

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

20-05766-02

Docket or Reference number

030-01879

Amendment No. 37

Lahey Clinic Foundation
41 Mall Road
Burlington Massachusetts 01805

"OFFICIAL RECORD COPY"

In accordance with letter dated April 24, 1985, application dated May 1, 1985 and letter dated July 25, 1985, License Number 20-05766-02 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. 2 curies of each byproduct material authorized in Subitem 6.B. |
| C. Iodine 131 | C. Any iodide that has been manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to the manufacturer by an Agreement State pursuant to equivalent State Regulation. | 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. 2000 millicuries total for sources authorized in Subitem 6.E. |
| F. Any byproduct material listed in Section 31.11(a) of 10 CFR 31 | F. Prepackaged kits | F. 3 millicuries of each byproduct material authorized in Subitem 6.F. |

8509190779 850830
REG1 LIC30
20-05766-02 PDR

ML18

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

20-05766-02

Docket or Reference number

030-01879

Amendment No. 37

(continued)

- | | | |
|--|---|--|
| . 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 |
| . 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. 400 millicuries |
| . Uranium (Depleted in Uranium 235) | H. Encapsulated in copper tube and chrome plated | H. 10 kilograms |
| . Strontium 90 | I. Sealed source (Tracer RA-1A) | I. 27 millicuries |
| . Strontium 90 | J. Sealed source (Nuclear Enterprises Model 2503/3) | J. 10 millicuries |
| . Nickel 63 | K. Sealed source | K. 11 millicuries |
| . Hydrogen 3 | L. Any | L. 10 millicuries |
| . Carbon 14 | M. Any | M. 10 millicuries |
| . Iodine 129 | N. Sealed sources | N. 0.2 microcuries |
| . Americium 241 | O. Sealed sources | O. 6 microcuries |
| . Cesium 137 | P. Sealed sources | P. 201 millicuries |
| . Chromium 51 | Q. Any | Q. 2 millicuries |
| . Iodine 125 | R. Sodium iodide | R. 20 millicuries |

Authorized use

- . Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100 Title 10, Code of Federal Regulations.
- . 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.
- . Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- . Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- . Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- . In vitro studies.
- . Blood flow and pulmonary function studies.
- . As X-ray beam absorber.
- . Treatment of superficial eye disease
- . and K. Standards for instrument calibration
- . through Q. In vitro studies. Instrument calibration.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

20-05766-02

Docket or Reference number

030-01879

Amendment No. 37

9. continued)

10. In vitro studies.

Conditions 12. and 19. are amended to read:

2. 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:

Sanford R. Kurtz, M.D.

In vitro studies

Theodore Lo, M.D.

Group VI

Ferdinand A. Salzman, M.D.

Group VI

Francis Scholz, M.D.

Groups I, II and III

In vitro studies

Xenon-133

Peter Winter, M.D.

Groups I, II and III

Iodine 131 as iodide for treatment of
hyperthyroidism, cardiac dysfunction, and
thyroid carcinoma

Xenon-133

Robert E. Wise, M.D.

Groups I, II and III

In vitro studies

Xenon-133

Marvin Wool, M.D.

Iodine 131 as iodide for treatment of
hyperthyroidism, cardiac dysfunction and
thyroid carcinoma

Robert S. Wenstrup, Ph.D.

In vitro studies

Depleted uranium

Strontium 90 and Nickel 63 for instrument
calibration

Kenneth Wright, M.S.

In vitro studies

Depleted uranium

Strontium 90 and Nickel 63 for instrument
calibration

William Curby, M.S.

In vitro studiesIodine 129, Americium 241, and Cesium 137
for instrument calibration

Mitchell A. Swartz, M.D.

Group VI

Patricia Leasure

Iodine 125 as iodide for In vitro studies

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number

20-05766-02

Docket or Reference number

030-01879

Amendment No. 37

(continued)

9. 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 July 15, 1980; letter dated May 8, 1981, containing ALARA Program; letters dated February 15, 1984, March 19, 1984, June 5, 1984, February 13, 1985 and April 24, 1985; application dated May 1, 1985 and letter dated July 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.



For the U.S. Nuclear Regulatory Commission

Original Signed By:
John E. Glenn

By

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

Date

AUG 30 1985