

BYPRODUCT MATERIAL LICENSE Amendment No. 34  
(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.

<b>Licensee</b>  1. Department of the Army Fitzsimons Army Medical Center and U. S. Army Medical Research and Nutrition Laboratory Denver, Colorado 80240	<b>In accordance with application dated</b> February 22, 1974,  3. License Number 05-00046-13 is amended in its entirety to read as follows:  4. Expiration date April 30, 1979  5. Reference No.	
<b>6. Byproduct material</b> (element and mass number)  A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35  B. Iodine 131 C. Iodine 131  D. Iodine 131 E. Iodine 125 F. Iodine 125 G. Iodine 125 or 131 H. Phosphorus 32 I. Phosphorus 32  J. Gold 198 K. Chromium 51  L. Hydrogen 3 M. Sodium 24	<b>7. Chemical and/or physical form</b>  A. Any radio-pharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35  B. Iodide C. Iodinated Human Serum Albumin D. Thyroxine E. Iodide F. Thyroxine G. Any H. Soluble Phosphate I. Colloidal Chromic Phosphate J. Colloidal K. Sodium chromate and chromic chloride L. Water M. Sodium chloride	<b>8. Maximum amount of radioactivity which licensee may possess at any one time</b>  A. As necessary for uses authorized in Subitem 9. A.  B. 250 millicuries C. 5 millicuries  D. 2 millicuries E. 1 millicurie F. 1 millicurie G. 5 millicuries H. 50 millicuries I. 50 millicuries  J. 250 millicuries K. 10 millicuries  L. 25 millicuries M. 1 millicurie

1, 3, and 7

Conditions numbered \_\_\_\_\_ printed on the reverse side of this page shall apply to this license.

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## Supplementary Sheet

Continued From Page 1License Number 05-00046-13

Amendment No. 34

6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radio activity wh licensee may possess at any one time
N. Xenon 133	N. Free gas or in saline	N. 2 curies
O. Technetium 99m	O. Labeled albumin microspheres (human) prepared by the licensee using the 3M kit	O. 150 millicuries
P. Technetium 99m	P. Sulfur Colloid	P. 150 millicuries
Q. Technetium 99m	Q. Pertechnetate	Q. 500 millicuries
R. Technetium 99m	R. Labeled polyphosphates prepared by the licensee using the NEN kit	R. 150 millicuries
S. Technetium 99m	S. Labeled disodium etidronate prepared by the licensee using the Procter & Gamble kit	S. 150 millicuries
T. Molybdenum 99	T. Molybdenum 99/ Technetium 99m Generators (E. R. Squibb and Sons Model Nos. 08871 and 09650; Abbott Labs. Model Nos. 7721 and 6724; NEN Pharmaceuticals Model No. NEP-196; Mallinckrodt Chemical Works Model Nos. 006 through 012 and 100 through 106; Cambridge Nuclear Corp. Model No. CN-4291; and Amersham/Searle Corp. Model Nos. GTC-50, GTC-100, GTC-200, GTC-300, and GTC-400)	T. 2 curies
U. Strontium 90	U. Tracerlab Model RA-1 Sealed Medical Applicator	U. 50 millicuries
V. Any byproduct material with Atomic Nos. 1-83, inclusive	V. Any	V. 500 millicuries each, except: Hydrogen 3 - 5 curies. Total not to exceed 10 curies

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## Supplementary Sheet

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6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radio activity wh licensee may possess at any one time
W. Cesium 137	W. Any	W. 1 millicurie
X. Cesium 137	X. Sealed sources (Amersham/Searle)	X. 626 millicuries
Y. Technetium 99m	Y. Iron-ascorbate- diethylenetriamine pentaacetic acid complex (prepared by the licensee using the Squibb kit)	Y. 50 millicuries

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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.
- D. Determination of thyroxine turnover.
- E. Thyroid imaging.
- F. Determination of thyroxine turnover.
- G. In vitro studies, tests.
- H. Treatment of polycythemia vera, leukemia, and bone metastases.
- I. Intracavitary treatment of malignant effusions.
- J. Intracavitary treatment of malignant effusions. Interstitial treatment and general treatment of prostatic carcinoma.
- K. Determination of gastrointestinal bleeding. Spleen imaging.
- L. Determination of total body water.
- M. Determination of total exchangeable sodium.
- N. Pulmonary function studies. Blood flow studies.
- O. Lung imaging.
- P. Liver and spleen imaging.
- Q. Joint imaging in accordance with protocol dated April 20, 1970.
- R. Bone imaging.
- S. Bone imaging.
- T. Production of technetium 99m pertechnetate.
- U. Treatment of superficial eye conditions.
- V. Laboratory research in vitro and in lower animals, in vitro testing.
- W. Standard for assay of molybdenum content of eluate of Molybdenum generator.
- X. Interstitial treatment of carcinoma. For use in medical applicators for the intracavitary treatment of carcinoma.
- Y. Kidney imaging.

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Supplementary Sheet

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CONDITIONS

Amendment No. 34

10. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."
11. A. Byproduct material shall be used by, or under the supervision of, individuals designated by the Fitzsimons Army Medical Center Radioisotope Committee.  
  
B. The use of byproduct material in or on humans shall be by a physician.
12. Biological products labeled with radionuclides or kits used to prepare such products shall be procured from a supplier who holds an unsuspended or unrevoked license issued by the Secretary of the Department of Health, Education, and Welfare to propagate, manufacture, prepare, label, or distribute the products. The labeled biological products shall be used only for the medical indications covered by the supplier's Department of Health, Education, and Welfare license.
13. Technetium 99m labeled sulfur colloid preparations which appear flocculent or aggregated shall not be used in humans.
14. Patients containing Cesium 137 implants shall remain hospitalized until the implants are removed.
15. Sealed sources containing byproduct material shall not be opened.
16. 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) 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.

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CONDITIONS

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16. continued

- 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 USAEC, Region IV, Directorate of Regulatory Operations, 10395 West Colfax Avenue, Denver, Colorado, describing the equipment involved, the test results, and the corrective action taken.
17. 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 February 22, 1974, and letter dated April 15, 1974.

JUN 17 1974

For the U. S. Atomic Energy Commission

Original Signed By

LEO WADE, JR.

Materials Branch

by

Directorate of Licensing  
Washington, D. C. 20545

6-17-74  
*[Signature]*



## MATERIALS DATA INPUT MEDICAL

1. FILE COPY

## A. TYPE OF ACTION:

<input type="checkbox"/> NEW LICENSE	<input checked="" type="checkbox"/> AMENDMENT TO RENEW LICENSE	<input type="checkbox"/> AMENDMENT TO TERMINATE	<input type="checkbox"/> VOID	<input type="checkbox"/> CHANGE LICENSEE NAME/ADDRESS
<input type="checkbox"/> NEW LICENSE AND NEW LICENSEE	<input type="checkbox"/> OTHER AMENDMENT	<input type="checkbox"/> CLERICAL CHANGE NO AMENDMENT		

## B. INDICATIVE INFORMATION:

DOCKET NUMBER 030-01233	MAIL CONTROL NO. 47342	DATE REQUEST REC'D 04/18/74	INSTITUTION CODE 0046	PENDING PROG. CODE	ACTUAL PROG. CODE
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## SECONDARY PROGRAM CODES AS REQUIRED:

#1	#2	#3	#4	#5
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NAME (LAST, FIRST, MIDDLE)	NAME (LAST, FIRST, MIDDLE)
NAME (LAST, FIRST, MIDDLE)	NAME (LAST, FIRST, MIDDLE)
NAME (LAST, FIRST, MIDDLE)	NAME (LAST, FIRST, MIDDLE)

ORGANIZATION NAME (ALPHABETIC SEQUENCE) Army, Department of the Fitzsimons Army Medical Center and U. S. Army Medical Research and Nutrition Laboratory	TYPE OF ORGANIZATION <input checked="" type="checkbox"/> U. S. GOVERNMENT AGENCY <input type="checkbox"/> EDUCATIONAL INSTITUTION <input type="checkbox"/> MEDICAL INSTITUTION <input type="checkbox"/> INDUST <input type="checkbox"/> OTHER
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BUILDING, STREET	CITY Denver	STATE CO	ZIP CODE 80240
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## C. STATISTICAL INFORMATION:

LICENSE NUMBER 05-00046-13	DATE LICENSE ISSUED OR ACTION COMPLETED 06 17 74	EXPIRATION DATE APR 30, 1979
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## USAGE OF MEDICAL BYPRODUCT:

<input type="checkbox"/> FOR HUMAN USE ONLY	<input checked="" type="checkbox"/> FOR HUMAN AND NONHUMAN USE	<input type="checkbox"/> FOR NONHUMAN USE ONLY
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## POSSESSION OF THE MATERIAL IS AUTHORIZED IN ONE OF THE FOLLOWING AREAS:

<input checked="" type="checkbox"/> SAME AS 'STATE' IN ADDRESS	<input type="checkbox"/> ALL STATES	<input type="checkbox"/> ALL AGREEMENT STATES	<input type="checkbox"/> ALL NON-AGREEMENT STATES
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## AND/OR IN THE STATE(S), TERRITORY(S), COUNTRY CHECKED BELOW:

ALABAMA -AL	GEORGIA -GA	MARYLAND -MD	NEW JERSEY -NJ	SOUTH CAROLINA -SC	WYOMING -WY
ALASKA -AK	HAWAII -HI	MASSACHUSETTS -MA	NEW MEXICO -NM	SOUTH DAKOTA -SD	
ARIZONA -AZ	IDAHO -ID	MICHIGAN -MI	NEW YORK -NY	TENNESSEE -TN	AMERICAN SAMOA -AS
ARKANSAS -AR	ILLINOIS -IL	MINNESOTA -MN	NORTH CAROLINA -NC	TEXAS -TX	CANAL ZONE -CZ
CALIFORNIA -CA	INDIANA -IN	MISSISSIPPI -MS	NORTH DAKOTA -ND	UTAH -UT	GUAM -GU
COLORADO -CO	IOWA -IA	MISSOURI -MO	OHIO -OH	VERMONT -VT	PUERTO RICO -PR
CONNECTICUT -CT	KANSAS -KS	MONTANA -MT	OKLAHOMA -OK	VIRGINIA -VA	VIRGIN ISLANDS -VI
DELAWARE -DE	KENTUCKY -KY	NEBRASKA -NB	OREGON -OR	WASHINGTON -WA	
WASHINGTON DC -DC	LOUISIANA -LA	NEVADA -NV	PENNSYLVANIA -PA	WEST VIRGINIA -WV	CANADA -CN
FLORIDA -FL	MAINE -ME	NEW HAMPSHIRE -NH	RHODE ISLAND -RI	WISCONSIN -WI	

## D. POSSESSION LIMITS OF SOURCE AND SPECIAL NUCLEAR MATERIALS AND TRITIUM

TYPE OF MATERIAL	AMOUNT AUTHORIZED	UNIT OF MEASUREMENT		SEALED/UNSEALED CONFIGURATION	MAXIMUM ENRICHMENT
U235		<input type="checkbox"/> GRAMS	<input type="checkbox"/> KILOGRAMS	<input type="checkbox"/> SEALED <input type="checkbox"/> UNSEALED	
U233		<input type="checkbox"/> GRAMS	<input type="checkbox"/> KILOGRAMS	<input type="checkbox"/> SEALED <input type="checkbox"/> UNSEALED	'X' HERE IF FOR POWER REACTOR <input type="checkbox"/>
PU		<input type="checkbox"/> GRAMS	<input type="checkbox"/> KILOGRAMS	<input type="checkbox"/> SEALED <input type="checkbox"/> UNSEALED	
URANIUM		<input type="checkbox"/> GRAMS	<input type="checkbox"/> KILOGRAMS	<input type="checkbox"/> SEALED <input type="checkbox"/> UNSEALED	
THORIUM		<input type="checkbox"/> GRAMS	<input type="checkbox"/> KILOGRAMS	<input type="checkbox"/> SEALED <input type="checkbox"/> UNSEALED	
TRITIUM		<input type="checkbox"/> MICRO-CURIES	<input type="checkbox"/> MILLI-CURIES	<input type="checkbox"/> CURIES	RIS CODE

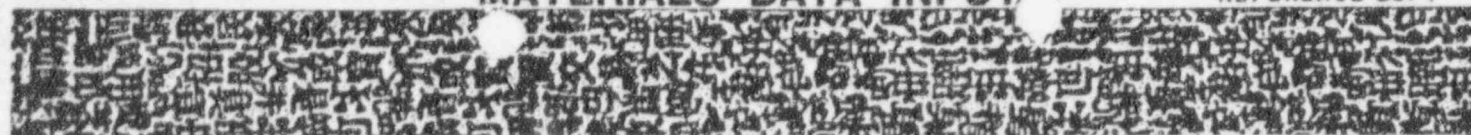
## E. FEE CATEGORIES:

EX	1A	1B	1C	2A	2B	3A	3B	3C	3D	3E
4A	5A									

A/104



## MATERIALS DATA INPUT

MEDICAL BYPRODUCT  
REFERENCE COPY

DOCKET NUMBER <b>030-01233</b>	MAIL CONTROL NO. <b>47342</b>	DATE REQUEST REC'D <b>04/18/74</b>	PROGRAM CODE (ERIMARY)
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SECONDARY PROGRAM CODES:

#1	#2	#3	#4	#5
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NAME	NAME
NAME	NAME
NAME	NAME

ORGANIZATION NAME

**Army, Department of the**  
**Walter Reed Army Medical Center and U. S. Army**  
**Medical Research and Nutrition Laboratory**

TYPE OF ORGANIZATION

<input checked="" type="checkbox"/> U. S. GOVERNMENT AGENCY	<input type="checkbox"/> EDUCATIONAL INSTITUTION
<input type="checkbox"/> MEDICAL INSTITUTION	<input type="checkbox"/> INDUSTRY
<input type="checkbox"/>	<input type="checkbox"/> OTHER

BUILDING, STREET

CITY

STATE

ZIP CODE

**Denver****CO****80240**

BYPRODUCT	FORM	USE	POSS. LIMIT
I 125 or I 131	TRIIODOTHYRONINE AND THYROXINE	IN VITRO STUDIES	
		THYROID IMAGING	
I 131	IODIDE	TREATMENT OF HYPERTHYROIDISM, CARDIAC DYSFUNCTION AND THYROID CARCINOMA	
	I H S A	CISTERNOGRAPHY	
Cr 51	CHROMATE	PLACENTA LOCALIZATION	
	LABELED HSA		
P 32	SOLUBLE PHOSPHATE	TREATMENT OF LEUKEMIA, POLYCYTHEMIA VERA, BONE METASTASES,	
	COLLOIDAL CHROMIC PHOSPHATE	INTERSTITIAL TREATMENT OF CARCINOMA	
Au 198	COLLOIDAL SUSPENSION	INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS	
Cs 137	ANY	FOR USE AS A STANDARD FOR CALIBRATION PURPOSES	
Co 60	ENCASED IN NEEDLES AND/OR APPLICATOR CELLS	FOR USE IN MEDICAL APPLICATORS FOR THE INTRACAVITARY TREATMENT OF CARCINOMA	
Sr 90	SEALED SOURCE	TREATMENT OF SUPERFICIAL EYE DISEASES	
Tc 99m	PERTECHNETATE		
	SULFUR COLLOID	LIVER AND SPLEEN IMAGING	
	DTPA	KIDNEY IMAGING	
	MHSA	LUNG IMAGING	
Mo 99	Mo99/Tc99m GENERATORS	PRODUCTION OF Tc99m PERTECHNETATE	
C 14			
H 3	ANY	IN VITRO STUDIES, ANIMAL STUDIES	
Se 75	SELENOMETHIONINE	PANCREAS IMAGING	
Xe 133	FREE GAS OR SOLUTION	BLOOD FLOW STUDIES	
Kr 85	GAS	PULMONARY FUNCTION STUDIES	
Ir 192	SEEDS ENCAPSULATED IN NYLON RIBBON		
Hg 197	CHLORMERODRIN	RENAL FUNCTION STUDIES	
Sr 85	CHLORIDE OR NITRATE	BONE IMAGING ON PATIENTS WITH KNOWN OR SUSPECTED CANCER	
Group I	<i>Copy sent to 6 (application)</i> <i>IA 509, 54, 53, 9A Fitzgerald Aug 74. Dr. Redington Aug 74 90.550</i> <i>orig. cont. 16 x 16 11 A(4) B C 14 question Feb 22, 1974 and 11/15/74</i>		
Group II			
Group I & II			

MAIL TO:

DATE MAILED

REVIEWER

DATE COMPLETE



## MATERIALS DATA INPUT

MEDICAL BYPRODUCT  
REFERENCE COPY

DOCKET NUMBER

030-01233

MAIL CONTROL NO.

47342

DATE REQUEST REC'D

04/16/74

PROGRAM CODE (PRIMARY)

SECONDARY PROGRAM CODES:

#1

#2

#3

#4

#5

NAME

NAME

NAME

NAME

NAME

NAME

ORGANIZATION NAME

Army, Department of the  
DEPARTMENT OF BUREAU  
Vittum Army Medical Center and U. S. Army  
Medical Research and Nutrition Laboratory

TYPE OF ORGANIZATION

U. S. GOVERNMENT AGENCY

EDUCATIONAL INSTITUTION

MEDICAL INSTITUTION

INDUST

OTHER

BUILDING, STREET

CITY

STATE

ZIP CODE

Denver

CO

80240

BYPRODUCT

FORM

USE

POSS. LIMIT

I 125 or  
I 131TRIIODOTHYRONINE AND  
THYROXINE

IN VITRO STUDIES

THYROID IMAGING

I 131

IODIDE

I H S A

TREATMENT OF HYPERTHYROIDISM,  
CARDIAC DYSFUNCTION AND THYROID CARCINOMA

CISTERNOGRAPHY

Cr 51

CHROMATE

LABELED HSA

PLACENTA LOCALIZATION

P 32

SOLUBLE PHOSPHATE

COLLOIDAL CHROMIC PHOSPHATE

TREATMENT OF LEUKEMIA, POLYCYTHEMIA VERA,  
BONE METASTASES

INTERSTITIAL TREATMENT OF CARCINOMA

Au 198

COLLOIDAL SUSPENSION

INTRACAVITARY TREATMENT OF  
MALIGNANT EFFUSIONS

Cs 137

ANY

FOR USE AS A STANDARD FOR CALIBRATION PURPOSES

Co 60

ENCASED IN NEEDLES AND/OR  
APPLICATOR CELLSFOR USE IN MEDICAL APPLICATORS FOR THE  
INTRACAVITARY TREATMENT OF CARCINOMA

Sr 90

SEALED SOURCE

TREATMENT OF SUPERFICIAL  
EYE DISEASES

Tc 99m

PERTECHNETATE

SULFUR COLLOID

LIVER AND SPLEEN IMAGING

DTPA

KIDNEY IMAGING

MHSA

LUNG IMAGING

Mo 99

Mo99/Tc99m GENERATORS

PRODUCTION OF Tc99m PERTECHNETATE

C 14

H 3

ANY

IN VITRO STUDIES, ANIMAL STUDIES

Se 75

SELENOMETHIONINE

PANCREAS IMAGING

Xe 133

FREE GAS OR SOLUTION

BLOOD FLOW STUDIES

Kr 85

GAS

PULMONARY FUNCTION STUDIES

Ir 192

SEEDS ENCAPSULATED IN NYLON RIBBON

Hg 197

CHLORMERODRIN

RENAL FUNCTION STUDIES

Sr 85

CHLORIDE OR NITRATE

BONE IMAGING ON PATIENTS WITH  
KNOWN OR SUSPECTED CANCER

Group I

Group II

Group I &amp; II

Copy sent to (application)

4-22-74

Dean R. Smith

1A 509, 54, 53, 9A Pigeon Creek Rd. Ch. Redington, Minn. 55054

Copy sent 11/14/74

14 Application Feb 24, 1974 and 11/14/74

MAIL TO:

DATE MAILED

REVIEWER

DATE COMPLETE