(4-66)

BYPRODUCT MATERIAL LICENSE

Supplementary Sheet

License Number 50-05642-03

Amendment No. 01

James Walter Coin, M.D.
Doctor's Clinic
625 L Street
Anchorage, Alaska 99501

In accordance with letter dated June 26, 1969, License Number 50-05642-03 is amended as follows:

To add:

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
H. Technetium 99m	H. Sulfur Colloid	H. 100 millicuries

9. Authorized use

H. Liver and spleen scans.

Condition 15.C. is added:

15.C. Technetium 99m labeled sulfur colloid shall be procured and/or prepared in accordance with statements, representations, and procedures contained in letter dated June 26, 1969, signed by Dr. James W. Coin.

For the U. S. Atomic Energy Commission

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

Date JUL 8 1969

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BYPRODUCT MATERIAL LICENSE

Supplementary Sheet

License Number 50-05642-03

15. (Continued) CONDITIONS

B. Technetium 99m Pertechnetate shall be procured in separated, prepackaged, precalibrated form from a pharmaceutical supplier who manufactures the product under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility, and pyrogenicity. Notwithstanding the foregoing requirement, 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 February 14, 1968.

For the U. S. Atomic Energy Commission

Date MAR 28 1968

by Isotopes Branch

Division of Materials Licensing
Washington, D. C. 20545

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9. (Continued)

B. Treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma.
C. Treatment of leukemia, polycythemia vera, and bone metastases.
D. and E. Intracavitary treatment of pleural and peritoneal effusions and/or ascites.
F. In vitro studies.
G. Production of Technetium 99m Pertechnetate.

CONDITIONS

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

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

12. Byproduct material shall be used by James Walter Coin, M.D.

13. Byproduct material shall not be used in humans until its pharmaceutical quality and assay have been established.

14. 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.

15. 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, Code of Federal Regulations, Part 73, "Biological Products."

STATE OF CALIFORNIA
DEPARTMENT OF PUBLIC HEALTH

RADIOACTIVE MATERIAL LICENSE

Pursuant to the California Administrative Code, Title 17, Chapter 5, Subchapter 4, Group 2, Licensing of Radioactive Material, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, use, possess, transfer or dispose of radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Department of Public Health now or hereafter in effect and to any conditions specified in this license.

1. Licensee: Eisenhower Medical Center

2. Address: 39000 Bob Hope Drive
Palm Desert, CA 92260

Attn: James W. Coin, M.D., Chairman
Radiation Safety Officer

3. License no. 2425-33
Amendment no.

4. Expiration date: January 4, 1980

5. Inspection agency: Bureau of Radiological Health

6. Nuclide	7. Form	9. Authorized use
	Category C - Sample-counting procedures For authorizations in this category,	see Condition 12.
	Category D - Organ-monitoring procedures For authorizations in this category,	see Condition 12.
	Category E - Organ-visualization procedures For authorizations in this category,	see Condition 12.
	Category F - Therapeutic procedures For authorizations in this category,	see Condition 12.
(cont'd)	(cont'd)	(cont'd)

8. Possession limit

Categories C-D-E - Diagnostic procedures

Combined possession limit 500 mCi

Category F - Therapeutic procedures

Combined possession limit 500 mCi (cont'd)

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

11. This license is subject to an annual fee of two hundred twenty (220) dollars due and payable on the anniversary of the date of issue of this license, January 4, 1973.

12. (a) The individuals named below are authorized the specified uses of radioactive material described in Items 6, 7 and 9 of this license:

Authorized user	Category A	Category B	Category G	Category H
(1) James W. Coin, M.D.	N/A	N/A	N/A	all
(2) Craig L. Fischer, M.D.	N/A	N/A	N/A	all

(b) The individuals named below are authorized the specified uses of radioactive material described on Form RH 3010R:

Authorized user	Category C	Category D	Category E	Category F
(1) James W. Coin, M.D.	all	all	all	F3-F5, F7, F9, F12
(2) Craig L. Fischer, M.D.	all	all	all	none

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RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

License Number 2425-33

Amendment Number

continued

6. Nuclide (cont'd)	7. Form (cont'd)	9. Authorized use (cont'd)
Category H - Non-human uses		
1. Molybdenum 99 technetium 99m	1. Sterile generator	1. Source of technetium 99m

8. Possession limit (cont'd)

Category H - Non-human uses

Included with C-D-E

13. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 7 and 8 of this license in accordance with statements, representations and procedures contained in the following documents:

(a) application (RH 3000I) dated August 18, 1972 signed by J. L. Coin and C. L. Fischer, M.D.'s, with attachments.

14. (a) The radiation safety officer in this program shall be Craig L. Fischer, M.D.

(b) The chairman of the radiation safety committee shall be James W. Coin, M.D.

Conditions 15 through 25 continued on Page 3.

STATE OF CALIFORNIA
DEPARTMENT OF PUBLIC HEALTH

Continued

RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

License Number 2425-33

Amendment Number _____

This license is subject to all numbered conditions below.
Conditions to which this license is not subject are marked N/A.

15. Except as otherwise specifically provided by this license, radioactive pharmaceuticals to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who is registered with the United States Food and Drug Administration in accordance with Section 510 of the Federal Food, Drug, and Cosmetic Act, and who guarantees the pharmaceutical quality of each product.

16. Except as otherwise specifically provided by this license, radioactive biologicals (including human serum albumin) to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who is licensed for the preparation and distribution of such products by the Division of Biologics Standards of the National Institutes of Health, pursuant to Part 73 of the Public Health Service Regulations, or by the Bureau of Biologics, U. S. Food and Drug Administration.

17. Radioactive material prepared, processed, or modified by the licensee shall not be administered to humans except as specifically authorized by this license.

18. Technetium 99m generators approved by the Department may be used as sources of technetium 99m for use in preparations to be administered to humans, provided the generators are used in strict accordance with the manufacturer's instructions concerning sterile technique, pyrogenicity and sterility testing, molybdenum breakthrough testing, radioassay of eluate, and radiation protection of personnel. (A list of approved generators is available from the Bureau of Radiological Health.)

19. Where users or their assistants are engaged in elution of pertechnetate-99m from generators and/or preparation of labelled pharmaceuticals from kits to such an extent that radiation exposures to fingers or hands exceed, or are likely to exceed, the 5-rem quarterly limit specified in Section 30276 of the California Radiation Control Regulations, exposures to the fingers or hands of these individuals shall be monitored, using appropriate dosimeters, until it has been demonstrated that such monitoring is no longer required.

20. Technetium-99m labelled pharmaceuticals prepared by the licensee by aseptic addition of pertechnetate to sterile, pyrogen-free reagents procured in the form of kits which have been approved by the Department, may be administered to humans provided all instructions and recommendations contained in the manufacturer's package insert information are strictly followed, and provided the radioassay of the final product is determined with an overall error not exceeding 10%. (A list of kits approved by the Department may be obtained from the Bureau of Radiological Health.)

21. Counting equipment for radiometric assay of pharmaceuticals, body fluids, excreta, or in vitro assay samples, shall be calibrated and tested sufficiently often to insure the medical validity and reliability of data obtained. The stability of the equipment shall be checked at least once on each day of use, using appropriate standards or reference sources.

22. Production or processing of radiopharmaceuticals for the purpose of distribution to other licensees is not authorized by this license.

23. The licensee shall not use radioactive material in the form of gas or aerosol in such a manner as to produce an airborne concentration exceeding the appropriate limit specified in Section 30266 or 30269 of the California Radiation Control Regulations.

24. Placenta localization studies authorized by this license shall be performed only on patients who are in the third trimester and are bleeding, and only when, in the judgment of the obstetrician, the study is needed for the benefit of the patient's health.

N/A Where clinical test studies of a new radiopharmaceutical product are authorized by this license, the responsible physician shall observe all subjects for any significant reactions, and shall prepare and maintain reports of such reactions, and of the clinical efficacy of each study. Copies of all such reports shall be provided to the sponsoring firm supplying the product within 30 days of completion of the clinical test series. Any adverse reactions shall be reported immediately to the Department of Public Health.

25. The licensee shall not routinely use doses exceeding those specified on the Department's "Routine Uses" list unless a non-routine authorization for use of a different dose range is included in the license.

For the State Department of Public Health

Date January 4, 1973

by C. J. Must

Solomon Kinsman, Ph.D., Chief
Bureau of Radiological Health
2151 Berkeley Way, Berkeley, California 94704

REV. 8-69, FORM 227-2551-K 11/72

STATE OF CALIFORNIA
DEPARTMENT OF HEALTH

Page 1 of 1 Pages

RADIOACTIVE MATERIAL LICENSE

License Number 2425-33

Supplementary Sheet

Amendment Number 6

Eisenhower Medical Center
39000 Bob Hope Drive
Palm Desert, CA 92260

Attention: James W. Coin, M.D., Chairman
Radiation Safety Committee

In response to a letter dated June 28, 1974, License No. 2425-33 is hereby amended in part as follows:

To read:

12.(a) The individuals named below are authorized the specified uses of radioactive material described in Items 6, 7 and 9 of this license.

Authorized user	Category A	Category B	Category C	Category H
(1) James W. Coin, M.D.	N/A	N/A	G.1.	all
(2) Craig L. Fischer, M.D.	N/A	N/A	none	all
(3) Dwight K. Oxley, M.D.	N/A	N/A	none	all

(b) The individuals named below are authorized the specified uses of radioactive material described on Form RH 2010-R:

Authorized user	Category C	Category D	Category E	Category F
(1) James W. Coin, M.D.	all	none	all	all
(2) Craig L. Fischer, M.D.	all	none	all	none
(3) Dwight K. Oxley, M.D.	all	none	all	F-53 only

14.(1) The chairman of the radiation safety committee shall be James W. Coin, M.D.

Date July 19, 1974

For the State Department of Health

by D. A. Pickler
for Simon Kinsman, Ph.D., Chief
Radiologic Health Section
744 P Street, Sacramento, Calif. 95814

FORM SH 2551 (9/73)

STATE OF CALIFORNIA
DEPARTMENT OF HEALTH

RADIOACTIVE MATERIAL LICENSE

Supplementary Sheet

License Number 2425-33

Amendment Number 5

Eisenhower Medical Center
39000 Bob Hope Drive
Palm Desert, CA 92260

Attention: Donald L. Holmquist, M.D., Chairman
Radiation Safety Committee

License No. 2425-33 is hereby amended in part as follows:

To add:

6. Nuclide	7. Form	9. Authorized use
Category G - Non-routine uses		
1. Technetium 99m	1. Labelled HAM, pharmaceutical (3 M Co.)	1. Myocardial perfusion scanning in accordance with applicatio (RH 3000E) received April 25, 1974 and assigned N.R. No. 74-41. Authorization expires June 30, 1975. A report of experience, including a correlation of findings, is to be submitted by June 30, 1975. Any adverse reaction is to be reported within 24 hours of occurrence.

To read:

9. Authorized use

Category J: Manufacturer-sponsored clinical investigations

1. Clinical trials (Phase 3 clinical investigations) conducted in strict accordance with IND's sponsored by the firm or firms named below, which have been accepted in writing by the USFDA. Phase 1 or Phase 2 investigations are not hereby authorized.

   (a) Medi-Physics, Inc.

   (b) 3 M Co.

To read:

8. Possession limits

   Combined possession limit for Categories C, E, F, G, H, & J - 2.0 curies

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To add:

13. (c) application (RH 3000J) dated January 4, 1974 signed by Donald L. Holmquist, M.D.

For the State Department of Health

Date May 29, 1974

by D. A. Pickler

for Simon Kinsman, Ph.D., Chief
Radiologic Health Section
744 P Street, Sacramento, Calif. 95814

FORM RH 2551 (9/73)