

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License number

29-02575-01

Docket or Reference number

030-02449

Amendment No. 49

Muhlenberg Hospital
Randolph Road
Plainfield, New Jersey 07061

"OFFICIAL RECORD COPY"

In accordance with application dated April 29, 1985 and letter dated May 24, 1985, License Number 29-02575-01 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. 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. 1300 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. |
| G. Xenon 133 | G. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA | G. 150 millicuries |

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(Items 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. Americium 241 | H. Sealed Sources (Searle Model SS-10244 Anatomical Marker) | H. Two sources not to exceed 15 millicuries each |
| I. Americium 241 | I. Sealed Sources (Amersham Model AMC-D1) | I. Two sources, not to exceed 45 millicuries each |
| J. Gadolinium 153 | J. Sealed Sources (BMA, Lunar DP3 or Norland 2600 Gulf Nuclear Model GD-1) | J. Two sources, not to exceed 2000 millicuries each |
| K. Iodine 125 | K. Sealed Sources (BMA, Lunar K. SP2 or Norland 2780 [2740] AECL Models C-235 or C-236 C-324 or Amersham Model IMC.P2, IMC-129, 4052, 4040) | K. Two sources, not to exceed 700 millicuries each 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. In vitro studies.
- G. Blood flow and pulmonary function studies.
- H. For use as an anatomical marker.
- I. For use in Norland 2780 bone mineral analyzer.
- J. For use in Lunar Radiation Corporation DP3 or Norland 2600 bone mineral analyzer.
- K. For use in Lunar Radiation Corporation Model SP2 or Norland 2780 bone mineral analyzer.

CONDITIONS

Conditions 12. and 18. are amended to read:

12. 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:

Marvin R. Agran

Groups I, II, III, IV and V

In vitro studies

Xenon 133

Americium 241 as an anatomical marker

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(12. continued)

CONDITIONS

E. Arthur Kratzman, M.D.

Groups I, II, III, IV and V

In vitro studies

Xenon 133

Americium 241 as an anatomical marker

Young Ho Park, M.D.

Groups I, II, III, IV and V

In vitro studies

Xenon 133

Americium 241 as an anatomical marker

Iodine 125, Gadolinium 153 and

Americium 241 for bone mineral
analysis

Paul K. Johnson, M.D.

Iodine 131 as iodide for thyroid uptake
studies, thyroid imaging, and treatment
of hyperthyroidism and cardiac dysfunction

Richard R. Meyers, M.D.

Groups IV and VI

Iodine 131 as iodide for treatment of
thyroid carcinoma

Robert C. Lauer, M.D.

Technetium 99m radiopharmaceuticals in
Groups II and III for cardiac imaging and
diagnosis of cardiac function
Americium 241 as an anatomical marker

Alan Kalischer, M.D.

Technetium 99m radiopharmaceuticals in
Groups II and III for cardiac imaging and
diagnosis of cardiac function
Americium 241 as an anatomical marker

18. 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 January 15, 1979; letters dated December 20, 1979, March 26, 1980, May 5, 1982, October 11, 1982, December 3, 1982, November 23, 1983, December 11, 1984; application dated April 29, 1985 and letter dated May 24, 1985 and Model ALARA Program contained in Appendix O of Regulatory Guide 10.8 (Rev. 1), "Guide for the Preparation of Applications for Medical Programs", October 1980. 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.

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(continued)

CONDITIONS

Condition 21. is added:

21. The Licensee may use the Lineator device for doing linearity tests of his dose calibrator provided he follows the procedures in the Atomic Products Corporation Lineator Instructions Manual dated June 20, 1983.



For the U.S. Nuclear Regulatory Commission

Original Signed By:

John D. Kinneman

By

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

Date

JUN 25 1985