FOR 374
10 CFR 30

U. S. ATOMIC ENERGY COMMISSION
BYPRODUCT MATERIAL LICENSE

License No. 05-00046-13
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Amendment No. 15

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, 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. Department of the Army Fitzsimons General Hospital and U. Army Medical Research and 2. Nutrition Laboratory Denver, Colorado 80240	In accordance with application dated June 25, 1968, 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. Gas	M. 2 curies
N. Xenon 133	N. Gas dissolved in saline	N. 50 millicuries

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6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radio activity which licensee may possess at any one time
O. Molybdenum 99	O. E. R. Squibb and Sons Model No. 08871 Generator	O. 600 millicuries
P. Strontium 90	P. Tracerlab Model RA-1 Sealed Medical Applicator	P. 25 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 Corporation Model LAB-369-1 Sealed Source	W. 1 source of 13 millicuries
X. Cesium 137	X. Any	X. 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, Part 35.
B. Treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma.
C. Placenta localization.
D. Determination of thyroxine turnover.
E. Thyroid scanning.

9. Authorized use (continued)

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 scanning.
K. Determination of total body water.
L. Determination of total exchangeable sodium.
M. Determination of pulmonary function.
N. Measurement of myocardial blood flow.
O. Source 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.

CONDITIONS

10. Byproduct material may only be used at the licensee's address stated in Item 2 above.

11. One millicurie of Carbon 14, 1 millicurie of Iodine 131, 1 millicurie of Iodine 125, 1 millicurie of Chromium 51, 5 millicuries of Hydrogen 3, 5 millicuries of Sulfur 35, and 5 millicuries of Bromine 82 may be used at the summit of Pikes Peak, Colorado for metabolic studies in lower animals.

12. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 20, "Standards for Protection Against Radiation."

13. 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.

CONDITIONS

(Continued)

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

15. 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.

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 Director, Division of Materials 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 the Director, Region IV, Division of Compliance, USAEC, 10395 West Colfax Avenue, Denver, Colorado, 80215.

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CONDITIONS

(Continued)

16. Byproduct material to be administered to humans shall be procured in separated, prepackaged, precalibrated form from a supplier who manufactures or repackages the product under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility, and pyrogenicity.

17. A. Iodine 131 labeled Macroaggregated Iodinated Human Serum Albumin, Chromium 51 labeled Human Serum Albumin, and Iodine 131 labeled Colloidal (Microaggregated) Human Serum Albumin 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 this material pursuant to Title 42, Chapter 1, Code of Federal Regulations, Part 73, "Biological Products."

    B. 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.

18. 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.

19. 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 June 25, 1968.

For the U. S. Atomic Energy Commission

Date APR 28 1969

Original Signed by
Nathan Bassin

by ~~Isotopes Branch~~
Division of Materials Licensing
Washington, D. C. 20545

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