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10 CFR 30

U. S. ATOMIC ENERGY COMMISSION

BYPRODUCT MATERIAL LICENSE Amendment No. 28

(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	In accordance with application dated March 12, 1973,
1. Department of the Army Fitzsimons General Hospital and U. S. Army Medical Research and 2. Nutrition Laboratory Denver, Colorado 80240	3. License Number 05-00046-13 is amended in its entirety to read as follows:
	4. Expiration date April 30, 1974
	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. Iodine 131	B. Iodide	B. 250 millicuries
✓ C. Iodine 131	C. Iodinated Human Serum Albumin	C. 5 millicuries
✓ D. Iodine 131	D. Thyroxine	D. 2 millicuries
✓ E. Iodine 125	E. Iodide	E. 1 millicurie
✓ F. Iodine 125	F. Thyroxine	F. 1 millicurie
G. Phosphorus 32	G. Soluble Phosphate	G. 25 millicuries
H. Phosphorus 32	H. Colloidal Chromic Phosphate	H. 25 millicuries
I. Gold 198	I. Colloidal	I. 250 millicuries
J. Chromium 51	J. Sodium Chromate and Chromic Chloride	J. 10 millicuries
K. Hydrogen 3	K. Water	K. 25 millicuries
L. Sodium 24	L. Sodium Chloride	L. 1 millicurie
M. Xenon 133	M. Free gas or in saline	M. 2 curies

Conditions numbered 1, 2, 3, 4, & 7 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 radio activity whi licensee may possess at any one time
N. Technetium 99m	N. Labeled albumin microspheres (human) prepared by the licensee using the 3M kit	N. 100 millicuries
O. Molybdenum 99	O. E. R. Squibb and Sons Model No. 08871 Generator	O. 1 curie
P. Strontium 90	O. Tracerlab Model RA-1 Sealed Medical Applicator	P. 50 millicuries
Q. Calcium 45	Q. Calcium Chloride	Q. 10 millicuries
R. Calcium 47	R. Calcium Chloride	R. 10 millicuries
S. Carbon 14	S. Vitamins, Carbohydrates, Amino Acids, Lipids, Acetate	S. 10 millicuries of each
T. Hydrogen 3	T. Vitamins, Water	T. 50 millicuries of each
U. Magnesium 28	U. Oxide, Chloride, Citrate	U. 10 millicuries of each
V. Any byproduct material with Atomic Nos. 1-83, inclusive	V. Any	V. 500 millicuries of each, except: Hydrogen 3 - 5 curies Total not to exceed 10 curies
W. Strontium 90	W. U. S. Radium Corperation Model LAB-369-1 Sealed Source	W. 1 source of 13 millicuries
X. Cesium 137	X. Any	X. 1 millicurie
Y. Carbon 14	Y. Glucose	Y. 1 millicurie
Z. Technetium 99m	Z. Sulfur Colloid	Z. 100 millicuries

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radio activity whi licensee may possess at any one time
AA. Technetium 99m	AA. Pertechnetate	AA. 100 millicuries
BB. Selenium 75	BB. Selenite	BB. 2 millicuries
CC. Technetium 99m	CC. Labeled Polyphosphates prepared by the licensee using the NEN kit	CC. 100 millicuries
DD. Cesium 137	DD. Sealed Source (Amersham/Searle)	DD. 626 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. Treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma. Diagnosis of functioning metastases from thyroid carcinoma.
C. Placenta localization. Cisternography and ventriculography in accordance with protocol dated April 20, 1970.
D. Determination of thyroxine turnover.
E. Thyroid imaging.
F. Determination of thyroxine turnover.
G. Treatment of polycythemia vera, leukemia, and bone metastases.
H. Intracavitary treatment of malignant effusions.
I. Intracavitary treatment of malignant effusions. Interstitial treatment of prostatic carcinoma.
J. Determination of gastrointestinal bleeding. Spleen imaging.
K. Determination of total body water.
L. Determination of total exchangeable sodium.
M. Pulmonary function studies. Blood flow studies.
N. Lung imaging.
O. Production of technetium 99m pertechnetate.
P. Treatment of superficial eye conditions.
Q. through U. Metabolic and physiological tracer studies in volunteers.
V. Laboratory research in vitro and in lower animals.
W. For use in Glowall Corporation Model AD-10 Ionization Detector in a Glowall Corporation gas chromatograph.
X. Standard for assay of molybdenum content of eluate of molybdenum generator.
Y. Study of glucose metabolism in 24 normal male volunteers at the address in Item 2, at Fort Sam Houston, Texas, and at the Summit of Pikes Peak, Colorado. This study shall be conducted by, or under the supervision of, Captain Raymond F. Burk, MC, in accordance with the statements, representations, and procedures in application dated January 5, 1971.

9. Authorized use (continued)

Z. Liver and spleen imaging.
AA. Joint imaging in accordance with protocol dated April 20, 1970.
BB. Determine site and nature of selenium protein bond in 25 cancer patients plasma to evaluate nutritional liver disease. Within six weeks after the completion of the study, the licensee shall submit a report to the Commission which summarizes the results obtained.
CC. Bone imaging in 100 additional patients in accordance with letters dated November 16, 1972, and March 9, 1973. Within six weeks after completion of the study, the licensee shall submit a report to the Commission which summarizes the results obtained.
DD. Interstitial treatment of carcinoma. For use in medical applicators for the intracavitary treatment of carcinoma.

CONDITIONS

10. One millicurie of Carbon 14, 1 millicurie of Iodine 131, 3 millicuries of Iodine 125, 3 millicuries of Chromium 51, 5 millicuries of Hydrogen 3, 5 millicuries of Sulfur 35, 5 millicuries of Bromine 82, 10 millicuries of Potassium 42, 10 millicuries of Sodium 24, 2 millicuries of Strontium 85, 2 millicuries of Cerium 141, and 2 millicuries of Ytterbium 169 may be used at the summit of Pikes Peak, Colorado, for studies in lower animals.

11. A. Byproduct material shall be used by, or under the supervision of, individuals designated by the Fitzsimons General Hospital and U. S. Army Medical Research and Nutrition Laboratory Radioisotope Laboratory.

B. The use of byproduct material in or on humans shall be by a physician.

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 application dated June 25, 1968.

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

B. Technetium 99m labeled sulfur colloid shall be procured and/or prepared in accordance with statements, representations, and procedures contained in application dated October 17, 1969.

CONDITIONS

(Continued)

14. 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 application dated June 22, 1972, and letter dated November 9, 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."

15. Patients containing Cesium 137 implants shall remain hospitalized until the implants are removed.

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

17. 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. 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) 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.

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CONDITIONS

17. continued

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.

18. 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 applications dated June 25, 1968, and March 12, 1973.

For the U. S. Atomic Energy Commission

Original Signed By
John E. Boyer
Materials Branch

Date APR 24 1973

by 4-24-73

Directorate of Licensing
Washington, D. C. 20545