FORM AEC-374 (M-3)
(2/70)
10 CFR 30

License No. 30-00392-02
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U. S. ATOMIC ENERGY COMMISSION
BYPRODUCT MATERIAL LICENSE Amendment No. 41
(Medical - Groups I & II)

Pursuant to the Atomic Energy Act of 1954 and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 32, 33, 34, and 35, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer and import byproduct material listed below; and to use such byproduct material for the purpose(s) and at the place(s) designated below. 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 Atomic Energy Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Lovelace Clinic and Foundation Department of Radiology 2. 5200 Gibson Boulevard, S.E. Albuquerque, New Mexico 87108	In accordance with application dated January 27, 1973, 3. License Number 30-00392-02 is amended in its entirety to read as follows: 4. Expiration date January 31, 1978 5. Reference No.

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
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. Molybdenum 99	B. Molybdenum 99/Technetium 99m Generators (E.R. Squibb and Sons Model No. 08871; Abbott Labs. Model Nos. 7721 and 6724; NEN Pharmaceuticals Model No. NRP-196; Mallinckrodt Chemical Works Model Nos. 012 and 006 through 009; Cambridge Nuclear Corp. Model No. CN-4291; and Amersham/Searle Corporation Model Nos. GTC-50, GTC-100, GTC-200, GTC-300 and GTC-400)	B. 1000 millicuries

Conditions numbered 2, 3, & 4 printed on the reverse side of this page shall apply to this license.

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6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
C. Phosphorus 32	C. Soluble Phosphate	C. 10 millicuries
D. Cesium 137 - Barium 133	D. Mock Iodine Capsules	D. 100 microcuries
E. Phosphorus 32	E. Colloidal Chromic Phosphate	E. 100 millicuries
F. Selenium 75	F. Selenomethionine	F. 3 millicuries
G. Xenon 133	G. Free Gas or Solution	G. 3 curies
H. Strontium 90	H. Sealed Source (Tracerlab Model No. Rs-1)	H. 50 millicuries
I. Iodine 131	I. Iodide	I. 200 millicuries
J. Technetium 99m	J. Pertechnetate	J. 10 millicuries
K. Technetium 99m	K. Sulfur Colloid (Prepared by Cambridge Nuclear, Mallinckrodt, CIS Radiopharmaceuticals, Medi-Physics-Radimed Division, or Union Carbide, or prepared by the licensee using the Squibb, Abbott 7768, Mallinckrodt, CIS Radiopharmaceuticals, or NEN kit)	K. 100 millicuries
L. Technetium 99m	L. Iron-ascorbate-diethylenetriamine pentaacetic acid complex (prepared by the licensee using the Squibb kit)	L. 50 millicuries
M. Technetium 99m	M. Labeled albumin microspheres (human) prepared by the licensee using the 3M kit	M. 100 millicuries
N. Technetium 99m	N. Labeled Polyphosphates prepared by the licensee using the Diagnostic Isotopes or NEN kit	N. 100 millicuries

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6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radioactivity which licensee may possess at any one time
O. Hydrogen 3	O. Tritiated water	O. 400 millicuries
P. Sodium 24	P. Chloride	P. 10 millicuries
Q. Iodine 125 or 131	Q. Any	Q. 50 millicuries
R. Strontium 90	R. Sealed Source (Tracerlab Special Medical Applicator)	R. 50 millicuries
S. Barium 140 Lanthanum 140	S. Any	S. 5 millicuries
T. Cerium 144 Praseodymium 144	T. Any	T. 5 millicuries
U. Cesium 137	U. Any	U. 5 millicuries
V. Ruthenium 106	V. Any	V. 5 millicuries
W. Strontium 85	W. Any	W. 5 millicuries
X. Strontium 90	X. Any	X. 5 millicuries
Y. Tellurium Iodine 132	Y. Any	Y. 5 millicuries
Z. Iodine 131	Z. Iodinated Human Serum Albumin	Z. 1 millicurie

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. Production of Technetium 99m Pertechnetate.
C. Treatment of leukemia, polycythemia vera, and bone metastases.
D. For use as a standard for calibration purposes.
E. Intracavitary treatment of malignant effusions. Treatment of prostatic, cervical, or bladder cancer.
F. Pancreas imaging.
G. Blood flow studies. Pulmonary function studies.
H. Treatment of superficial eye diseases.
I. Treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma.
J. Placenta localization.
K. Liver and spleen imaging.
L. Kidney imaging.
M. Lung imaging.
N. Bone imaging.

9. Authorized use (continued)

O. Measurement of total body water.
P. Total exchangeable water.
Q. In vitro studies.
R. Animal studies.
S. through Y. In vitro studies, animal studies.
Z. Cisternography.

CONDITIONS

10. Byproduct material shall be used only at Lovelace Clinic and Foundation, 5200 Gibson Boulevard, S.E., Albuquerque, New Mexico. Byproduct material listed under Subitem B. may also be used at Bataan Memorial Methodist Hospital, 5400 Gibson Boulevard, S.E., Albuquerque, New Mexico.

11. Byproduct material shall be used by, or under the supervision of, J. W. Greenman, M.D., Donald E. Butler, M.D., or Carl G. Cain, M.D. Byproduct material listed under Subitem B. may also be used by, or under the supervision of, L. E. Flank, M.D. The use of Selenium 75 for pancreas imaging shall be under the direction of Donald E. Butler, M.D.

12. Technetium 99m pertechnetate may be eluted and prepared from a Molybdenum 99/Technetium 99m generator in accordance with statements, representations, and procedures contained in letter dated December 15, 1966.

13. Patients containing Iodine 131 for the treatment of thyroid carcinoma shall remain hospitalized until the residual activity is 30 millicuries or less.

14. A. Technetium 99m labeled sulfur colloid shall be procured and/or prepared in accordance with statements, representations, and procedures contained in letter dated July 1, 1969.

B. Technetium 99m labeled sulfur colloid preparations which appear flocculent or aggregated shall not be used in humans.

15. Iodine 131 as iodinated human serum albumin for use in cisternography shall be procured from a supplier who holds an unexpended or unrevoked license issued by the Secretary, Department of Health, Education, and Welfare, to prepare or manufacture and prepare, label, or distribute IHSA for cisternography pursuant to Title 42, Chapter 1, Code of Federal Regulations, Part 73, "Biological Products."

16. Technetium 99m labeled iron-ascorbate-diethylenetriamine pentaacetic acid complex shall be procured and/or prepared in accordance with statements, representations, and procedures contained in letter dated January 26, 1971, signed by Dr. Donald E. Butler.

17. A. Technetium 99m labeled albumin microspheres (human) for lung imaging shall be procured and/or prepared in accordance with statements, representations, and procedures contained in letter dated February 15, 1972.

B. Technetium 99m labeled albumin microspheres (human) or commercial kits used to prepare the product shall be procured from a supplier who holds an unsuspended or unrevoked license issued by the Secretary, Department of Health, Education, and Welfare to propagate or manufacture and prepare, label, or distribute the material for the purpose of lung imaging pursuant to Title 42, Chapter 1, Code of Federal Regulations, Part 73, "Biological Products."

18. Notwithstanding Condition 15., a medical emergency cisternography may be performed on one patient. Within six weeks after completion of this study, the licensee shall submit a report to the Commission which summarizes the results obtained.

19. Technetium 99m labeled polyphosphates for bone imaging shall be procured and/or prepared in accordance with statements, representations, and procedures contained in letter dated April 12, 1973.

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

21. Individuals involved in operations which utilize, at any one time, more than 100 millicuries of Hydrogen 3 in a non-contained form, other than metallic foil, shall have bioassays performed within one week following a single operation and at weekly intervals for continuing operations.

22. Sealed sources containing byproduct material shall not be opened.

CONDITIONS

(Continued)

23. A(1) Each sealed source containing byproduct 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, the sealed source 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 5 days of the test with the Directorate of Licensing, U. S. Atomic Energy Commission, Washington, D. C. 20545, describing the equipment involved, the test results, and the corrective action taken. A copy of such report shall also be sent to Region IV, Directorate of Regulatory Operations, USAEC, 10395 West Colfax Avenue, Denver, Colorado 80215.

D. Tests for leakage and/or contamination shall be performed by, or under the supervision of, J. L. Howarth, Stanley Waligora, Jr., or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

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CONDITIONS

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24. Except as specifically provided otherwise by this license, the licensee shall possess and use byproduct material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated January 27, 1973, and letter dated April 23, 1973.

Date JUL 3 1973

For the U. S. Atomic Energy Commission
Original Signed By
John E. Bowyer
by Materials Branch 7-3-73
Directorate of Licensing
Washington, D. C. 20545

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