Kaysen, Ph.D., M.D. | In vitro studies, animal studies |

**MATERIALS LICENSE**
SUPPLEMENTARY SHEET

License number
04-02956-02

Docket or Reference number
030-01228

Amendment No. 50

CONDITIONS

(continued)

| | |
|---|---|
| Paul A. Farrer, M.D. | Groups I, II, III, IV and V<br>Americium 241 Anatomical Marker<br>In vitro studies, animal studies<br>Xenon 133 |
| Adhip Majumdar, Ph.D. | In vitro studies, animal studies |
| Brian Berman, M.D., Ph.D. | In vitro studies, animal studies |
| Edwin M. Leidholdt, Ph.D | In vitro studies, Cesium 137<br>for instrument calibration |

B. The Radiation Safety Officer for the activities authorized by this license is Edwin M. Leidholdt, Jr., Ph.D.

13. For a period not to exceed sixty (60) days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

(a) Has the prior written permission of the hospital's Administrator and its Medical Isotopes Committee, and

(b) Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and

(c) Performs only those procedures for which he is specifically authorized by a Nuclear Regulatory Commission license.

The licensee shall maintain for inspection by the Commission, copies of the written permission specified in subitem (a) above and of the license(s) specified in subitems (b) and (c) above. These records shall be maintained for five (5) years from the time the licensee grants its permission under subitem (a) above.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
04-02956-02

Docket or Reference number
030-01228

Amendment No. 50

CONDITIONS

(continued)

14. A. (1) 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. 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. 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 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.

C. If the test 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 five (5) days of the test with the U. S. Nuclear Regulatory Commission, Region V, Office of the Regional Administrator, 1450 Maria Lane, Suite 210, Walnut Creek, California 94596, 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.

15. Sealed sources containing licensed material shall not be opened.

16. 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.

**MATERIALS LICENSE**
SUPPLEMENTARY SHEET

License number
04-02956-02

Docket or Reference number
030-01228

Amendment No. 50

CONDITIONS

(continued)

17. Licensed material shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.

18. 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.

19. 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 October 25, 1984 and letter dated February 4, 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

Date MAY 10 1985

By _____

Beth A. Riedlinger
Health Physicist (Licensing)
Nuclear Materials Safety Section
Region V